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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 58

[Doc. No. AMS-DA-22-0064]

RIN 0581-AE20

Plant Records To Include Grade Label Butterfat Testing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule adopts amendments to the plant records requirement for the Agricultural Marketing Service (AMS) Dairy Grading and Inspection Program. The amendments allow butterfat tests to be performed at an in-house or approved third party laboratory and add a requirement for plants to maintain and make such records available for examination by a United States Department of Agriculture (USDA) inspector. These amendments increase efficiency by conforming to current industry practice.

DATES: This final rule is effective February 18, 2025.

FOR FURTHER INFORMATION CONTACT: Whitney Rick, Grading and Standardization Division, Dairy Program, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2530-South Building Mail Stop 0225, 1400 Independence Avenue SW, Washington, DC 20250-0230; Telephone: (202) 236-8241; Email: Whitney.Rick@usda.gov.

SUPPLEMENTARY INFORMATION: The Secretary of Agriculture is authorized by the Agricultural Marketing Act (AMA) of 1946, as amended (7 U.S.C. 1621, *et seq.*), to provide voluntary Federal dairy inspection and grading services that enables consumers to purchase high quality dairy products and facilitates orderly marketing. Plants participating in the voluntary, fee-based AMS Dairy

Grading and Inspection Program process milk into dairy foods that enter commerce as retail products, ingredients for further processing, purchases for Federal food assistance programs, and exports to other countries. Services provided by the program enhance the marketability and add value to dairy products and foods that contain dairy. Dairy products manufactured in plants complying with the USDA inspection requirements are eligible to be graded against official quality standards and specifications established by AMS. Dairy products tested and graded by AMS have certificates issued describing the product's quality and condition.

When the Grading and Inspection Program was implemented, the quality of butter was inconsistent, and quality-control testing by USDA was necessary to ensure a consistent product for the market. Today, plants more consistently manufacture high-quality butter products and maintain the butterfat standard necessary to be granted a USDA grade label for butter.

Currently, USDA inspectors or designated plant personnel perform tests of butter samples that have been selected by a USDA inspector for quality control on randomized batches of finished product pursuant to 7 CFR 58.338. Testing frequency varies by the volume of butter processed and whether a batch is randomly selected. Typically, USDA conducts monthly or weekly testing depending on the volume of butter processed. It is also current industry practice for plants to perform routine internal tests on their butter products to ensure quality and compliance with composition standards. Specific requirements for these tests are outlined in 7 CFR 58.336.

During manufacturing it is normal to have fluctuations in butterfat composition at different stages in butter making and, consequently, test results may not be consistent throughout the process. Therefore, butter processing plants continually monitor butterfat composition throughout production and make necessary adjustments to maintain the 80 percent butterfat required for butter (7 CFR 58.305). The plant maintains these monitoring records as part of its internal quality program and testing procedures.

Under the current Dairy Grading and Inspection Program, USDA conducts a single butterfat test at the time of

grading, which provides a limited perspective on overall butterfat composition of butter manufactured by the plant.

The amendments will provide plants an alternative to butterfat testing administered by a USDA inspector and allow in-plant quality control testing to satisfy butterfat testing requirements. This final rule authorizes a review of a plant's testing records performed by AMS as an alternative to testing performed by a USDA inspector at the time of grading. A records review of a plant's routine testing rather than a single-point test provides a more accurate picture of whether the plant's butter products meet quality standards. It also reduces costs to a plant by providing an alternative to duplicate butterfat testing by a USDA inspector. As explained in the Regulatory Flexibility Analysis below, AMS estimates authorizing an alternative records review option will save participating plants \$4,560 to \$31,560 annually.

Currently, the final butter product must contain a minimum of 80 percent butterfat by weight for it to comply with the regulations. That requirement will not change as a result of this final rule. However, pursuant to this rule, AMS will annually review each plant's butterfat test records to gauge the plant's compliance with the regulations. Butterfat tests are already conducted as a normal, standard business operating procedure by plants that manufacture butter. If a records review reveals a plant is out of compliance, AMS will perform more frequent reviews to determine what preventative and corrective actions are being taken. As described below, failure to rectify the problem over multiple consecutive reviews may result in ineligibility to use the USDA Grade Label shield on products produced by the plant.

Records inspected include plant records of butterfat tests performed as required under 7 CFR 58.336, and analysis of records. The change to the recordkeeping requirements applies to records kept in the regular course of business by the plant. As records will be reviewed on-site by USDA inspectors, plants will not be required to submit information to the agency.

A proposed rule was published in the **Federal Register** on August 15, 2023 (88 FR 55426). Copies of the proposed rule

were made available through the internet by the USDA and the Office of the Federal Register. The rule provided a 60-day comment period which ended October 16, 2023. Seven comments were received. Four of the comments supported the proposed changes. The comments in support of the rule noted the change will continue to promote high quality products and will lower the cost to manufacturers, which will result in savings to the consumer.

Of the four supportive comments, the American Butter Institute (ABI) requested clarification on four items related to this rulemaking. First, ABI asked which tests will be reviewed. The tests reviewed must be sufficient to evaluate the plant's process to control quality and adjust butterfat composition during manufacturing and ensure final butterfat composition meets the 80 percent requirement. Tests may include but are not limited to Kohman method or inline and benchtop infrared analysis.

Second, ABI sought clarification on which records will be reviewed. Records reviewed will vary by plant depending on which records are kept by the individual plant in the normal course of business. Records reviewed may include the plant's sample selection process, butterfat testing methods, quality control of butterfat composition during manufacturing, final butterfat results, management of out of specification product, and training documentation. Review of records will be on an annual basis.

Third, ABI sought clarification on accepted butterfat testing methodologies. Acceptable testing methodologies include those that are intended for the analysis of butterfat composition in butter. Testing equipment may be calibrated using the Kohman or modified Kohman as a reference testing method. Additional validated methodologies available in the future may be considered provided the purpose of the test is for the analysis of butterfat composition.

Fourth, ABI requested clarification on compliance and enforcement. If during a normal review of records, a plant is found to have test records demonstrating the plant's butter products did not meet composition requirements, USDA will review additional documentation. Such additional documentation will include the plant's policy to maintain butterfat composition, corrective actions taken after product was found to not meet the 80 percent requirement, and training and/or preventative measures taken to reduce the occurrence of butter products not meeting composition requirements.

If a plant fails to take corrective action as instructed by USDA over the course of three consecutive reviews, or releases product not meeting the composition requirement on three occasions, USDA may notify the plant to discontinue use of the butter shield.

Two commenters opposing the proposed rule expressed concern that allowing plants to forego a USDA inspection in favor of a records review of an in-house or third-party testing regime could jeopardize quality for consumers. An additional commenter expressed the change would impact the value of the 'Made in Wisconsin' butter symbol because of what the commentator viewed as less regulatory oversight. The rule does not lessen USDA's oversight of plants to ensure adherence to the regulations and the quality standards set by USDA. USDA will conduct a review of each butter manufacturing plant's quality production records to verify the butterfat testing program meets regulatory requirements. Additionally, third-party industry laboratory test experts routinely audit and validate non-USDA-laboratory test procedures. The review of records provided by this rule offers USDA a more thorough view of the composition of a plant's butter products over time, rather than a single point in time test, to ensure product is meeting the required butterfat composition standard.

AMS is making no changes to the proposed rule based on these comments.

Finally, this final rule corrects a misspelling in the regulations. A revision to § 58.336(a) replaces the word "insure" with "ensure." ABI commented that the correction should also be made to the new § 58.336(b). AMS agrees and is making the corresponding change.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), AMS requested approval of new information collection and recordkeeping requirements for the AMS Dairy Grading and Inspection Program and comments were invited on this new information collection. AMS received no public comments on the Office of Management and Budget (OMB)-approved information collection portion of the final rule.

Title: Regulations Governing the Review of Butterfat Testing Records for the Dairy Grading and Inspection Butter Program.

OMB Number: 0581-0340.

Expiration Date of Approval: This is a NEW collection.

Type of Request: Approval of New Information Collection.

Abstract: The Dairy Grading and Inspection Program is a voluntary, fee-based program authorized under the Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621-1627). The regulations governing inspection and grading services of manufactured or processed dairy products are contained in 7 CFR part 58. Under the program, a plant can submit to grading and inspection of its butter products by a USDA grader following the U.S. Grade Standards to ensure each product meet the U.S. grade requirements. This program provides uniform quality of dairy products in the marketplace. The information collection requirements in this request are essential to carry out the intent of the AMA—to ensure that dairy products are produced under sanitary conditions and buyers are purchasing a quality product.

Estimate of Burden: Public recordkeeping burden for this collection of information is estimated to average 2.5 hours per year.

Recordkeepers: Butter manufacturers.

Estimated Number of Recordkeepers: 17.

Estimated Number of Hours per Recordkeeper: 2.5 hours.

Estimated Total Annual Burden on Recordkeepers: 42.5 hours.

Comments: No comments were received on the information collection in the proposed rule.

The information collection adds an annual review of a plant's butterfat testing records as an alternative to testing by USDA inspectors. The review encompasses plant records of butterfat tests performed as required under 7 CFR 58.336, and analysis of records. Plants seeking USDA inspection for butter grading conduct their own routine, audited, butterfat tests to ensure quality and compliance with composition standards. The information sought in this collection is contained in records kept in the regular course of business by the inspected plant. Records will be reviewed on-site by a USDA inspector. The plant will not be required to submit information to the agency.

E-Government Act

USDA is committed to complying with the E-Government Act (44 U.S.C. 3601, *et seq.*) by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Orders 12866 and 13563

USDA is issuing this rule in conformance with Executive Orders 12866 and 13563, which direct agencies

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

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. This rule will not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule.

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601–612), AMS has considered the economic impact of the action on small entities. Accordingly, AMS has prepared this Regulatory Flexibility Analysis (RFA).

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. The Small Business Administration's definition (13 CFR 121.201) of small agricultural service firms, which includes dairy processors, varies based on the type of dairy product manufactured. Small butter manufacturers processors are defined as having 750 or fewer employees. Seventeen (17) plants producing grade label butter in the U.S. participate in the Grade Label Program. According to AMS calculations, about twelve (12), or approximately two-thirds, are operated by dairy farmer cooperatives, while the remaining five (5) are independently owned. AMS estimates that six (6) of the seventeen (17) participating butter processors would be considered small businesses.

AMS has determined that establishment of this proposal will not have a significant economic impact on small entities. The Dairy Program Grading and Inspection Program is a voluntary program. Small businesses have the option to participate. The change will not unduly or disproportionately burden small butter

processing entities. It will reduce costs to small businesses by providing an alternative to a redundant butterfat test currently performed by USDA. AMS expects most or all plants to choose a review of records. AMS estimates the cost to plants for meeting USDA butterfat testing requirements ranges from \$5,000 to \$32,000 annually. The significant cost difference depends on whether the plant has an approved onsite laboratory or must ship samples to an outside AMS laboratory, and the frequency of butterfat samples submitted for testing.

The change will add a review of records of butterfat tests that manufacturers currently conduct in the normal course of business to ensure quality and compliance with composition standards as an alternative to a USDA-inspector test. The plants will be charged for the inspectors' time to conduct the records review, estimated to take four hours annually. At an hourly rate of \$110, a records review will cost the plant approximately \$440. This results in annual net saving to plants ranging from \$4,560 to \$31,560.

Program provisions will be applied uniformly to both large and small businesses and is not expected to burden small entities unduly or disproportionately.

Executive Order 13175

This rule has been reviewed under E.O. 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this rule is unlikely to 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.

List of Subjects in 7 CFR Part 58

Dairy product, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 58 as follows:

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

■ 1. The authority for part 58 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 2. Amend § 58.148 by adding paragraph (h) to read as follows:

§ 58.148 Plant records.

* * * * *

(h) Butterfat test records. Retain for 12 months.

■ 3. Amend § 58.336 by revising paragraphs (a) and (b) to read as follows:

§ 58.336 Frequency of sampling for quality control of cream, butter and related products.

(a) *Microbiological.* Samples shall be taken from churnings or batches and should be taken as often as is necessary to ensure microbiological control.

(b) *Sampling and testing.*—(1) *Composition.* Sampling and testing for product composition shall be made on churns or batches as often as is necessary to ensure adequate composition control. For in-plant control, the Kohman or modified Kohman test may be used.

(2) *Sampling.* Butterfat sampling may be performed as part of an in-plant quality program.

* * * * *

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2025–00760 Filed 1–15–25; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 204

[CIS No. 2800–25; DHS Docket No. USCIS–2006–0010]

RIN 1615–AB50

Eligibility of Arriving Aliens in Removal Proceedings To Apply for Adjustment of Status and Jurisdiction To Adjudicate Applications for Adjustment of Status; Correction

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS)

ACTION: Interim final rule; correcting amendments.

SUMMARY: On May 12, 2006, the Department of Homeland Security (DHS) and the Department of Justice (DOJ) published an interim final rule titled “*Eligibility of Arriving Aliens in Removal Proceedings To Apply for Adjustment of Status and Jurisdiction To Adjudicate Applications for Adjustment of Status*” The rule amended DHS and DOJ regulations governing applications for adjustment of

status filed by paroled “arriving aliens” seeking to become lawful permanent residents and removed certain provisions. In that rule, DHS removed a paragraph from its regulations and redesignated the paragraph that followed to close the gap. DHS inadvertently failed to make a conforming amendment to a related regulatory provision to reflect the redesignation. This document describes the oversight and corrects the CFR. This action makes no substantive changes.

DATES: Effective on January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Need for Correction

On May 12, 2006, DHS and DOJ published an interim final rule, with a request for comments, in the **Federal Register** titled “*Eligibility of Arriving Aliens in Removal Proceedings To Apply for Adjustment of Status and Jurisdiction To Adjudicate Applications for Adjustment of Status.*”¹ The 2006 interim final rule amended DHS and DOJ regulations governing applications for adjustment of status filed by paroled “arriving aliens” seeking to become lawful permanent residents. As part of the rulemaking, DHS and DOJ amended their respective regulations. Among other changes, DHS removed then paragraph (c)(8) of 8 CFR 245.1 and redesignated then paragraph (c)(9) as paragraph (c)(8) to close the gap.² DHS did not substantively amend then paragraph (c)(9). DHS merely shifted that provision to paragraph (c)(8) after DHS removed paragraph (c)(8)’s content. Accordingly, 8 CFR 245.1(c)(8) now contains the same content that was previously in paragraph (c)(9), and paragraph (c)(9) no longer exists.

DHS, however, inadvertently failed to make conforming changes to a separate provision of DHS’s regulations, 8 CFR 204.2(a)(1)(iii), which continues to reference 8 CFR 245.1(c)(9).

Specifically, the second sentence of 8 CFR 204.2(a)(1)(iii) refers to 8 CFR 245.1(c)(9) and 245.1(c)(9)(iii)(F).³ DHS should have amended the references in this sentence to refer to paragraphs (c)(8) and (c)(8)(iii)(F) respectively. This

document now corrects this oversight in the CFR to ensure that 8 CFR 204.2(a)(1)(iii) correctly cross-references 8 CFR 245.1(c)(8).

DHS is not substantively changing 8 CFR 204.2(a)(1)(iii) and 245.1(c)(8). Those long-standing provisions codify and implement certain statutory requirements that generally prohibit USCIS from approving certain visa petitions⁴ or applications for adjustment of status⁵ based on a marriage that occurred during exclusion, deportation, or removal proceedings, or related judicial proceedings. Prior to the 2006 interim final rule, then 8 CFR 245.1(c)(9) implemented the statutory prohibition for adjustment of status applications. Similarly, 8 CFR 204.2(a)(1)(iii) implements the prohibition for certain visa petitions. DHS did not either substantively or non-substantively revise the content of 8 CFR 245.1(c)(9), related to adjustment of status based on marriages during exclusion, deportation, or removal proceedings, or related judicial proceedings, when DHS redesignated that paragraph as 8 CFR 245.1(c)(8) in 2006.⁶ Similarly, this correction document is not substantively amending the content in 8 CFR 204.2(a)(1)(iii) related to visa petitions based on such marriages, or making any edits to 8 CFR 245.1(c)(8). Rather, DHS is merely amending 8 CFR 204.2(a)(1)(iii) to correctly cross-reference the provisions of 8 CFR 245.1(c)(8) to reflect DHS’s redesignation of that paragraph in the 2006 interim final rule.

Administrative Procedure Act

Section 553(b) of the Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect.⁷ In addition, section 553(d) of the APA requires agencies to delay the effective date of final rules by a minimum of 30 days after the date of their publication in the **Federal Register**.⁸ An agency may bypass notice-and-comment rulemaking and a delayed effective date when the agency “for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”⁹

⁴ See INA sec. 204(g), 8 U.S.C. 1154(g).

⁵ See INA sec. 245(e), 8 U.S.C. 1255(e).

⁶ See 71 FR at 27591.

⁷ See 5 U.S.C. 553(b).

⁸ See 5 U.S.C. 553(d)(3).

⁹ See 5 U.S.C. 553(b)(B), (d)(3).

DHS believes there is good cause for publishing this correction document without prior notice and opportunity for public comment and with an effective date of less than 30 days because DHS finds that such procedures are unnecessary. As explained above, this document corrects an oversight in the regulatory text and does not make substantive changes to the policies that were adopted in the 2006 interim final rule or any other rule, including those reflected in 8 CFR 204.2(a)(1)(iii) and 8 CFR 245.1(c)(8) that generally prohibit USCIS from approving certain visa petitions and applications for adjustment of status based on a marriage that occurred during exclusion, deportation, or removal proceedings, or related judicial proceedings subject to certain exemptions. This document merely corrects a cross-reference in 8 CFR 204.2(a)(1)(iii) to ensure that it accurately reflects that DHS redesignated then 8 CFR 245.1(c)(9) as 8 CFR 245.1(c)(8) in the 2006 interim final rule, which was itself a non-substantive change. Therefore, DHS believes that it has good cause to waive the notice and comment and effective date requirements of section 553 of the APA.

List of Subjects in 8 CFR Part 204

Administrative practice and procedure, Adoption and foster care, Immigration, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, 8 CFR part 204 is amended as follows:

PART 204—IMMIGRANT PETITIONS

- 1. The authority citation for part 204 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1151, 1153, 1154, 1182, 1184, 1186a, 1255, 1324a, 1641; 8 CFR part 2.

- 2. Amend § 204.2 by revising the second sentence of paragraph (a)(1)(iii) to read as follows:

§ 204.2 Petitions for relatives, widows and widowers, and abused spouses and children.

(a) * * *

(1) * * *

(iii) * * * Determination of

commencement and termination of proceedings and exemptions shall be in accordance with § 245.1(c)(8) of this chapter, except that the burden in visa petition proceedings to establish eligibility for the exemption in

¹ See 71 FR 27585 (May 12, 2006) (2006 interim final rule).

² See *id.* at 27591.

³ See 8 CFR 204.2(a)(1)(iii) (2024).

§ 245.1(c)(8)(iii)(F) of this chapter shall rest with the petitioner.

* * * * *

Christina E. McDonald,

Associate General Counsel for Regulatory Affairs, U.S. Department of Homeland Security.

[FR Doc. 2025–01031 Filed 1–15–25; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2024–BT–TP–0010]

RIN 1904–AB99

Energy Conservation Program: Test Procedure for General Service Lamps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (“DOE”) is adopting clarifications to the test procedures for general service lamps (“GSLs”) located in appendix W, appendix BB and appendix DD. Specifically, DOE is clarifying instructions that GSLs must not be tested as colored lamps and that lamps with additional components that do not affect light output must be turned off during testing. The clarifications also specify that non-integrated lamps be tested with a fluorescent lamp ballast, high intensity discharge (“HID”) lamp ballast or external light-emitting diode (“LED”) driver selected based on compatibility lists and availability; and provide specifications regarding the starting method, ballast factor, and number of lamps. This rulemaking is limited in scope and is providing clarifications to the current test procedures that are required for certification of compliance with existing applicable GSL energy conservation standards. Further, this rulemaking does not satisfy the Energy Policy and Conservation Act (“EPCA”) requirement that, at least once every 7 years, DOE review the test procedures for GSLs.

DATES: The effective date of this rule is February 18, 2025. The amendments will be mandatory for product testing starting July 15, 2025. The incorporation by reference of certain material listed in the rule was approved by the Director of the Federal Register as of November 21, 2016.

ADDRESSES: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at

www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket web page can be found at www.regulations.gov/docket/EERE-2024-BT-TP-0010. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: ApplianceStandardsQuestions@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT:

Dr. Jordan Wilkerson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. Email: ApplianceStandardsQuestions@ee.doe.gov.

Ms. Kiana Daw, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–4798. Email: kiana.daw@hq.doe.gov.

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I. Authority and Background

GSLs are included in the list of “covered products” for which the DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6291(30)(BB); 42 U.S.C. 6291(30)(DD); 42 U.S.C. 6295(i)(6)) GSLs include but are not limited to general service incandescent lamps (“GSILs”), incandescent reflector lamps (“IRLs”), compact fluorescent lamps (“CFLs”), and integrated LED lamps. DOE’s test procedure for GSILs and IRLs are set forth at 10 CFR part 430, subpart B, appendix R (“appendix R”). DOE’s test procedure for CFLs is set forth at 10 CFR part 430, subpart B, appendix W (“appendix W”). DOE’s test procedure for integrated LED lamps is set forth at 10 CFR part 430, subpart B, appendix BB (“appendix BB”). DOE’s test procedure for GSLs that are not GSILs, IRLs, CFLs, or integrated LED lamps is set forth at 10 CFR part 430, subpart B, appendix DD (“appendix DD”). The following sections discuss DOE’s authority to establish and amend test procedures for GSLs and relevant background information regarding DOE’s consideration of test procedures for this product.

A. Authority

The Energy Policy and Conservation Act, Public Law 94–163, as amended (“EPCA”),¹ authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317, as codified) Title III, Part B of EPCA² established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include GSLs, the subject of this document. (42 U.S.C. 6295(6))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42

¹ All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

² For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA (42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of those products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with any relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle (as determined by the Secretary) or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including GSLs, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

If the Secretary determines, on her own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** proposed test procedures and afford interested persons an opportunity to

present oral and written data, views, and arguments with respect to such procedures. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)). If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures.

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption into the overall energy efficiency, energy consumption, or other energy descriptor, unless the current test procedure already incorporates the standby mode and off mode energy consumption, or if such integration is technically infeasible. (42 U.S.C. 6295(gg)(2)(A)(i)–(ii)) If an integrated test procedure is technically infeasible, DOE must prescribe separate standby mode and off mode energy use test procedures for the covered product, if a separate test is technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the International Electrotechnical Commission (“IEC”) Standard 62301³ and IEC Standard 62087⁴ as applicable. (42 U.S.C. 6295(gg)(2)(A))

In this final rule, DOE is adopting clarifications to the test procedures for GSLs to address specific issues and to make minor clarifications to the current test procedures that are required for certification of compliance with applicable GSL energy conservation standards. Further, this final rule does not satisfy the EPCA requirement that, at least once every 7 years, DOE review the test procedures for GSLs. (42 U.S.C. 6293(b)(1)(A))

B. Background

DOE’s existing test procedures for GSLs appear at 10 CFR part 430, subpart B, appendix R for GSILs and IRLs, appendix W for CFLs, appendix BB for integrated LED lamps and appendix DD for all GSLs that are not GSILs, IRLs,

CFLs, or integrated LED lamps. In this final rule, DOE is adopting clarifications to appendix W, appendix BB, and appendix DD.

On July 1, 2016, DOE published a final rule adopting a test procedure for integrated LED lamps in appendix BB. 81 FR 43404. On August 19, 2016, DOE published a final rule amending test procedures for medium base CFLs and adopting test procedures for new metrics for all CFLs including hybrid CFLs and CFLs with bases other than medium screw base in appendix W. 81 FR 59386. On October 20, 2016, DOE published a final rule adopting new test procedures for GSLs that are not integrated LED lamps, CFLs, or GSILs in appendix DD. 81 FR 72493.

On May 9, 2022, DOE published a final rule codifying the 45 lumens per watts (“lm/W”) backstop requirement for GSLs that Congress prescribed in amendments to EPCA. 87 FR 27439. DOE issued a phased-in enforcement policy for the 45 lm/W backstop requirement.⁵ On October 14, 2022, DOE issued a guidance document⁶ stating that manufacturers and importers are not currently required to certify compliance to the 45 lm/W backstop requirement and that DOE may address the certification requirements for the backstop in a separate, future rulemaking. On October 9, 2024, DOE published a final rule stating because DOE has reached the full enforcement phase of the enforcement policy, manufacturers and importers must certify compliance to the backstop requirement for GSLs. 89 FR 81994, 82052–82053.

On January 11, 2023, DOE published a notice of proposed rulemaking (“January 2023 NOPR”) proposing amended energy conservation standards for GSLs. 88 FR 1638. On April 19, 2024, DOE published a final rule adopting amended energy conservation standards for GSLs (“April 2024 Final Rule”). 89 FR 28856. Note, in the April 2024 Final Rule, for certain lamps, DOE determined that because the market is rapidly developing it was unable to make a clear and accurate determination regarding the consumer utility, how various technology options would affect the efficiency, and maximum technologically feasible efficiency of these lamps, which prevented DOE from determining whether a specific standard for these lamps would be economically justified. Accordingly, the standards

³ IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

⁴ IEC 62087, *Audio, video and related equipment—Methods of measurement for power consumption* (Edition 1.0, Parts 1–6: 2015, Part 7: 2018).

⁵ See https://www.energy.gov/sites/default/files/2022-04/GSL_EnforcementPolicy_4_25_22.pdf.

⁶ See https://www1.eere.energy.gov/buildings/appliance_standards/pdfs/GSL_Cert_Guidance_Final.pdf.

adopted in the April 2024 Final Rule do not apply to these lamps (see 10 CFR 430.32(dd)(1)(iv)(C)). DOE did note that these lamps are still subject to the 45 lm/W sales prohibition at 10 CFR 430.32(dd). 89 FR 28856, 28886–28888.

On November 25, 2024, DOE published a notice of proposed rulemaking (“November 2024 NOPR”) that proposed clarifications to the test procedures for GSLs to address specific issues and to make minor corrections to the current test procedures that are

required for certification of compliance with applicable GSL energy conservation standards. 89 FR 92855. DOE received comments in response to the November 2024 NOPR from the interested parties listed in Table I.1.

TABLE I.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE NOVEMBER 2024 NOPR

Commenter(s)	Reference in this final rule	Comment No. in the docket	Commenter type
Bay Area Compliance Laboratories Corp. (“BACLC”)	BACLC	2	Laboratory.
Michael Ravnitzky	Ravnitzky	3	Individual.
Individual	Individual	4	Individual.
Individual ⁷	Individual	6	Individual.
Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison; collectively, the California Investor-Owned Utilities (“CA IOUs”).	CA IOUs	7	Utility.
Westinghouse Lighting	Westinghouse	8	Manufacturer.
Signify	Signify	9	Manufacturer.
National Electrical Manufacturers Association (“NEMA”)	NEMA	10	Industry Association.
Appliance Standards Awareness Project (“ASAP”), Northwest Energy Efficiency Alliance (“NEEA”), National Consumer Law Center.	ASAP <i>et al.</i>	11	Efficiency Organizations.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.⁸

II. Synopsis of the Final Rule

In this final rule, DOE is adopting clarifications to appendix W, “Uniform Test Method for Measuring the Energy Consumption of Compact Fluorescent Lamps;” appendix BB, “Uniform Test Method for Measuring the Input Power, Lumen Output, Lamp Efficacy, Correlated Color Temperature (CCT), Color Rendering Index (CRI), Power Factor, Time to Failure, and Standby Mode Power of Integrated Light-Emitting Diode (LED) Lamps;” and appendix DD, “Uniform Test Method for

Measuring the Energy Consumption and Energy Efficiency of General Service Lamps That Are Not General Service Incandescent Lamps, Compact Fluorescent Lamps, or Integrated LED Lamps.” DOE is adopting clarifications to appendices W, BB and DD to specify: (1) lamps must not be tested as colored lamps; and (2) lamps with additional components that do not affect the light output of the lamp (*e.g.*, camera, speaker) must be tested with as many components turned off as possible.

Additionally, in this final rule, DOE is adopting clarifications to appendix DD as follows: (1) remove the instruction to operate non-integrated LED lamps at the manufacturer-declared input voltage and current; (2) specify that non-

integrated lamps be tested on a fluorescent lamp ballast, HID lamp ballast, or external LED driver, in an order of preference based on being on a manufacturer-provided compatibility list and/or commercially available; (3) specify the starting method and ballast factors for the fluorescent lamp ballasts used in testing; and (4) specify that fluorescent lamp ballasts, HID lamp ballasts, or external LED drivers used in testing operate the maximum number of lamps and instructions for calculating individual lamp values where more than one lamp is operated.

DOE’s actions are summarized in Table II.1 compared to the current test procedure as well as the reason for the change.

TABLE II.1—SUMMARY OF CHANGES IN TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Clarification to test procedure	Attribution
Does not include instruction to ensure lamps are not tested as a colored lamp.	Provides instructions that lamps must not be tested as colored lamps.	Response to industry comments.
Does not include instructions to test lamps with additional components that do not affect the light output of the lamp (<i>e.g.</i> , camera, speaker) with as many features turned off as possible.	Provides instructions to turn off as many components as possible during testing for lamps with additional components that do not affect the light output of the lamp (<i>e.g.</i> , camera, speaker).	Response to industry comments.
Includes instructions to test non-integrated LED lamps at the manufacturer-declared input voltage and current.	Removes instructions to test non-integrated LED lamps at the manufacturer-declared input voltage and current and instead specifies to test non-integrated lamps with a fluorescent lamp ballast, HID lamp ballast or external LED driver selected in order of preference based on compatibility list and availability.	Response to industry comments.
Does not include instructions for starting method and ballast factor for a fluorescent lamp ballast used in testing non-integrated lamps.	Specifies that a fluorescent lamp ballast used in testing non-integrated lamps must have certain starting methods and ballast factors.	Response to industry comments.

⁷ This comment was also submitted as comment No. 5 in the docket, <https://www.regulations.gov/document/EERE-2024-BT-TP-0010-0001>. In this document, the comment is referenced as comment No. 6.

⁸ The parenthetical reference provides a reference for information located in the docket of DOE’s rulemaking to develop test procedures for insert product. (Docket No. EERE–2024–BT–TP–0010, which is maintained at: www.regulations.gov). The

references are arranged as follows: (commenter name, comment docket ID number at page of that document).

TABLE II1—SUMMARY OF CHANGES IN TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE—Continued

Current DOE test procedure	Clarification to test procedure	Attribution
Does not include instructions for number of lamps for a fluorescent lamp ballast, HID lamp ballast used in testing non-integrated lamps.	Specifies that a fluorescent lamp ballast, HID lamp ballast used in testing non-integrated lamps must operate the maximum number of lamps and provides instructions for calculating individual lamp values where more than one lamp is operated.	Response to industry comments.
Does not include certain test instructions for non-integrated lamps.	Adds language in appendix DD that provide relevant test setup instructions for testing non-integrated lamps that are designed and marketed to replace fluorescent lamps and HID lamps.	Response to industry comments.

DOE has determined that the clarifications described in section III of this document and adopted in this document will not alter the measured efficiency of GSLs, or require retesting or recertification solely as a result of DOE's adoption of the clarifications to the test procedures. Additionally, DOE has determined that the clarifications will not increase the cost of testing. Discussion of DOE's actions are addressed in detail in section III of this document.

The effective date for the amended test procedures adopted in this final rule is 30 days after publication of this document in the **Federal Register**. Representations of energy use or energy efficiency must be based on testing in accordance with the amended test procedures beginning 180 days after the publication of this final rule.

III. Discussion

In the following sections, DOE discusses certain clarifications to its test procedures for GSLs. For each clarification DOE provides relevant background information, explains why the clarification merits consideration, discusses relevant public comments, and its final approach.

A. Scope of Applicability

This rulemaking applies to GSLs. DOE defines a GSL as a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps (as set out in this definition), or is able to operate at any voltage for non-integrated lamps (as set out in this definition); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps,

general service light-emitting diode lamps, and general service organic light emitting diode lamps. 10 CFR 430.2. There are 26 lamp types exempt from the GSL definition.⁹

B. Clarifications to Appendix W, Appendix BB, and Appendix DD

In this document, DOE is adopting clarifications to the existing test procedures for GSLs to ensure consistent testing to comply with the 45 “lm/W” backstop requirement for GSLs that Congress prescribed in amendments to EPCA. (42 U.S.C. 6295(i)(6)(A)(v)) DOE has determined these clarifications will further ensure consistency and repeatability in testing. To the extent that other GSLs may not be able to be tested in accordance with DOE's test procedures, manufacturers may petition DOE for test procedure waivers in accordance with 10 CFR 430.27.

DOE received general comments regarding the clarifications to the GSL test procedures proposed in the November 2024 NOPR. The CA IOUs stated their general support for DOE's proposals and recommended certain amendments to the proposed changes, suggesting that if these cannot be included in this final rule, DOE collaborate with CA IOUs and other stakeholders to consider them for a future update. (CA IOUs, No. 7 at pp. 1, 4) ASAP *et al.* supported DOE's proposed clarifications in the November 2024 NOPR and agreed with DOE's tentative determination that these clarifications would not alter the measured efficacy of GSLs nor require retesting or recertification. (ASAP *et al.*, No. 11 at p. 1) Additionally, one individual commenter, Michael Ravnitzky, stated support of DOE's efforts to provide clarifications to the GSL test procedures in the November 2024 NOPR. (Ravnitzky, No. 3 at p.1)

One individual commented in opposition to the proposed clarifications to the GSL test procedures, stating they

lead to unnecessary regulation of GSLs. (Individual, No. 4 at p. 1) Another individual stated concern regarding the complexity of the test procedures in particular for newer smart appliances and recommended DOE ensure test conditions better reflect real-world usage. They also stated that some of the proposed clarifications were vague, and DOE should provide clearer instructions, frequently answered questions (“FAQs”), and practical examples—possibly in the form of webinars and step-by-step guidance—to help manufacturers better understand the test procedures. (Individual, No. 6 at pp. 1, 1–2)

In this final rule, DOE is adopting clarifications to existing GSL test procedures to ensure they provide the appropriate and necessary instructions for showing compliance to existing GSL energy conservation standards. Moreover, in this final rule, in response to comments received on the November 2024 NOPR, DOE has adopted several amendments to the proposed clarifications to further improve clarity. Specific comments regarding amendments to the proposals in the November 2024 NOPR are discussed in the following sections. Additionally, DOE has a web page through which it provides guidance and answers Frequently Asked Questions (FAQs) on its appliance standards program.¹⁰

DOE also received comments on aspects of the GSL test procedures for which DOE did not propose clarifications in the November 2024 NOPR. Signify and NEMA stated that DOE should replace the current industry reference for measuring standby mode,

⁹ See definition of “general service lamp” in 10 CFR 430.2 for the specific exemptions from the definition.

¹⁰ Appliance Standards Guidance and Frequently Asked Questions (FAQs), available at www.energy.gov/eere/buildings/appliance-standards-guidance-and-frequently-asked-questions-faqs.

IEC 62301¹¹ with ANSI C137.63103,¹² which is a national adoption of IEC 63103.¹³ (Signify, No. 9 at p. 6–7; NEMA, No. 10 at p. 2) Signify stated that this standard is similar to IEC 62301 except it includes test setups specific to lighting products (e.g., LED lamps) and its adoption would increase repeatability, reduce lab-to-lab setup variability, and harmonize with international test methods. (Signify, No. 9 at p. 6–7) NEMA stated that the currently referenced IEC 62301 is ineffective for use with lighting products and if DOE cannot replace it in this rule, it should do so in a future rulemaking. (NEMA, No. 10 at p. 2)

This final rule is limited in scope to providing clarifications to the current GSL test procedures that are required for certification of compliance with existing GSL energy conservation standards. Standby mode power consumption of GSLs is not currently subject to standards and therefore, is not within the scope of this rulemaking.

Finally, Ravnitzky recommended adjustments to the language implementing the clarifications proposed in the November 2024 NOPR, stating those adjustments would enhance clarity without changing meaning. (Ravnitzky, No. 3 at pp. 2–7) DOE reviewed the recommendations and adopted certain suggestions that it determined improved clarity while maintaining the original meaning. For example, stating “select a ballast” instead of “choose a ballast;” stating “test report must specify” instead of “manufacturer must indicate in the test report;” stating “if the procedure in section 3.1.3.1 is not possible” instead of “if section 3.1.3.1 is not possible.”

The following sections discuss in detail the clarifications proposed in the November 2024 NOPR, relevant public comments, and DOE’s final approach.

1. Lamps With Multiple Modes

Appendices W, BB, and DD specify instructions to test at maximum input power for all lamps, including those that may operate in multiple modes. Section 3.1.4 of appendix BB and section 3.5 of appendix DD specify to operate the lamp at the maximum input power; and if multiple modes occur at the same maximum input power (such as variable CCT or color rendering index

(“CRI”)) select any of these modes and ensure all measurements are taken at the same selected mode. Section 3.1.4 of appendix W specifies to operate the lamp, including those that are dimmable or multi-level, at the labeled wattage, defined as the highest wattage marked on the lamp and/or lamp packaging.

In the November 2024 NOPR, in section 3 of appendices W, BB, and DD, DOE proposed to specify to operate the lamp as not a colored lamp (as defined in 10 CFR 430.2) and if the lamp can operate at multiple CCTs to operate the lamp at 2700 K, or the closest available CCT greater than 2700 K. DOE also proposed to require manufacturers to indicate on the test report which CCT (numerical or on the graphical user interface) is selected for testing and include details such that another laboratory could operate the lamp at the same CCT. 89 FR 92855, 92859.

ASAP *et al.* stated its support for DOE’s clarification that lamps not be tested as colored lamps, noting that it ensures color tunable lamps are not tested as colored lamps which are exempt from the GSL definition. (ASAP *et al.*, No. 11 at p. 1)

DOE also received several comments regarding DOE’s proposal to test at 2700 K or the closest available CCT greater than 2700 K. ASAP *et al.* stated its support for the proposal. (ASAP *et al.*, No. 11 at p. 1) The CA IOUs stated that the proposal does not account for color tunable GSLs that can achieve the same CCT through various combinations of LED outputs, resulting in varying levels of electricity consumption. The CA IOUs cited NEMA’s recommendation that in cases where the same chromaticity can be achieved with multiple primary settings, the manufacturer be the one to determine the test conditions and provide instruction for how to repeat the condition for the highest input power white light chromaticity as per ANSI C78.377.¹⁴ The CA IOUs stated that DOE did not adopt NEMA’s recommendation or offer alternative guidance for testing such GSLs and should provide further guidance in the final rule. (CA IOUs, No. 7 at p. 2) Ravnitzky stated they supported the proposal to test lamps at 2700 K or the closest available CCT greater than 2700 K because it ensures test conditions that reflect typical consumer usage. However, Ravnitzky asked for clarification on what “maximum input power” means for

lamps with multiple modes. (Ravnitzky, No. 3 at p. 1)

The current test procedures in sections 3.1.4 of appendix W, BB, and section 3.5 of appendix DD already specify that the lamp must be operated at maximum input power. In the November 2024 NOPR, DOE proposed to also clarify that the lamp must not be operated as a colored lamp and that if it could operate at multiple CCTs, it must be operated at 2700 K or the closest available CCT greater than 2700 K. 89 FR 92855, 92859. These instructions mean the lamp is tested at the maximum input power at which the lamp is not operating as a colored lamp and operating at 2700 K or the closest available CCT greater than 2700 K, and thereby align with NEMA’s recommendation for testing color tunable lamps at the highest input power white light chromaticity. To further clarify this, in this final rule, DOE has slightly rephrased the proposed language for this instruction from “Operate the lamp at the maximum input power and not as a colored lamp” to “Ensure that the lamp is not operating as a colored lamp and operate the lamp at maximum input power.”

Signify stated it supported DOE’s proposal to require that the lamp not be operated as a colored lamp (as defined in 10 CFR 430.2) but did not support using 2700 K as the only operating set point. Signify commented that tunable white lamps can always produce white light but at different CCTs and California Energy Commission (“CEC”) and ENERGY STAR require testing these lamps at maximum input power which typically occurs at CCTs as high as 4000 K or as low as 2700 K. Signify stated that maximum input power has been the historical set point and renders realistic images with good color fidelity. Signify added stated that removing the proposed requirement to test at a specific CCT would avoid confusion rooted in different testing set points, enable comparison with existing databases and prevent test burden duplication. (Signify, No. 9 at p. 2–3) Similarly, BACLC stated that DOE’s proposal to test GSLs at 2700 K or the closest available CCT greater than 2700 K does not align with ENERGY STAR Lamps V2.1 Final Specification, California’s Title 20 (Appliance Efficiency Proceedings), or California’s Title 24 (Building Standards Code) requirements to respectively, test at the most consumptive white light setting, typically testing at maximum power consumption, and at the least efficient CCT. (BACLC, No. 2 at p. 1) Westinghouse supported DOE’s

¹¹ International Electrotechnical Commission, *IEC 62301 Household electrical appliances—Measurement of standby power*, (Edition 2.0, 2011–01).

¹² American National Standards Institute, *ANSI C137.63103 Lighting Systems—Non-Active Mode Power Measurement*, Approved December 13, 2021.

¹³ IEC 63103, *Lighting Equipment—Non-Active Mode Power Measurement* (Edition 1.0, 2020–07).

¹⁴ American National Standards Institute, *ANSI C78.377—2017 American National Standard for Electric Lamps—Specifications for the Chromaticity of Solid-State Lighting Products*, Approved 2017.

proposal to test at 2700 K or the closest available CCT greater than 2700 K, but stated it should be implemented for future testing. Westinghouse recommended that to prevent retest of thousands of lamps, for GSLs already on the market, DOE should allow prior test data used to certify the lamps to the ENERGY STAR specifications including lamps tested at higher than 2700 K. (Westinghouse, No. 8 at p. 1) NEMA also stated that for many years manufacturers have been testing according to ENERGY STAR specifications, including testing tunable and selectable CCT lamps at the most consumptive white light setting, often at nominal CCTs higher than 2700 K. NEMA stated that this test data was gathered voluntarily in accredited laboratories for provision to the Federal government and remains relevant for products on that market with unchanged designs. (NEMA, No. 10 at p. 3)

NEMA also stated that in its lighting product rulemakings, DOE should clearly distinguish between calculated and nominal CCT. NEMA stated that ANSI C78.377 assigns nominal CCTs (e.g., 2700 K, 3000K, 4000 K) to ranges of calculated CCTs defined with targets and tolerances (e.g., 2580 K–2870 K is nominal 2700 K). NEMA stated that this convention was created to simplify end user product selection and nominal values should not be used for compliance purposes. NEMA also stated that DOE should delineate between tunable CCT and selectable CCT lamps, explaining that tunable CCT lamps allow the user to tune the color appearance continuously by selecting any number of calculated CCTs within the design range while selectable CCT lamps allow for selection of limited, predetermined, stepped CCTs (e.g., 2700 K, 3000 K). (NEMA, No. 10 at p. 3)

In the November 2024 NOPR, DOE proposed to test GSLs that can operate at multiple CCTs at 2700 K because a colored lamp has a CCT less than 2500 K or greater than 7000 K (see 10 CFR 430.2 “colored lamp”). Therefore, operating at 2700 K would ensure that the lamp is not operating as a colored lamp. Further, DOE noted that 2700 K is a common CCT for GSLs. 89 FR 92855, 92859. DOE has reviewed the comments stating that because manufacturers have not been historically testing these GSLs at 2700 K, the proposed clarification to test at a 2700 K may result in having to retest lamps. To avoid retesting of lamps, in this final rule, DOE is not adopting the proposed clarification to test at 2700 K or the closest available CCT greater than 2700 K for lamps that can operate at

multiple CCTs. In this final rule, DOE is adopting the proposed clarification that the lamp cannot be tested as a colored lamp. DOE finds that the specification to not test as a colored lamp is sufficient to ensure that the lamp is not tested as a colored lamp, which is exempt from the GSL definition. DOE will consider adding the clarification of testing at a specific CCT, including NEMA’s suggested delineation of relevant terms, in a future rulemaking.

In the November 2024 NOPR, DOE proposed to remove the instruction in section 3.1 of appendix DD to take measurements at full light output. DOE explained that section 3.5 in appendix DD already specifies to operate the lamp at the maximum input power which is equivalent to operating the lamp at full light output. 89 FR 92855, 92859.

Signify, NEMA, and Westinghouse stated their support for DOE’s proposal to remove the test procedure instruction to take measurements at full light output in appendix DD. (Signify, No. 9 at p. 4; NEMA, No. 10 at p. 1; Westinghouse, No. 8 at p. 2)

In this final rule, DOE is adopting the clarification to remove of the instruction to take measurements at full light output in appendix DD as proposed in the November 2024 NOPR.

2. Lamps With Non-Illumination Components

In the November 2024 NOPR, for lamps with a component(s) that offer a distinct functionality (e.g., a speaker, a camera, an air purifier, etc.) where the component is integrated into the lamp but does not affect the light output of the lamp (e.g., does not turn the light on/off, dim the light, change the color of the light, etc.) and is capable of operating in standby mode, in section 3 of appendices W, BB, and DD, DOE proposed to specify to turn off as many of these components as possible during testing. DOE also proposed to require that the test report indicate which components were turned off and which, if any, components remained on. 89 FR 92855, 92859–92860.

Signify, NEMA, and ASAP *et al.* stated their support for DOE’s proposal to turn off all components that do not affect light output during testing. (Signify, No. 9 at p. 4; NEMA, No. 10 at p. 1; ASAP *et al.*, No. 11 at p. 1) Ravnitzky stated that the proposal to turn off non-illumination components during testing ensures the measured efficacy is not inflated by features that do not produce light. (Ravnitzky, No. 3, p. 1) The CA IOUs stated that DOE’s proposed clarification states that only completely different functions operating in standby mode should be turned off,

if possible, and does not address how to test a GSL that offers a different function but lacks a standby mode. For these GSLs, the CA IOUs asked that the test procedure clarify whether the electricity consumption associated with the different functionalities should be included with that for producing visible light when calculating energy efficiency. (CA IOUs, No. 7 at p. 3) The CA IOUs further stated that DOE’s proposed language “turn off as many of these components as possible” is unclear as to whether it is referring to only components that must be user-switchable independent of the lamp’s light output or also referring to components that are not user-switchable and should be mechanically or electrically turned off during testing. (CA IOUs, No. 7 at p. 3)

As noted, the proposed clarification is for lamps with component(s) that offer a distinct functionality where the component is integrated into the lamp but does not affect the light output of the lamp and is capable of operating in standby mode. 89 FR 92855, 92859–92860. In standby mode, the energy-using product is connected to a main power source and offers one or more of the following user-oriented or protective functions: (1) to facilitate the activation or deactivation of other functions (including active mode) by remote switch (including remote control), internal sensor, or timer; or

(2) continuous functions, including information or status displays (including clocks) or sensor-based functions. 10 CFR 430.2, 42 U.S.C. 6295(gg)(1)(A)(iii). If a lamp has components that provide additional non-lighting functionality and that can be deactivated, it would be capable of operating in standby mode, consistent with the definition of standby mode. DOE understands that lamps with component(s) that offer distinct functionality that does not affect light output can be continuous functions, and therefore not meet the definition of standby mode, and it may not be possible to turn them off. In this case, the energy consumption of the component that offers that distinct functionality will have to be included in measured values during testing.

Further, the proposed language to “turn off as many of these components as possible” means without permanently altering the product. To clarify this meaning, in this final rule, DOE is adding language to clearly state to turn off components without permanently altering the product where permanently altering constitutes the cutting of wires, use of a soldering iron, or damage to or destruction of the lamp

and does not constitute connecting or disconnecting wire nuts, fasteners or screws, or preserving the lamp as it was sold. If such components cannot be turned off without permanently altering the product, their energy consumption must be included in measurements.

In summary, in this final rule, DOE is adopting the clarification regarding turning off components that do not affect light output during testing, as proposed in the November 2024 NOPR with the added clarification that this instruction must be carried out without permanently altering the product. To the extent that a lamp would not be able to be tested in accordance with these provisions, manufacturers may petition for a test procedure waiver in accordance with 10 CFR 430.27.

3. Non-Integrated Lamps

Section 3.4 of appendix DD provides instructions to operate a non-integrated lamp at the manufacturer-declared input voltage and current. In the November 2024 NOPR, DOE proposed to remove the instruction in section 3.4 of appendix DD to operate non-integrated LED lamps at the manufacturer-declared input voltage and current and specify that the remaining instructions regarding rated voltages apply to integrated lamps. Additionally, DOE proposed to add a section to appendix DD that specifies that a non-integrated lamp be operated on a fluorescent lamp ballast or external driver that is selected based on manufacturer-provided compatibility list and availability, starting method, and ballast factor. Finally, DOE proposed to add instructions for testing with a fluorescent lamp ballast or external driver in terms of number of lamps used, and references to relevant industry standards. 89 FR 92855, 92860. The proposal and relevant public comments are discussed in the following sections.

a. Selection of Fluorescent Lamp Ballast, HID Lamp Ballast or External LED Driver

In the November 2024 NOPR, DOE proposed that the fluorescent lamp ballast or external driver selected for testing must be, in the following order of preference: (1) from the lamp's publicly available manufacturer-provided compatibility list and commercially available; (2) commercially available and able to operate the lamp throughout the duration of the test; (3) previously procured and able to operate the lamp throughout the duration of the test. Only if the fluorescent lamp ballast and external driver cannot be selected from

the previous preference should the next preference be availed. Additionally, DOE proposed that the manufacturer record the fluorescent lamp ballast or external driver manufacturer and model name/number used for testing in the test report. 89 FR 92855, 92860.

DOE received general comments regarding this proposal. Ravnitzky supported DOE's proposal to test non-integrated lamps with a fluorescent lamp ballast or external driver selected from a compatibility list or based on availability, stating it would replicate real-world usage conditions. (Ravnitzky, No. 3, p. 1) ASAP *et al.* supported DOE's proposed specifications for selecting fluorescent lamp ballast or external driver and, if applicable, the starting method and/or ballast factor; stating they improved repeatability and ensured representativeness. (ASAP *et al.*, No. 11 at p. 2) Signify and NEMA stated they supported the order of preference of selection based on: (A) described in the lamp manufacturer compatibility list, (B) commercially available, (C) starting method as described in Table III.1 of the November 2024 NOPR and (D) ballast factor as described in Table III.2 of the November 2024 NOPR. (Signify, No. 9 at p. 4; NEMA, No. 10 at p. 2)

DOE also received specific comments regarding (1) definitions and terminology, (2) the organization of the proposed clarifications, (3) use of previously procured ballasts or external drivers, (4) instructions on preheat start fluorescent lamp ballasts, and (5) starting methods and ballast factors. These are discussed in detail in the following sections.

Definitions and Terms

DOE received comments on definitions and terms used in the proposed clarifications for selecting ballasts or external drivers for testing non-integrated lamps. NEMA recommended that, consistent with ANSI/Illuminating Engineering Society ("IES") LS-1–22,¹⁵ DOE employ the standardized term "LED driver" rather than "driver". (NEMA, No. 10 at p. 3) DOE agrees that aligning with industry terminology will be a helpful clarification. Therefore, in this final rule, DOE is adopting the proposed clarifications in appendix DD with the term "driver" replaced with "LED driver."

NEMA also recommended that DOE replace all instances of "fluorescent"

with "fluorescent or HID," given the inclusion of LED replacements for HID lamps in the proposed clarifications. (NEMA, No. 10 at p. 4) In the November 2024 NOPR, it was DOE's intent to ensure that its proposed clarifications address testing of all non-integrated lamps including those that operate on HID lamp ballasts. While DOE proposed clarifications stating that non-integrated lamps that operate on HID lamp ballasts must be tested according to ANSI C78.53 (see section III.B.3.b of this document), DOE did not appropriately reference HID lamp ballasts in the proposed clarifications for selecting the ballast in the November 2024 NOPR. Therefore, in this final rule, DOE is adopting the proposed clarifications in appendix DD with the inclusion of the term "HID lamp ballast". Note, that the specific ballast factors and starting methods proposed in the November 2024 NOPR are applicable only to fluorescent lamp ballasts. 89 FR 92855, 92860–92861.

In the November 2024 NOPR, DOE proposed to define the term "commercially available fluorescent lamp ballast or external driver" as one that can be purchased by an individual consumer at a readily accessible retailer (*i.e.*, retailer with storefront or online purchasing). 89 FR 92855, 92860.

Signify and NEMA stated it concurred with DOE's definition of "commercially available" as meaning the lamp can be purchased by a consumer in a readily accessible retail storefront or online. (Signify, No. 9 at p. 4; NEMA, No. 10 at p. 2) Ravnitzky recommended that DOE define "commercially available fluorescent lamp ballast" as a ballast that can be purchased by an individual consumer at an accessible retailer, that has either a storefront or online purchasing platform, and include the term in a glossary. (Ravnitzky, No. 3 at p. 1)

The proposed definition, which was included in the definitions section of appendix DD, aligns with Ravnitzky's suggested definition. As noted in previous paragraphs, in this final rule, DOE is adding the term HID lamp ballast and also replacing the term "driver" with "LED driver". Accordingly, in this final rule, DOE is renaming the proposed term "commercially available fluorescent lamp ballast or external driver" to "commercially available fluorescent lamp ballast, high intensity discharge ("HID") ballast, or external LED driver."

Ravnitzky recommended that DOE define "publicly available manufacturer-provided compatibility list" as lists made available by manufacturers on their official websites

¹⁵ American National Standards Institute, Illuminating Engineering Society, *Lighting Science: Nomenclature and Definitions for Illuminating Engineering*, available at <https://www.ies.org/standards/definitions/>.

or through publicly accessible documents which detail the ballasts or drivers that are compatible with specific lamp models. (Ravnitzky, No. 3 at p. 1)

The term “publicly available manufacturer-provided compatibility list” is used throughout the proposed language in section 3.1.3 of appendix DD. 89 FR 92855, 92867. DOE agrees that defining this term will provide further clarification to the proposed instructions. DOE’s review of compatibility lists indicates that the information provided can range from a general statement that the lamp is compatible with electronic ballasts to specifying ballast or external LED driver models which are compatible with the lamp. Additionally, DOE’s intent in using the term “manufacturer-provided” is to ensure that the information is provided by the manufacturer either through the manufacturer’s website or publicly available documents. Therefore, in this final rule, DOE adopts language in appendix DD that defines “publicly available manufacturer-provided compatibility list” as a list or statement made available by the manufacturer on the manufacturer’s official website or made available by the manufacturer through publicly available documents (e.g., product literature, catalogs, and packaging labels), that provides information on the ballasts or external LED drivers that are compatible with the lamp.

Organization of Proposed Clarifications

The CA IOUs stated that the proposed language in section 3.1.3 of appendix DD for selecting ballasts is challenging to understand and follow, including the tables of ballast factors and starting methods. The CA IOUs stated that the proposed section 3.1.3.2.1.1 provides instructions for selecting ballasts on a “publicly available manufacturer-provided compatibility list” when based on the structure of the section, the instructions should be for selecting ballasts that are commercially available. (CA IOUs, No. 7 at p. 3)

The proposed language in section 3.1.3 of appendix DD is divided into three main subsections or scenarios that specify how the fluorescent lamp ballast or external driver must be selected and in the order of preference of: (1) on a publicly available manufacturer-provided compatibility list and commercially available (section 3.1.3.1); (2) commercially available and able to operate the lamp throughout the duration of the test (section 3.1.3.2); and (3) previously procured and able to operate the lamp throughout the duration of the test (section 3.1.3.3). Only if the fluorescent lamp ballast and

external driver cannot be selected per the instructions of the previous subsection, is it necessary to move to next subsection. Within each of these subsections, DOE provides instructions for selecting the ballast factor and starting method. This presents a complete set of instructions for choosing the ballast or driver within each subsection. DOE has determined that this is the clearest presentation of the instructions allowing the user to step through the selection process, in the appropriate order of preference.

DOE agrees with CA IOUs that the proposed language in section 3.1.3.2.1.1 is incorrect. This is a subsection under 3.1.3.2, which includes the provisions for cases in which the ballast or external driver is being selected from what is commercially available and can operate the lamp throughout the duration of the test. Therefore, it should not reference ballasts on the publicly available manufacturer-provided compatibility list, but rather commercially available ballasts. This is corrected in this final rule.

The CA IOUs commented that DOE’s proposal to allow non-integrated GSLs to be tested using “previously procured ballasts or drivers” seems to endorse pairing of efficient tubular LED (“TLED”) GSLs with inefficient magnetic ballasts and DOE should remove this option. The CA IOUs stated that T12 fluorescent lamps and magnetic ballasts use twice the electricity to produce the same light output as a LED luminaire. The CA IOUs stated that the exemption for high CRI linear fluorescent lamps from energy conservation standards has kept T12 lamps as well as magnetic ballasts on the market, and while the national inventory of T12 lamps has dropped from 941 million in 2010 to 341 million in 2020, the amount of remaining stock is unclear. (CA IOUs, No. 7 at pp. 3–4)

DOE’s proposed language requires that the ballast or external driver: be selected first from the lamp’s publicly available manufacturer-provided compatibility list and be commercially available; if that is not possible, then be commercially available and able to operate the lamp throughout the duration of the test; if neither of the previous options are possible, then be previously procured and able to operate the lamp throughout the duration of the test. Based on this order of selection, testing would be conducted with commercially available ballasts, first and foremost, whenever possible. Additionally, in a scenario where the lamp under test is only compatible with a ballast or external driver that is no longer commercially available, the

option of using something that is previously procured minimizes issues of incompatibility.

Preheat Start Fluorescent Lamp Ballasts

DOE understands that because low frequency, preheat start fluorescent lamp ballasts are an older technology, they may not be commercially available. In the November 2024 NOPR, for lamps that operate only on such ballasts, and these ballasts are not available, DOE proposed to specify to operate the lamp on the manufacturer-declared voltage and current, and if this information is not provided, to operate the lamp in accordance with the applicable lamp voltage and current conditions specified in ANSI C78.901–2016. Finally, DOE proposed the manufacturer must indicate in the test report the voltage and current with which the lamp was operated. 89 FR 92855, 92860.

Signify and NEMA stated it supported DOE’s proposal to use the lamp voltage and current specified by the manufacturer for preheat lamps meant to be used with magnetic ballasts when no commercial ballast is available. (Signify, No. 9 at p. 4; NEMA, No. 10 at p. 2)

As noted, in the November 2024 NOPR, DOE proposed to include the statement that if the manufacturer-declared voltage and current is not provided, to operate the lamp in accordance with lamp voltage and current conditions in ANSI C78.901–2016. Upon further review, DOE has determined that this instruction is unnecessary as manufacturers would have the necessary voltage and current for a given lamp, which could include voltages and currents as specified in ANSI C78.901–2016. The test procedure directs manufacturers to indicate in the test report the voltage and current with which the lamp was operated. Therefore, this information would be available from the manufacturers and the additional direction to operate the lamp on the settings specified in ANSI C78.901 is not needed. Therefore, in this final rule, DOE is adopting the method for testing non-integrated lamps that operate only on low frequency, preheat start fluorescent lamp ballasts as proposed in the November 2024 NOPR, with the removal of the statement regarding use of ANSI C78.901.

Starting Methods and Ballast Factors

In the November 2024 NOPR, DOE proposed that for the ballasts identified based on availability (*i.e.*, manufacturer-provided compatibility list, commercially available, previously procured), if all the ballasts have the same starting method, choose a ballast

with that starting method. If there is more than one starting method among them, choose a ballast with a starting method based on lamp type as specified in Table III.1. If the starting method in Table III.1 is not included among fluorescent lamp ballasts under consideration, then select any starting method. 89 FR 92855, 92860.

TABLE III.1—STARTING METHOD BY LAMP TYPE

Lamp type	Starting method
T8 medium bipin	Instant Start.
T8 recessed double contact.	Instant Start.
T5 miniature bipin	Programmed Start.
T12 single pin, slimline	Instant Start.
T12 medium bipin	Rapid Start.
T12 recessed double contact.	Rapid Start.
All other lamp types	Any.

Signify and NEMA commented DOE should add a clarification that if fluorescent lamp ballasts under consideration do not employ any of the starting methods in the proposed table, then select any starting method utilized by a ballast on the compatibility list. Signify stated this would prevent potential compatibility risks. (Signify, No. 9 at p. 4–5; NEMA, No. 10 at p. 2) DOE agrees this suggestion would help ensure testing is not conducted with a ballast or driver that is not compatible. Therefore, in this final rule, in the scenario where the ballast or driver is being selected from the lamp's publicly available manufacturer-provided compatibility list, DOE is revising the instruction that “if starting method in Table III.1 is not included among fluorescent lamp ballasts under consideration, then select any starting method” and changing it to “select any starting method on the lamp's publicly available manufacturer-provided compatibility list.” Aside from this change, in this final rule, DOE is adopting the clarifications for selecting starting method as proposed in the November 2024 NOPR.

In the November 2024 NOPR, DOE proposed that for the set of ballasts that have been identified based on availability and starting method, if the ballasts have more than one ballast factor available, choose a ballast with a ballast factor based on lamp type as specified in Table III.2. If the ballast factor in Table III.2 is not included among ballasts under consideration, select a ballast with a ballast factor closest to the one listed in Table III.2. 89 FR 92855, 92860–92861.

TABLE III.2—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

Signify and NEMA stated their support of DOE's proposal for selection of the fluorescent lamp ballast factor used in testing. (Signify, No. 9 at p. 5; NEMA, No. 10 at p. 2) In this final rule, DOE is adopting the clarifications for selecting the ballast factor as proposed in the November 2024 NOPR.

b. Testing With Ballast or External LED Driver

DOE understands that a ballast or external LED driver can operate more than one lamp at a time. Therefore, in the November 2024 NOPR, DOE proposed to specify that the fluorescent lamp ballast or external drivers be loaded with the maximum number of lamps when measuring the initial lumen output, initial input power, input voltage, and input current, and these measured values be divided by the maximum number of lamps. 89 FR 92855, 92861.

In response, the CA IOUs stated that placing multiple 4-foot TLED lamps in an integrating sphere to measure lumen output, if even physically possible, would result in some lumens emitted by one lamp to be absorbed by the other lamps, making the measurement inaccurate. The CA IOUs stated that DOE does not allow for the use of goniophotometer, an alternative method to testing light output, nor does it suggest alternative instrumentation for these situations. (CA IOUs, No. 7 at p. 4) Further, the CA IOUs stated that not all measured values may be appropriately divided by the number of lamps (e.g., input voltage). The CA IOUs also recommended that DOE reference a standard like ANSI/IES LM-79.¹⁶ (CA IOUs, No. 7 at p. 4)

Signify, Westinghouse, and NEMA stated they supported testing the lamp with a ballast that is fully loaded (i.e., with the maximum number of lamps) but recommended DOE clarify that only one lamp at a time be tested in the integrating sphere. Signify and NEMA

stated that testing multiple lamps in the integrating sphere could lead to optical interference skewing lumen output measurements. (Signify, No. 9 at p. 5–6; NEMA, No. 10 at p. 2; Westinghouse, No. 8 at p. 2)

Signify, Westinghouse, and NEMA also provided alternative instructions for testing multiple non-integrated lamps in an integrating sphere. Signify recommended DOE provide clarification that only one lamp be placed in the sphere, its light output, voltage, current, and power be recorded, and the lamp efficacy be the average efficacy of all the lamps measured. NEMA recommended testing one lamp at a time in the sphere while operating others outside of the sphere and the averaged light output reported as the certified value to DOE. Westinghouse supported NEMA's recommendation and also specified to divide values of each lamp by the number of lamps operated by the ballast. (Signify, No. 9 at p. 5–6; NEMA, No. 10 at p. 2; Westinghouse, No. 8 at p. 2)

DOE agrees that there could be potential issues with initial lumen output measurements when testing multiple non-integrated lamps in the integrating sphere. DOE reviewed the alternative instructions suggested by commentators for conducting such testing and found these to provide similar instructions—to test one lamp at a time and take an average of measured values. Considering these recommendations, in this final rule, DOE is adding language to clarify that when testing multiple lamps, one lamp at a time be tested in the integrating sphere while operating the other lamps outside of the sphere; and the initial lumen output, initial input power, input voltage, and input current be measured for each lamp. Additionally, in this final rule, DOE is removing the proposed instruction to divide measured values by the maximum number of lamps. Instead, in sections 3.3.2 and 3.3.3 which provide instructions on calculating lamp efficacy and power factor, respectively, DOE is adding language stating that if multiple lamps are tested, the initial lamp efficacy and power factor will be determined as the average of the values of each lamp.

Regarding CA IOUs' suggestion to reference ANSI/IES LM-79, DOE notes that this standard is already referenced in section 3.6 of appendix DD for measuring the initial lumen output, input power, input voltage, and input current of non-integrated LED lamps.

In summary, DOE is adopting the proposed clarification regarding testing with the ballast or external LED driver loaded with the maximum number of

¹⁶ Illuminating Engineering Society, *Approved Method: Optical and Electrical Measurements of Solid-State Lighting Products*.

lamps as proposed in the November 2024 NOPR with the modifications that ensure that one lamp at a time is tested in the integrating sphere.

Additionally, in the November 2024 NOPR, DOE proposed to incorporate by reference the applicable industry standard, ANSI C78.53–2023, in appendix DD and reference it as follows: (1) for a non-integrated lamp marketed to replace a fluorescent lamp and operate on the existing fluorescent lamp ballast, testing should be conducted in accordance with the setup provisions in sections 5.6.3 (Thermal) and 5.6.4 (Electrical Characteristics) of ANSI C78.53–2023; and (2) for a non-integrated lamp marketed to replace a HID lamp and operate on the existing HID lamp ballast, testing should be conducted in accordance with the setup provisions in sections 5.7.2.1 (Thermal), 5.7.3 (Electrical Characteristics), and 5.7.5 (Compatibility Criteria) of ANSI C78.53–2023 sections. 89 FR 92855, 92861.

Signify, NEMA, and Westinghouse stated their support for DOE's proposal to incorporate by reference, ANSI C78.53–2023 for appendix DD. (Signify, No. 9 at p. 6; NEMA, No. 10 at p. 2; Westinghouse, No. 8 at p. 2)

Upon further review, DOE determined that ANSI C78.53–2023 includes instructions that would not be relevant to a non-integrated lamp being tested under the DOE test procedure. For example, instructions referencing de-lamping (*i.e.*, disabling or removing lamps) are not relevant as DOE is requiring testing be conducted with the ballast loaded with the maximum number of lamps (see section III.B.3.b of this document). Therefore, in this final rule, DOE is not adopting the proposal to incorporate by reference ANSI C78.53–2023 in appendix DD and is instead adding language in appendix DD that provides only the relevant setup instructions applicable for testing non-integrated lamps from ANSI C78.53–2023. DOE has determined that this approach would improve clarity of the test procedure requirements proposed in the November 2024 NOPR.

Additionally, in this final rule, DOE is revising the proposed language “for a non-integrated lamp marketed to replace a fluorescent/HID lamp and operate on the existing fluorescent lamp/HID ballast” to state “designed and marketed” instead of “marketed”. Because “designed and marketed” is a term defined by DOE and specific to lighting products, it will provide further clarity to the instruction (see 10 CFR 430.2 “designed and marketed”).

C. Test Procedure Costs

EPCA requires that test procedures amended by DOE not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) The following section discusses DOE's evaluation of estimated costs associated with the clarifications in this final rule, including relevant public comments.

NEMA and Westinghouse stated their overall support for the proposed clarifications but, referencing ENERGY STAR testing, noting that manufacturers should not be required to retest lamps already on the market that have been tested and certified prior to market introduction. (NEMA, No. 10 at p. 2; Westinghouse, No. 8 at p. 2) In this final rule, DOE is not adopting the clarification to test at 2700 K or the closest available CCT greater than 2700 K, which will allow manufacturers to use previous test data submitted to entities such as ENERGY STAR (see section III.B.1 for complete discussion).

DOE is adopting two updates to appendices W, BB, and DD that provide clarification for testing lamps by specifying: (1) not to test the lamp as a colored lamp; and (2) to turn off components that do not affect light output. These clarifications only provide further clarification and more complete information regarding how to appropriately test certain lamps. Therefore, DOE has determined that the clarifications would not impact the representations of GSL energy efficiency based on the determination manufacturers would be able to rely on data generated under the current test procedure. As such, retesting of GSLs would not be required solely as a result of DOE's adoption of the clarifications to the test procedure.

Finally, in this final rule, DOE is adopting updates to appendix DD to remove the instruction to operate non-integrated LED lamps at the manufacturer-declared input voltage and current and instead specify that non-integrated lamps be operated on a fluorescent lamp ballast, HID lamp ballast or external LED driver. Based on comments from manufacturers, the instruction reflects how these lamps are currently being tested by manufacturers (see III.B.3 of this document). Additionally, the DesignLights Consortium (“DLC”) administers a voluntary certification program for high performing lighting products and lists almost 6,000 non-integrated lamps as qualified products. DLC testing requirements for non-linear integrated lamps,¹⁷ which manufacturers must use

¹⁷ DLC, “Testing and Reporting Requirements for Linear Replacement Lamps under Technical

to qualify their products, also require testing on a fluorescent lamp ballast or external LED driver. DOE has determined that manufacturers would be able to rely on data already generated for such lamps. As such, DOE has determined that the clarifications would not impact the representations of GSL energy efficiency.

In summary, DOE does not expect that the clarifications outlined in the November 2024 NOPR, and that are being adopted in this final rule, will result in increased costs or burden to manufacturers.

D. Effective and Compliance Dates

The effective date for the adopted test procedure amendment will be 30 days after publication of this final rule in the **Federal Register**. EPCA prescribes that all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with an amended test procedure, beginning 180 days after publication of the final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2)) EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6293(c)(3)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866, 13563, and 14094

Executive Order (“E.O.”) 12866, “Regulatory Planning and Review,” as supplemented and reaffirmed by E.O. 13563, “Improving Regulation and Regulatory Review,” 76 FR 3821 (Jan. 21, 2011) and amended by E.O. 14094, “Modernizing Regulatory Review,” 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of

Requirements V5.1”, July 1, 2020, available at https://designlights.org/wp-content/uploads/2023/06/DLC_Testing-Reporting-Requirements_Linear-Replacement-Lamps_V5-1_20230616.pdf.

cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (“OIRA”) in the Office of Management and Budget (“OMB”) has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this final regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit “significant regulatory actions” to OIRA for review. OIRA has determined that this final regulatory action does not constitute a “significant regulatory action” under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a final regulatory flexibility analysis (“FRFA”) for any final rule where the agency was first required by law to publish a proposed rule for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003 to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel’s website: www.energy.gov/gc/

office-general-counsel. DOE reviewed this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

DOE has conducted a focused inquiry into small business manufacturers of the GSLs covered by this rulemaking. For this test procedure, DOE referenced the small business list created for the April 2024 Final Rule. In that final rule, DOE identified potential small manufacturers based on Small Business Administration guidelines categorizing businesses operating under North American Industry Classification System code 335139, “electric lamp bulb and other lighting equipment manufacturing”, with under 1,250 employees (including parent and affiliate companies) as a small business. The size standards are codified at 13 CFR part 121. DOE accessed the Compliance Certification Database¹⁸ to create a list of companies that import or otherwise manufacture the GSLs covered by this final rule. Using information from D&B Hoovers, DOE screened out companies that have more than 1,250 employees, are completely foreign owned and operated, or do not manufacture GSLs in the United States—ultimately identifying 261 small domestic businesses that assemble GSLs.

None of the identified small businesses are expected to incur costs because of the clarifications adopted in this rule. The clarifications to GSL test procedures being adopted in this final rule only provide further clarification regarding how to appropriately test certain lamps with additional functionality. These clarifications would not result in additional test costs, nor would they require retesting for any manufacturers. DOE is also adopting clarifications regarding testing non-integrated GSLs which reflect how these lamps are currently being tested by manufacturers and therefore, would also not result in additional test costs nor require retesting by any manufacturers—including small manufacturers.

An individual stated that the proposed changes could create significant financial challenges for small businesses, especially those without the resources (e.g., specialized equipment, trained personnel, and a controlled testing environment) to conduct the required testing. The individual recommended that DOE consider simplifying the testing requirements or

offering financial support through grants, loans, or extended deadlines for small manufacturers. (Individual, No. 6 at p. 1)

DOE notes that the test procedure amendments established in this final rule are not estimated to increase manufacturer testing costs and are intended as clarifications for manufacturers, corresponding to how those manufacturers have been testing covered products.

Therefore, DOE concludes that the cost effects accruing from the final rule would not have a “significant economic impact on a substantial number of small entities,” and that the preparation of a FRFA is not warranted. DOE has submitted a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of GSLs must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including GSLs. (*See generally* 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (“PRA”). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

DOE is not amending the certification or reporting requirements for GSLs in this final rule.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

¹⁸ U.S. Department of Energy Compliance Certification Database, available at: www.regulations.doe.gov/certification-data/products.html.

D. Review Under the National Environmental Policy Act of 1969

In this final rule, DOE establishes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for GSLs. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, appendix A to subpart D, A5 and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of

new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 ("UMRA") requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104-4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a)-(b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might

significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at www.energy.gov/gc/office-general-counsel. DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. When developing a Family Policymaking Assessment, agencies must assess whether: (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society. In evaluating the above factors, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment as none of the above factors are implicated. Further, this determination would not have any financial impact on families nor any impact on the autonomy or integrity of the family as an institution.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M-19-15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf. DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order, and is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95-91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; "FEAA") Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission ("FTC") concerning the impact of the commercial or industry standards on competition.

The modifications to the test procedures for general service lamps adopted in this final rule do not incorporate any new commercial standards or test procedures that are not already incorporated by reference at 10 CFR 430.3 and therefore DOE has not reassessed such standards as part of this final rule.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

N. Description of Materials Incorporated by Reference

The following standards were previously approved for incorporation by reference in the regulatory sections where they appear, and no changes are made: IEC 62031-DD, IES LM-9-09-DD,¹⁹ IES LM-20-13,²⁰ IES LM-45-15,²¹ and IES LM-79-08-DD.²²

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

¹⁹ Illuminating Engineering Society, *IES Approved Method for the Electrical and Photometric Measurement of Fluorescent Lamps*, Approved January 31, 2009.

²⁰ Illuminating Engineering Society, *IES Approved Method: Photometry of Reflector Type Lamps*, Approved February 4, 2013.

²¹ Illuminating Engineering Society, *IES Approved Method: Electrical and Photometric Measurement of General Service Incandescent Filament Lamps*, Approved August 8, 2015.

²² Illuminating Engineering Society, *IES LM-79-08 Approved Method: Electrical and Photometric Measurements of Solid-State Lighting Products*, Approved December 31, 2007.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on January 10, 2025, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 10, 2025.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE amends part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend appendix W to subpart B by:

- a. Revising the note at the beginning of the appendix;
- a. Redesignating sections 3.1.5 through 3.1.7 as sections 3.1.6 through 3.1.8; and
- b. Adding new section 3.1.5 and section 3.1.9.

The additions read as follows:

Appendix W to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Compact Fluorescent Lamps

Note 1 to appendix W to subpart B: On and after July 15, 2025, any representations made with respect to the energy efficiency of compact fluorescent lamps must be made in accordance with the results of testing

pursuant to this appendix W. Manufacturers conducting tests of compact fluorescent lamps prior to July 15, 2025, must conduct such tests in accordance with either this appendix or the procedures in appendix W as it appeared in the Code of Federal Regulations on January 1, 2023. Any representations made with respect to the energy efficiency of compact fluorescent lamps must be in accordance with whichever version is selected.

* * * * *

3. * * *

3.1. * * *

3.1.5. If the lamp can operate in multiple modes at the labeled wattage, operate the lamp as not a colored lamp (as defined in 10 CFR 430.2). If multiple modes occur at the same labeled wattage (such as variable CCT or CRI), select any of these modes for testing; however, all measurements must be taken at the same selected mode. The test report must specify which mode was selected for testing and include details such that another laboratory can replicate the test at the same mode.

* * * * *

3.1.9. For a CFL that has one or more component(s) that offer a completely different functionality (e.g., a speaker, a camera, an air purifier, etc.) where the component is integrated into the lamp but does not affect the light output of the lamp (e.g., does not turn the light on/off, dim the light, change the color of the light, etc.) and is capable of operating in standby mode, turn off as many of these components as possible during testing, without permanently altering the product. Permanently altering the product constitutes the cutting of wires, use of a soldering iron, or damage to or destruction of the lamp and does not constitute connecting or disconnecting wire nuts, fasteners or screws, or preserving the lamp as it was sold. If such components cannot be turned off without permanently altering the product, their energy consumption must be included in measurements. The test report must specify which components were turned off and any features that remained on.

* * * * *

■ 3. Amend appendix BB to subpart B by:

- a. Revising the note at the beginning of the appendix;
- b. Revising section 3.1.4; and
- c. Adding section 3.1.5.

The revisions and addition read as follows:

Appendix BB to Subpart B of Part 430—Uniform Test Method for Measuring the Input Power, Lumen Output, Lamp Efficacy, Correlated Color Temperature (CCT), Color Rendering Index (CRI), Power Factor, Time to Failure, and Standby Mode Power of Integrated Light-Emitting Diode (LED) Lamps

Note 1 to appendix BB to subpart B: On and after July 15, 2025, any representations made with respect to the energy efficiency of integrated LED lamps must be made in

accordance with the results of testing pursuant to this appendix BB. Manufacturers conducting tests of integrated LED lamps prior to July 15, 2025, must conduct such tests in accordance with either this appendix or the previous version of appendix BB as it appeared in the Code of Federal Regulations on January 1, 2023. Any representations made with respect to the energy efficiency of integrated LED lamps must be in accordance with whichever version is selected.

* * * * *

3. * * *

3.1. * * *

3.1.4. Ensure that the lamp is not operating as a colored lamp (as defined in 10 CFR 430.2) and operate the lamp at maximum input power. If multiple modes occur at the same maximum input power (such as variable CCT or CRI), select any of these modes for testing; however, all measurements must be taken at the same selected mode. The test report must specify which mode was selected for testing and include details such that another laboratory can replicate the test at the same mode.

3.1.5. For a lamp that has one or more component(s) that offer a completely different functionality (e.g., a speaker, a camera, an air purifier, etc.) where the component is integrated into the lamp but does not affect the light output of the lamp (e.g., does not turn the light on/off, dim the light, change the color of the light, etc.) and is capable of operating in standby mode, turn off as many of these components as possible during testing, without permanently altering the product. Permanently altering the product constitutes the cutting of wires, use of a soldering iron, or damage to or destruction of the lamp and does not constitute connecting or disconnecting wire nuts, fasteners or screws, or preserving the lamp as it was sold. If such components cannot be turned off without permanently altering the product, their energy consumption must be included in measurements. The test report must specify which components were turned off and any features that remained on.

* * * * *

■ 4. Revise appendix DD to subpart B to read as follows:

Appendix DD to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption and Energy Efficiency of General Service Lamps That Are Not General Service Incandescent Lamps, Compact Fluorescent Lamps, or Integrated LED Lamps

Note 1 to appendix DD to subpart B: On and after July 15, 2025, any representations made with respect to the energy efficiency of general service lamps that are not general service incandescent lamps, compact fluorescent lamps, or integrated LED lamps must be made in accordance with the results of testing pursuant to this appendix DD. Manufacturers conducting tests of such general service lamps prior to July 15, 2025, must conduct such tests in accordance with either this appendix or the version of

appendix DD as it appeared in the Code of Federal Regulations on January 1, 2023. Any representations made with respect to the energy efficiency of such general service lamp must be in accordance with whichever version is selected. 1. *Scope:* This appendix DD specifies the test methods required to measure the initial lumen output, input power, lamp efficacy, power factor, and standby mode energy consumption of general service lamps that are not general service incandescent lamps, compact fluorescent lamps, or integrated LED lamps.

2. Definitions:

Commercially available fluorescent lamp ballast, high intensity discharge (“HID”) ballast, or external LED driver means one that can be purchased by an individual consumer at a readily accessible retailer (i.e., retailer with storefront or online purchasing).

Measured initial input power means the input power to the lamp, measured after the lamp is stabilized and seasoned (if applicable), and expressed in watts (W).

Measured initial lumen output means the lumen output of the lamp, measured after the lamp is stabilized and seasoned (if applicable), and expressed in lumens (lm).

Power factor means the measured initial input power (watts) divided by the product of the input voltage (volts) and the input current (amps) measured at the same time as the initial input power.

Publicly available manufacturer-provided compatibility list means a list or statement made available by the manufacturer on the manufacturer’s official website or made available by the manufacturer through publicly available documents (e.g., product literature, catalogs, and packaging labels), that provides information on ballasts or external LED drivers that are compatible with the lamp.

3. Active Mode Test Procedures

3.1. Test Conditions and Setup

3.1.1. For single base OLED and non-integrated LED lamps, position a lamp in either the base-up and base-down orientation throughout testing. Test an equal number of lamps in the sample in the base-up and base-down orientations, except that, if the manufacturer restricts the orientation, test all of the units in the sample in the manufacturer-specified orientation. For double base OLED and non-integrated LED lamps, test all units in the horizontal orientation except that, if the manufacturer restricts the orientation, test all of the units in the sample in the manufacturer-specified orientation.

3.1.2. For integrated lamps, operate the lamp at the rated voltage throughout testing. For lamps with multiple rated voltages including 120 volts, operate the lamp at 120 volts. If a lamp is not rated for 120 volts, operate the lamp at the highest rated input voltage.

3.1.3. For non-integrated lamps, operate the lamp on a fluorescent lamp ballast, HID lamp ballast, or external LED driver in order of the following preference:

3.1.3.1. Select a commercially available fluorescent lamp ballast, HID lamp ballast, or external LED driver from the lamp’s publicly available manufacturer-provided compatibility list. The test report must

specify the manufacturer and model name/number of the fluorescent lamp ballast, HID lamp ballast, or external LED driver used in the test.

3.1.3.1.1. If all ballasts on the publicly available manufacturer-provided compatibility list use the same starting method, then select a ballast with that starting method to test the lamp.

3.1.3.1.1.1. If ballasts on the publicly available manufacturer-provided compatibility list are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.1. If the ballast factor in the table is not available among ballasts on the publicly available manufacturer-provided compatibility list, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.1—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.1.2. If ballasts on the publicly available manufacturer-provided compatibility list are available with multiple starting methods, then select a ballast with a starting method based on lamp type specified in Table 3.2. If the starting method in the table is not available among ballasts on the publicly available manufacturer-provided compatibility list, select any starting method on the publicly available manufacturer-provided compatibility list:

TABLE 3.2—STARTING METHOD BY LAMP TYPE

Lamp type	Starting method
T8 medium bipin	Instant Start.
T8 recessed double contact.	Instant Start.
T5 miniature bipin	Programmed Start.
T12 single pin, slimline	Instant Start.
T12 medium bipin	Rapid Start.
T12 recessed double contact.	Rapid Start.
All other lamp types	Any.

3.1.3.1.2.1. If ballasts on the publicly available manufacturer-provided compatibility list are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.3. If the ballast factor in the table is not available among ballasts on the publicly available manufacturer-provided compatibility list, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.3—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.2. If the procedure in section 3.1.3.1 is not possible, select any commercially available fluorescent lamp ballast, HID lamp ballast, or external LED driver that can operate the lamp throughout the duration of the test. The test report must specify the manufacturer and model name/number of the fluorescent lamp ballast, HID lamp ballast, or external LED driver used in the test.

3.1.3.2.1. If all commercially available ballasts use the same starting method, then select a ballast with that starting method to test the lamp.

3.1.3.2.1.1. If commercially available ballasts are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.4. If the ballast factor in the table is not available among commercially available ballasts, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.4—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.2.2. If commercially available ballasts are available with multiple starting methods, then select a ballast with a starting method based on lamp type specified in Table 3.5. If the starting method in the table is not available among commercially available ballasts, select any starting method:

TABLE 3.5—STARTING METHOD BY LAMP TYPE

Lamp type	Starting method
T8 medium bipin	Instant Start.
T8 recessed double contact.	Instant Start.
T5 miniature bipin	Programmed Start.
T12 single pin, slimline	Instant Start.
T12 medium bipin	Rapid Start.
T12 recessed double contact.	Rapid Start.
All other lamp types	Any.

3.1.3.2.2.1. If commercially available ballasts are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.6. If the ballast factor in the table is not available among commercially available ballasts, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.6—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.3. If the procedures in sections 3.1.3.1 and 3.1.3.2 are not possible, use any previously procured fluorescent lamp ballast, HID lamp ballast, or external LED driver that can operate the lamp throughout the duration of the test. The test report must specify the manufacturer and model name/number of the fluorescent lamp ballast, HID lamp ballast, or external LED driver used in the test.

3.1.3.3.1. If all previously procured ballasts use the same starting method, then select a ballast with that starting method to test the lamp.

3.1.3.3.1.1. If previously procured ballasts are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.7. If the ballast factor in the table is not available among the previously procured ballasts, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.7—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.3.2. If previously procured ballasts are available with multiple starting methods, then select a ballast with a starting method based on lamp type specified in Table 3.8. If the starting method in the table is not available among the previously procured ballasts, select any starting method:

TABLE 3.8—STARTING METHOD BY LAMP TYPE

Lamp type	Starting method
T8 medium bipin	Instant Start.

TABLE 3.8—STARTING METHOD BY LAMP TYPE—Continued

Lamp type	Starting method
T8 recessed double contact.	Instant Start.
T5 miniature bipin	Programmed Start.
T12 single pin, slimline	Instant Start.
T12 medium bipin	Rapid Start.
T12 recessed double contact.	Rapid Start.
All other lamp types	Any.

3.1.3.3.2.1. If previously procured ballasts are available with multiple ballast factors, then select a ballast with a ballast factor based on lamp type specified in Table 3.9. If the ballast factor in the table is not available among the previously procured ballasts, select a ballast with a ballast factor closest to the one listed in the table:

TABLE 3.9—BALLAST FACTOR BY LAMP TYPE

Lamp type	Ballast factor
T8 medium bipin	0.88.
T8 recessed double contact.	1.05.
T5 miniature bipin	1.
T12 single pin, slimline	Any.
T12 medium bipin	Any.
T12 recessed double contact.	Any.
All other lamp types	Any.

3.1.3.4. If the procedures in sections 3.1.3.1, 3.1.3.2 and 3.1.3.3 are not possible and the lamp only operates on a low frequency, preheat start fluorescent lamp ballast, operate the lamp on the manufacturer-declared voltage and current. The test report must specify the voltage and current with which the lamp was operated.

3.1.4. Operate the fluorescent lamp ballast, HID lamp ballast, or external LED driver loaded with the maximum number of lamps. Test one lamp at a time in the integrating sphere, while operating the other lamps outside of the sphere. Measure the initial lumen output, initial input power, input

voltage, and input current for each lamp according to section 3.2.1.

3.1.5. For a non-integrated lamp designed and marketed to replace a fluorescent lamp and operate on the existing fluorescent lamp ballast, conduct testing in accordance with the following setup provisions:

3.1.5.1. Thermal conditions: A compatible combination of ballast and LED replacement lamp designed for direct replacement of linear fluorescent lamp sources must not result in the overheating of components. LED replacement lamps that are compatible with a given ballast must not cause the ballast to operate at a higher temperature or power than the fluorescent ballast ratings. The temperature measured at the Tc point must not exceed the rating of the ballast. For magnetic ballasts and electronic ballasts with no Tc point identified, the ballast enclosure must not exceed 90 degrees Celsius.

3.1.5.2 Electrical conditions: LED replacement lamps must be measured with the ballast in the circuit, consistent with rated LED replacement lamp values on a given ballast condition (ballast type/ballast factor/lamp loading). Compatibility is based on the rated values specified by the LED lamp manufacturer. The lamp current must be equal to or less than the target lamp current. (The target lamp is the fluorescent lamp the replacement lamp is intended to replace.) The measured input power to the ballast must not exceed the rating of the ballast by more than 10%.

3.1.6. For a non-integrated lamp designed and marketed to replace an HID lamp and operate on the existing HID lamp ballast, conduct testing in accordance with the following setup provisions:

3.1.6.1. Thermal conditions: The LED replacement lamp must not exceed its maximum operational temperature rating as specified by the LED lamp manufacturer.

3.1.6.2. Electrical conditions: LED replacement lamps must be measured with the ballast in the circuit, consistent with rated LED replacement lamp values on a given ballast condition (ballast type/ballast factor/lamp loading). Compatibility is based on the rated values specified by the LED replacement lamp manufacturer. The LED replacement lamp voltage must be in a range of +/- 15 percent of the nominal HID lamp voltage. The lamp current must be equal to or less than the target lamp current. (The

target lamp is the HID lamp the device is intended to replace.) The measured input power to the ballast must not exceed the rating of the ballast by more than 10%.

3.1.6.3. Ballast conditions: For magnetic ballasts: (1) the ballast capacitor voltage for magnetic ballasts must not exceed the capacitor rating and (2) the ballast must not exceed the temperature described in its ballast temperature code. For electronic ballasts, the temperature at the Tc point must be equal or less than described on the ballast label.

3.1.7. Ensure that the lamp is not operating as a colored lamp (as defined in 10 CFR 430.2) and operate the lamp at maximum input power. If multiple modes occur at the same maximum input power (such as variable CCT or CRI), select any of these modes for testing; however, all measurements must be taken at the same selected mode. The test report must specify which mode was selected for testing and include details such that another laboratory can replicate the test at the same mode.

3.1.8. For a lamp that has one or more component(s) that offer a completely different functionality (e.g., a speaker, a camera, an air purifier, etc.) where the component is integrated into the lamp but does not affect the light output of the lamp (e.g., does not turn the light on/off, dim the light, change the color of the light, etc.) and is capable of operating in standby mode, turn off as many of these components as possible during testing, without permanently altering the product. Permanently altering the product constitutes the cutting of wires, use of a soldering iron, or damage to or destruction of the lamp and does not constitute connecting or disconnecting wire nuts, fasteners or screws, or preserving the lamp as it was sold. If such components cannot be turned off without permanently altering the product, their energy consumption must be included in measurements. The test report must specify which components were turned off and any features that remained on.

3.2. Test Method, Measurements, and Calculations

3.2.1. To measure initial lumen output, input power, input voltage, and input current use the test procedures in the table in this section. Do not use a goniophotometer.

TABLE 3.10—REFERENCES TO INDUSTRY STANDARD TEST PROCEDURES

Lamp type	Referenced test procedure
Compact fluorescent lamps	Appendix W to subpart B of 10 CFR part 430.
General service incandescent lamps	Appendix R to subpart B of 10 CFR part 430.
Integrated LED lamps	Appendix BB to subpart B of 10 CFR part 430.
Non-integrated LED lamps	IES LM-79-08-DD, sections 1.3 (except 1.3f), 2.0, 3.0, 5.0, 7.0, 8.0, 9.1 and 9.2.*
OLED lamps	IES LM-79-08-DD, sections 1.3 (except 1.3f), 2.0, 3.0, 5.0, 7.0, 8.0, 9.1 and 9.2.*
Other fluorescent lamps	IES LM-9-09-DD, sections 46, and section 7.5.*
Other incandescent lamps that are not reflector lamps	IES LM-45-15, sections 4-6, and section 7.1.*
Other incandescent lamps that are reflector lamps	IES LM-20-13, sections 4-6, and section 8.*

* Incorporated by reference, see § 430.3.

3.2.2. Determine initial lamp efficacy by dividing the measured initial lumen output

(lumens) by the measured initial input power (watts). Per section 3.1.4, if multiple lamps

were operated on the same ballast or external LED driver, determine the initial lamp

efficacy by calculating the initial lamp efficacy for each lamp and calculating the average.

3.2.3. Determine power factor by dividing the measured initial input power (watts) by the product of the measured input voltage (volts) and measured input current (amps). Per section 3.1.4, if multiple lamps were operated on the same ballast or external LED driver, determine the power factor by calculating the power factor for each lamp and calculating the average.

3.3. Standby Mode Test Procedure

3.3.1. Measure standby mode power only for lamps that are capable of standby mode operation.

3.3.2. The test conditions and setup described in section 3.1 of this appendix apply to this section.

3.3.3. Connect the lamp to the manufacturer-specified wireless control network (if applicable) and configure the lamp in standby mode by sending a signal to the lamp instructing it to have zero light output. Lamp must remain connected to the network throughout testing.

3.3.4. Operate the lamp at the rated voltage throughout testing. For lamps with multiple rated voltages including 120 volts, operate the lamp at 120 volts. If a lamp is not rated for 120 volts, operate the lamp at the highest rated input voltage.

3.3.5. Stabilize the lamp prior to measurement as specified in section 5 of IEC 62301-DD (incorporated by reference; see § 430.3).

3.3.6. Measure the standby mode power in watts as specified in section 5 of IEC 62301-DD (incorporated by reference; see § 430.3).

[FR Doc. 2025-00821 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE-2022-BT-STD-0025]

RIN 1904-AF36

Energy Conservation Program: Energy Conservation Standards for Portable Electric Spas

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of data availability.

SUMMARY: The U.S. Department of Energy (“DOE”) is publishing this notice of data availability (“NODA”) regarding certain data and analytical results being made available related to DOE’s evaluation of potential energy conservation standards for portable electric spas (“PESs”).

DATES: Written comments and information will be accepted on or before, February 18, 2025.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at

www.regulations.gov, under docket number EERE-2022-BT-STD-0025. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2022-BT-STD-0025, by any of the following methods:

Email:

PortableElecSpas2022STD0025@ee.doe.gov. Include the docket number EERE-2022-BT-STD-0025 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-1445. If possible, please submit all items on a compact disc (“CD”), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L’Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287-1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, including the data and analytical results being released with this notice, is available for review at

www.regulations.gov. The data and analytical results being made available with this NODA is available on the docket and consist of: (1) a report titled NODA Support Document, and (2) accompanying spreadsheet-based analytical tools respectively corresponding to the Life-Cycle Cost and Payback Period Analysis, the National Impact Analysis, and the Manufacturer Impact Analysis. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available. The docket web page can be found at www.regulations.gov/docket/EERE-2022-BT-STD-0025. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Shapiro, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-5649. Email: ApplianceStandardsQuestions@ee.doe.gov.

Ms. Kristin Koernig, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-4798. Email: Kristin.koernig@hq.doe.gov.

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287-1445 or by email: ApplianceStandardsQuestions@ee.doe.gov.

SUPPLEMENTARY INFORMATION:

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291-6317) Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency for certain consumer products, referred to generally as “covered products.” In addition to specifying a list of consumer products that are covered products, EPCA contains provisions that enable the Secretary of Energy to classify additional types of consumer products as covered products. (42 U.S.C. 6292(b)).

On September 2, 2022, in a final determination published in the **Federal Register** (“September 2022 NOFD”), DOE determined that PESs meet the criteria for classification as a covered product pursuant to EPCA and classified PESs as a covered product. 87 FR 54123. In the September 2022 NOFD, DOE established a definition of “portable electric spa,” which was “a factory-built electric spa or hot tub, supplied with equipment for heating and circulating water at the time of sale or sold separately for subsequent attachment.” *Id.* at 87 FR 54125; *see also* 10 CFR 430.2.

Following this determination of coverage, DOE published a test procedure (“TP”) final rule for PESs in the **Federal Register** on June 13, 2023 (“June 2023 TP Final Rule”). 88 FR 38600. In the June 2023 TP Final Rule, DOE incorporated by reference an industry test method published by the

Pool and Hot Tub Alliance (“PHTA”)¹ in partnership with the International Code Council (“ICC”) and approved by the American National Standards Institute (“ANSI”), ANSI/APSP/ICC–14 2019, American National Standard for Portable Electric Spa Energy Efficiency (“APSP–14 2019”) with certain exceptions and additions. 88 FR 38600, 38607–38619. The June 2023 TP Final Rule finalized a measure of the energy consumption of PESs (*i.e.*, the normalized average standby loss) that represents the average power consumed by the spa, normalized to a standard temperature difference between the ambient air and the water in the spa, while the cover is on and the product is operating in its default operation mode. *Id.* at 88 FR 38600. The DOE test procedure for PESs appears at title 10 of the Code of Federal Regulations (“CFR”) part 430, subpart B, appendix GG (“appendix GG”).

In a NODA published on November 17, 2022 (“November 2022 NODA”), DOE published data and certain preliminary analytical results related to DOE’s evaluation of potential energy conservation standards for PESs. 87 FR 69082.

DOE has considered comments received to date as part of the September 2022 NOFD, November 2022 NODA, and June 2023 TP Final Rule and has performed an updated evaluation of potential energy conservation standards informed by some of those comments, the results of which are presented and discussed in a support document accompanying this NODA (“NODA Support Document”). The NODA Support Document is a composite of various analyses, including results and their methodological descriptions, related to evaluating potential energy conservation standards for portable electric spas from several perspectives. Those analyses respectively focus on specific considerations of that evaluation. For example, the Life-Cycle Cost and Payback Period Analysis quantifies the economic effects of various potential standard levels on individual consumers, while the Manufacturer Impact Analysis quantifies the effects of potential energy conservation standards on the finances and profitability of manufacturers of portable electric spas. Collectively, these analysis of the NODA Support Document form a comprehensive basis for consideration of various potential

energy conservation standard levels. A list of topics included in the NODA Support Document can be found in chapter 1 of the NODA Support Document.

Public Participation

DOE will accept comments, data, and information regarding this NODA no later than the date provided in the **DATES** section at the beginning of this NODA. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (“CBI”). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed

simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail.

Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (“faxes”) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters’ names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked “confidential” including all the information believed to be confidential, and one copy of the document marked “non-confidential” with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

¹ The PHTA is a result of a 2019 merger between the Association of Pool and Spa Professionals (“APSP”) and the National Swimming Pool Foundation (“NSPF”). The reference to APSP has been retained in the ANSI designation of ANSI/APSP/ICC–14 2019.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

Signing Authority

This document of the Department of Energy was signed on January 10, 2025, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 10, 2025.

Treena V. Garrett,

*Federal Register Liaison Officer, U.S.
Department of Energy.*

[FR Doc. 2025-00816 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Parts 1209, 1217, and 1250

RIN 2590-AB45

Rules of Practice and Procedure; Civil Money Penalty Inflation Adjustment

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is adopting this final rule amending its Rules of Practice and Procedure and other agency regulations to adjust each civil money penalty within its jurisdiction to account for inflation, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective* January 16, 2025, and applicable beginning January 15, 2025.

FOR FURTHER INFORMATION CONTACT:

Frank R. Wright, Assistant General Counsel, at (202) 649-3087, Frank.Wright@fhfa.gov (not a toll-free

number); Federal Housing Finance Agency, 400 7th Street SW, Washington, DC 20219. 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 an independent agency of the Federal government, and the financial safety and soundness regulator of the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises), as well as the Federal Home Loan Banks (collectively, the Banks) and the Office of Finance under authority granted by the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act).¹ FHFA oversees the Enterprises and Banks (collectively, the regulated entities) and the Office of Finance to ensure that they operate in a safe and sound manner and maintain liquidity in the housing finance market in accordance with applicable laws, rules and regulations. To that end, FHFA is vested with broad supervisory discretion and specific civil administrative enforcement powers, similar to such authority granted by Congress to the Federal bank regulatory agencies.² Section 1376 of the Safety and Soundness Act (12 U.S.C. 4636) empowers FHFA to impose civil money penalties under specific conditions. FHFA's Rules of Practice and Procedure (12 CFR part 1209) (the Enforcement regulations) govern cease and desist proceedings, civil money penalty assessment proceedings, and other administrative adjudications.³ FHFA's Flood Insurance regulation (12 CFR part 1250) governs flood insurance responsibilities as they pertain to the Enterprises.⁴ FHFA's Implementation of the Program Fraud Civil Remedies Act of 1986 regulation (12 CFR part 1217) sets forth procedures for imposing civil penalties and assessments under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 *et seq.*) on any person that makes a false claim for property, services or money from FHFA, or makes a false material statement to FHFA in connection with a claim, where the amount involved does not exceed \$150,000.⁵

¹ See Safety and Soundness Act, 12 U.S.C. 4513 and 4631-4641.

² *Id.*

³ See 12 CFR part 1209.

⁴ See 12 CFR part 1250.

⁵ See generally, 31 U.S.C. 3801 *et seq.*

The Adjustment Improvements Act

The Federal Civil Penalties Inflation Adjustment Act of 1990 (Inflation Adjustment Act), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Adjustment Improvements Act), requires FHFA, as well as other federal agencies with the authority to issue civil money penalties (CMPs), to adjust by regulation the maximum amount of each CMP authorized by law that the agency has jurisdiction to administer.⁶ The Adjustment Improvements Act required agencies to make an initial "catch-up" adjustment of their CMPs upon the statute's enactment,⁷ and further requires agencies to make additional adjustments on an annual basis following the initial adjustment.⁸

The Adjustment Improvements Act sets forth the formula that agencies must apply when making annual adjustments, based on the percent change between the October Consumer Price Index for All Urban Consumers (the CPI-U) preceding the date of the last adjustment and the October CPI-U for the year before that.

II. Description of the Rule

This final rule adjusts the maximum penalty amount within each of the three tiers specified in 12 U.S.C. 4636 by amending the table contained in 12 CFR 1209.80 of the Enforcement regulations to reflect the new adjusted maximum penalty amount that FHFA may impose upon a regulated entity or any entity-affiliated party within each tier. The increases in maximum penalty amounts contained in this final rule may not necessarily affect the amount of any CMP that FHFA may seek for a particular violation, which may not be the maximum that the law allows; FHFA would calculate each CMP on a case-by-case basis in light of a variety of factors.⁹ This rule also adjusts the maximum penalty amounts for violations under the FHFA Flood Insurance regulation by amending the text of 12 CFR 1250.3 to reflect the new adjusted maximum penalty amount that FHFA may impose for violations under that regulation. This rule also adjusts the maximum amounts for civil money penalties under the Program Fraud Civil Remedies Act by amending the text of 12 CFR 1217.3 to reflect the new

⁶ See 28 U.S.C. 2461 note.

⁷ FHFA promulgated its catch-up adjustment of its CMPs with an interim final rule published July 1, 2016. 81 FR 43028.

⁸ FHFA promulgated its most recent annual adjustment of its CMP with a final rule published January 18, 2024. 89 FR 3331.

⁹ See, e.g., 12 CFR 1209.7(c); FHFA Enforcement Policy, AB 2013-03 (May 31, 2013).

adjusted maximum penalty amount that FHFA may impose for violations under that regulation.

The Adjustment Improvements Act directs federal agencies to calculate each annual CMP adjustment as the percent change between the CPI–U for the previous October and the CPI–U for October of the calendar year before.¹⁰ The maximum CMP amounts for FHFA penalties were last adjusted in 2024.¹¹

Since FHFA is making this round of adjustments in calendar year 2025, and the maximum CMP amounts were last set in calendar year 2024, the inflation adjustment amount for each maximum CMP amount was calculated by comparing the CPI–U for October 2023 with the CPI–U for October 2024, resulting in an inflation factor of 1.02598. For each maximum CMP calculation, the product of this inflation

adjustment and the previous maximum penalty amount was then rounded to the nearest whole dollar as required by the Adjustment Improvements Act, and was then summed with the previous maximum penalty amount to determine the new adjusted maximum penalty amount.¹² The tables below set out these items accordingly.

ENFORCEMENT REGULATIONS

U.S. Code citation	Description	Previous maximum penalty amount	Rounded inflation increase	New adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	14,206	369	14,575
12 U.S.C. 4636(b)(2)	Second Tier	71,031	1,845	72,876
12 U.S.C. 4636(b)(4)	Third Tier (Entity-affiliated party or Regulated entity).	2,841,242	73,815	2,915,057

PROGRAM FRAUD CIVIL REMEDIES REGULATION

U.S. Code citation	Description	Previous maximum penalty amount	Rounded inflation increase	New adjusted maximum penalty amount
31 U.S.C. 3802(a)(1)	Maximum penalty per false claim	13,946	362	14,308
31 U.S.C. 3802(a)(2)	Maximum penalty per false statement	13,946	362	14,308

FLOOD INSURANCE REGULATION

U.S. Code citation	Description	Previous maximum penalty amount	Rounded inflation increase	New adjusted maximum penalty amount
42 U.S.C. 4012a(f)(5)	Maximum penalty per violation	691	18	709
42 U.S.C. 4012a(f)(5)	Maximum total penalties assessed against an Enterprise in a calendar year.	199,251	5,177	204,428

III. Differences Between the Federal Home Loan Banks and the Enterprises

When promulgating any regulation that may have future effect relating to the Banks, the Director is required by section 1313(f) of the Safety and Soundness Act to consider the differences between the Banks and the Enterprises with respect to the Banks’ cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability (12 U.S.C. 4513(f)).¹³ The Director considered the differences between the Banks and the Enterprises, as they relate to the above factors, and determined that this final rule is appropriate. The inflation adjustments effected by the final rule are mandated by law, and the special features of the Banks identified in section 1313(f) of

the Safety and Soundness Act can be accommodated, if appropriate, along with any other relevant factors, when determining any actual penalties.

IV. Regulatory Impact

Administrative Procedure Act

FHFA finds good cause that notice and an opportunity to comment on this final rule are unnecessary under section 553(b) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b). The Adjustment Improvements Act states that the annual civil money penalty adjustments shall be made notwithstanding the rulemaking provisions of 5 U.S.C. 553.¹⁴ Furthermore, this rulemaking conforms with and is consistent with the statutory directive set forth in the Adjustment Improvements Act. As a result, there are no issues of policy discretion about which to seek public comment.

Accordingly, FHFA is adopting these amendments as a final rule.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA),¹⁵ an agency must prepare a regulatory flexibility analysis for all proposed and final rules that describes the impact of the rule on small entities, unless the head of an agency certifies that the rule will not have “a significant economic impact on a substantial number of small entities.” However, the RFA applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to the APA.¹⁶ As discussed above, FHFA has determined for good cause that the APA does not require a general notice of proposed rulemaking for this rule. Thus, the RFA does not apply to this final rule.

¹⁰ 28 U.S.C. 2461 note.

¹¹ See 89 FR 3331 (Jan. 18, 2024).

¹² 28 U.S.C. 2461 note.

¹³ So in original; no paragraphs (d) and (e) were enacted. See 12 U.S.C.A. 4513 n 1.

¹⁴ 28 U.S.C. 2461 note, section 4(b)(2).

¹⁵ 5 U.S.C. 603.

¹⁶ 5 U.S.C. 603(a), 604(a).

Congressional Review Act

The rule is not a “major rule” as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq.* The rule will not result in: (1) An annual effect on the economy of \$100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies.¹⁷

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) requires that regulations involving the collection of information receive clearance from the Office of Management and Budget (OMB). This rule contains no such collection of information requiring OMB approval under the Paperwork Reduction Act. Consequently, no

information has been submitted to OMB for review.

Lists of Subjects

12 CFR Part 1209

Administrative practice and procedure, Penalties.

12 CFR Part 1217

Civil remedies, Program fraud.

12 CFR Part 1250

Flood insurance, Government-sponsored enterprises, Penalties, Reporting and record keeping requirements.

Accordingly, for the reasons stated in the preamble and under the authority of 12 U.S.C. 4513b and 12 U.S.C. 4526, the Federal Housing Finance Agency hereby amends subchapters A and C of chapter XII of Title 12 of the Code of Federal Regulations as follows:

SUBCHAPTER A—ORGANIZATION AND OPERATIONS

PART 1209—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1209 continues to read as follows:

Authority: 5 U.S.C. 554, 556, 557, and 701 *et seq.*; 12 U.S.C. 1430c(d); 12 U.S.C. 4501, 4502, 4503, 4511, 4513, 4513b, 4517, 4526, 4566(c)(1) and (c)(7), 4581–4588, 4631–4641; and 28 U.S.C. 2461 note.

■ 2. Revise § 1209.80 to read as follows:

§ 1209.80 Inflation adjustments.

The maximum amount of each civil money penalty within FHFA’s jurisdiction, as set by the Safety and Soundness Act and thereafter adjusted in accordance with the Inflation Adjustment Act, is as follows:

TABLE 1 TO § 1209.80

U.S. Code citation	Description	New adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	\$14,575
12 U.S.C. 4636(b)(2)	Second Tier	72,876
12 U.S.C. 4636(b)(4)	Third Tier (Regulated Entity or Entity-Affiliated party)	2,915,057

■ 3. Revise § 1209.81 to read as follows:

§ 1209.81 Applicability.

The inflation adjustments set out in § 1209.80 shall apply to civil money penalties assessed in accordance with the provisions of the Safety and Soundness Act, 12 U.S.C. 4636, and subparts B and C of this part, for violations occurring on or after January 15, 2025.

PART 1217—PROGRAM FRAUD CIVIL REMEDIES ACT

■ 4. The authority citation for part 1217 continues to read as follows:

Authority: 12 U.S.C. 4501; 12 U.S.C. 4526; 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812.

■ 5. Amend § 1217.3 by revising paragraphs (a)(1) introductory text and (b)(1) introductory text to read as follows:

§ 1217.3 Basis for civil penalties and assessments.

(a) * * *

(1) A civil penalty of not more than \$14,308 may be imposed upon a person who makes a claim to FHFA for property, services, or money where the

person knows or has reason to know that the claim:

* * * * *

(b) * * *

(1) A civil penalty of up to \$14,308 may be imposed upon a person who makes a written statement to FHFA with respect to a claim, contract, bid or proposal for a contract, or benefit from FHFA that:

* * * * *

SUBCHAPTER C—ENTERPRISES

PART 1250—FLOOD INSURANCE

■ 6. The authority citation for part 1250 continues to read as follows:

Authority: 12 U.S.C. 4521(a)(4) and 4526; 28 U.S.C. 2461 note; 42 U.S.C. 4001 note; 42 U.S.C. 4012a(f)(3), (4), (5), (8), (9), and (10).

■ 7. Amend § 1250.3 by revising paragraph (c) to read as follows:

§ 1250.3 Civil money penalties.

* * * * *

(c) *Amount.* The maximum civil money penalty amount is \$691 for each violation that occurs before January 15, 2025, with total penalties not to exceed \$199,251. For violations that occur on or after January 15, 2025, the civil money

penalty under this section may not exceed \$709 for each violation, with total penalties assessed under this section against an Enterprise during any calendar year not to exceed \$204,428.

* * * * *

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

[FR Doc. 2025–00775 Filed 1–15–25; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2257; Airspace Docket No. 23–ASO–53]

RIN 2120–AA66

Establishment of Class E Airspace; Brevard, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700

¹⁷ 5 U.S.C. 804(2).

feet above the surface for Transylvania Community Hospital, Brevard, NC, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving the heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this heliport.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours a day, 365 days a year.

FAA Order JO 7400.11J, Airspace Designations, and Reporting Points, as well as subsequent amendments, can be viewed online at www.faa.gov/air-traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Marc Ellerbee, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone: (404) 305-5589.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it establishes Class E airspace extending upward from 700 feet above the surface at Transylvania Community Hospital, Brevard, NC.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA 2023-2257 in the **Federal Register** (89 FR 78831; September 26, 2024), proposing to establish Class E airspace extending upward from 700 feet above the surface for Transylvania Community Hospital, Brevard, NC. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received in favor of the proposal.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 6-mile radius of Transylvania Community Hospital, Brevard, NC, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at the heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

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

substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ASO NC E5 Brevard, NC [New]

Transylvania Community Hospital, NC
(Lat. 35°15'24" N, long. 82°42'39" W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Transylvania Community Hospital Heliport.

* * * * *

Issued in College Park, Georgia, on January 7, 2025.

Andree C. Davis,

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

[FR Doc. 2025-00822 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2024–1624; Airspace
Docket No. 24–ASW–16]

RIN 2120–AA66

**Establishment of Class E Airspace;
Victoria, TX**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Victoria, TX to support new public instrument procedures.

DATES: Effective date 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5874.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the

safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the surface at Citizens Medical Center, Victoria, TX, to support instrument flight rule operations at this airport.

History

The FAA published an NPRM for Docket No. FAA 2024–2222 in the **Federal Register** (89 FR 78834; September 26, 2024), proposing to establish the Class E airspace at Victoria, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024 and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing Class E airspace upward from 700 feet above the surface within a 6-mile radius of Citizens Medical Center, Victoria, TX.

This action supports new public instrument procedures.

Regulatory Notices and Analyses

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

economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ASW TX E5 Victoria, TX [Establish]

Citizens Medical Center, TX
(Lat. 28°48'43" N, long. 096°58'42" W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Citizens Medical Center.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

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

[FR Doc. 2025–00707 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2024–1707; Airspace
Docket No. 24–ASW–4]

RIN 2120–AA66

Amendment of VOR Federal Airways V–68, V–76, V–212, V–222, and V–558, and United States Area Navigation Route T–220 in the Vicinity of Industry, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, delay of effective date.

SUMMARY: This action delays the effective date of a final rule published in the **Federal Register** on December 9, 2024, amending Very High Frequency Omnidirectional Range (VOR) Federal Airways V–68, V–212, and V–222, and United States Area Navigation (RNAV) Route T–220; and revoking VOR Federal Airway V–558. The FAA is delaying the effective date to allow sufficient time for completing the update and flight inspection of a Standard Terminal Arrival Route (STAR) instrument procedure into George Bush Intercontinental/Houston Airport, TX, that failed the initial flight inspection and a STAR instrument procedure into San Antonio International Airport, TX, that also failed the initial flight inspection. The STARs are being amended in support of the planned decommissioning of the VOR portion of the Industry, TX (IDU), VOR/Tactical Air Navigation (VORTAC).

DATES: The effective date of the final rule published on December 9, 2024, (89 FR 97510) is delayed from February 20, 2025, to April 17, 2025. The Director of the Federal Register approved this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

The FAA published a final rule in the **Federal Register** for Docket No. FAA–2024–1707 (89 FR 97510; December 9, 2024), amending VOR Federal Airways V–68, V–212, and V–222, and United States RNAV Route T–220; and revoking

VOR Federal Airway V–558 due to the planned decommissioning of the VOR portion of the Industry, TX, VORTAC navigational aid. The effective date for that final rule is February 20, 2025. After the final rule was published, the FAA determined that the required update and flight inspection actions for the two failed STAR instrument procedures, one into George Bush Intercontinental/Houston Airport and one into San Antonio International Airport, would not be completed in time to meet the original planned decommissioning date. Therefore, the current STARs need to remain in place until the next chart date.

The FAA expects the required updates and flight inspections for the affected STARs into George Bush Intercontinental/Houston Airport and into San Antonio International Airport to be completed by April 17, 2025. Therefore, the rule amending VOR Federal Airways V–68, V–212, and V–222, and United States RNAV Route T–220; and revoking VOR Federal Airway V–558 is delayed to coincide with that date.

VOR Federal Airways are published in paragraph 6010(a) and United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Good Cause for No Notice and Comment

Section 553(b)(3)(B) of Title 5, United States Code, (the Administrative Procedure Act) 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 seeking comment prior to the rulemaking. The FAA finds that prior notice and public comment to this final rule is unnecessary due to the brief length of the extension of the

effective date and the fact that there is no substantive change to the rule.

Delay of Effective Date

■ Accordingly, pursuant to the authority delegated to me, the effective date of the final rule for Airspace Docket 24–ASW–4, as published in the **Federal Register** on December 9, 2024 (89 FR 97510), FR Doc. 2024–28750, is hereby delayed until April 17, 2025.

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

Issued in Washington, DC, on January 8, 2025.

Brian Eric Konie,

Manager (A), Rules and Regulations Group.

[FR Doc. 2025–00732 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Parts 740, 742, 758, and 774**

[Docket No. 250108–0012]

RIN 0694–AJ95

Controls on Certain Laboratory Equipment and Related Technology To Address Dual Use Concerns About Biotechnology

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Interim final rule.

SUMMARY: With this interim final rule (IFR), the Bureau of Industry and Security (BIS) is revising the Export Administration Regulations (EAR) to address the accelerating development and deployment of advanced biotechnology tools contrary to U.S. national security and foreign policy interests. This rule institutes new controls on certain biotechnology equipment and related technology. It further solicits public comments on the changes it implements.

DATES: This rule is effective January 16, 2025.

Comments must be received by BIS no later than March 17, 2025.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking portal (www.regulations.gov). The *regulations.gov* ID for this rule is: BIS–2024–0050. Please refer to RIN 0694–AJ95 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting

business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” Any submissions with file names that do not begin with either a “BC” or a “P” will be assumed to be public and will be made publicly available through <https://www.regulations.gov>. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: For all questions pertaining to this rule, contact Theodore Curtin, Director of Chemical Biological Controls Division; phone: 202–482–1979; Theodore.Curtin@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

As noted in Executive Order (E.O.) 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy” (87 FR 56849, September 15, 2022), advances in biotechnology possess great promise but are inherently dual-use in nature. Accordingly, the E.O. calls for safeguarding the United States from foreign adversaries that could acquire technologies and data that threaten our national security, while also promoting the ethical and responsible development and deployment of biotechnology globally. The E.O. provides a framework to ensure that biotechnologies do not contribute to global instability through irresponsible or malicious use.

The United States recognizes that ensuring the responsible use of biotechnology, particularly when combined with advances in artificial

intelligence (AI) and data science, is essential to safeguard public health, agriculture and food production, and the environment. At the same time, the United States needs to address the benefits and risks of dual-use biotechnology given the potential that its use, particularly when coupled with AI and biological design tools, could strengthen the military capabilities of countries of concern and lower barriers to the design, deployment, and use of novel weapons. As described in the 2024 Annual Threat Assessment from the Office of the Director of National Intelligence, “new technologies—particularly in the fields of AI and biotechnology—are being developed and are proliferating at a [challenging] rate” and that the consolidation of “these emerging technologies is likely to create breakthroughs, which could lead to the rapid development of asymmetric threats . . . to U.S. interests.” Certain countries are actively pursuing a strategy to exploit the combination of biotechnology with other enabling technologies for asymmetric military advantage through applications such as human performance enhancement and advanced biologically-derived materials for military-industrial use. Given the dual-use nature and relevance of specific biotechnology equipment to contribute to the research and development of certain militarily relevant technologies, calibrated export controls on these categories of equipment are necessary to limit immediate risks and protect against long-term national security threats in a field that could greatly impact security and defense capabilities.

This IFR identifies two categories of equipment for additional U.S. export controls necessary to help protect U.S. national security. These categories of equipment are: (1) high parameter flow cytometers, which are used to simultaneously measure several characteristics of individual cells or particles, and (2) liquid chromatography mass spectrometers specially designed for top-down proteomics, which are analytical instruments used to elucidate and quantify unknown biomolecular structures, characterize molecules, and aid in the study of molecular interactions. The field of proteomics generally aims to identify and characterize proteins and study their structures, functions, interactions, and post-translational modifications. All the items described can be used towards innovative solutions in health, climate change, energy, food, and agriculture. However, they can also be used for research and development of concern to

U.S. national security, including through the generation of large amounts of high-quality biological datasets that can be misused by countries of concern. This misuse includes training artificial intelligence systems for the development of certain militarily relevant applications, including as well as but not limited to human performance enhancement, brain-machine interfaces, biologically-inspired synthetic materials, and possibly biological weapons.

To address the national security concerns described above, this IFR establishes new controls narrowly focused on a subset of biotechnology equipment. This IFR creates specific Export Control Classification Numbers (ECCNs) for high-parameter flow cytometers and certain mass spectrometry equipment. These items generate high-quality, high-content biological data including that which is suitable for use to facilitate the development of AI and biological design tools. The new ECCNs facilitate identification of the items being controlled and will provide more transparency in trade flows for this equipment. Moreover, these controls will only apply to destinations that present a concern of potential misuse or diversion to activities of national security concern.

Regulatory Changes

New Export Control Classification Numbers and Corresponding Changes

Given the above-described national security concerns, BIS is moving high-parameter flow cytometers and certain mass spectrometry equipment from their current control under ECCN 3A999 into new ECCN 3A069. ECCN 3A069 contains two paragraphs as follows: paragraph .a identifies flow cytometers and cell sorters that are “specially designed” for spectral analysis or contain 26 or greater detectors or channels; and paragraph .b identifies liquid chromatography mass spectrometry instruments (LC/MS and LC-MS/MS) “specially designed” for top-down proteomic analysis. Flow cytometers and mass spectrometers that are devices, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(h), that have been authorized for marketing by the Food and Drug Administration under section 510(k), section 513, or section 515 of the FD&C Act, 21 U.S.C. 360(k), 21 U.S.C. 360c, 21 U.S.C. 360e, or are exempt from the requirement of premarket notification under section 510(k) of the FD&C Act, 21 U.S.C. 360(k), and that are included in a list

required by section 510(j) of the FD&C Act, 21 U.S.C. 360(j), are excluded from the scope of ECCN 3A069; the exclusion appears as a license requirement note to ECCN 3A069. This rule also makes two conforming changes. First, ECCN 3A999 is updated to reference ECCN 3A069 as a related control. Second, the heading of ECCN 3E001 is updated to reference ECCN 3A069 in the list of 3A items excepted.

Relatedly, BIS is creating ECCN 3E069 to describe “technology” for the “development” or “production” of ECCN 3A069 items. The list of items controlled is contained in the ECCN heading. ECCNs 3A069 and 3E069 have the same reasons for control and licensing policies, described below.

Reasons for Control, Authorizations, and EEI Filing Changes

ECCNs 3A069 and 3E069 are controlled for National Security, Regional Stability, and Anti-Terrorism reasons. No licenses are required for Country Group A:1 for these items. As described below, certain license exceptions are also available for these items.

National Security reasons for control are detailed under § 742.4. Under paragraph (a)(2), 3A069 and 3E069 items will require a license to all destinations, except those in Country Group A:1. This IFR adds paragraph (b)(11) to § 742.4, which identifies the license review policy for license applications as follows: (a) presumption of denial for destinations in both Country Group D:1 and D:5, Macau, or destinations in Country Group E; and (b) for all other destinations for which a license is required, case-by-case review based on a determination of whether the items would make a significant contribution to the military potential of any other destination or combination of destinations that would prove detrimental to the national security of the United States.

Regional Stability requirements for control are detailed under § 742.6. This IFR adds paragraph (a)(13) to § 742.6, which establishes a license requirement for the export, reexport, or transfer (in-country) of any item controlled under ECCNs 3A069 and 3E069 when destined to a Country Group D:5 destination or Macau. Consistent with the license review policy for NS reasons of control, for destinations that are in both Country Group D:1 and D:5, Macau, or destinations in Country Group E, license applications for these items will be reviewed under a presumption of denial. For all other destinations, applications will be subject to case-by-case review. This case-by-case review

policy includes license applications for countries in Country Group D:5 that are not also in Country Group D:1. This IFR adds the license review policy for RS for these items to paragraph (b)(14).

Commodities controlled under ECCN 3A069 are generally eligible for License Exception Shipments to Country Group B countries (GBS), set forth in § 740.4. However, License Exception GBS will not be available for destinations subject to the RS control described in ECCN 3A999. Technology controlled under ECCN 3E069 is eligible for License Exception Technology and software under restriction (TSR), detailed under § 740.6, except to destinations in Country Group D:5, destinations subject to the RS control described in ECCN 3A999, or Macau (in addition to existing destination-based restrictions on the use of TSR). Under TSR, written assurances are required from the importer that the technologies authorized under the License Exception will not be reexported or released under certain conditions. Since TSR eligibility will not apply to destinations in Country Group D:5, destinations subject to the RS control in ECCN 3A999, and Macau, this IFR adds paragraph (a)(1)(iv) to § 740.6, which provides that a written assurance is required for TSR authorization of ECCN 3E069 technology, assuring that the importer will not reexport or release the technology to those destinations.

Finally, to better track the export of the items in ECCN 3A069, this IFR revises the filing requirements for Electronic Export Information (EEI) filings in the Automated Export System (AES). Under new paragraph (b)(11) of § 758.1, EEI filings are required for exports of all items in ECCN 3A069 when destined for a Country Group D destination.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on January 16, 2025, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before February 18, 2025. Any such items not actually exported, reexported or transferred (in-country) before midnight, on February

18, 2025, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense

Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (codified, as amended, at 50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this rule. In particular, and as noted elsewhere, Section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, Section 1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, *inter alia*, the establishment of a list of controlled items; the prohibition of unauthorized exports, reexports, and transfers (in-country); the requirement of licenses or other authorizations for exports, reexports, and transfers (in-country) of controlled items; apprising the public of changes in policy, regulations, and procedures; and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

Rulemaking Requirements

1. This rule has been determined to be a significant regulatory action for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classifications, and carries a burden estimate of 29.7 minutes for a manual or electronic submission for a total burden estimate of 38,826 hours. Total burden hours associated with the PRA and OMB control number 0694–0088 are expected to increase as a result of this rule. This rule is expected to increase the licensing burden by approximately 1170 licenses per year; this will result

in an overall increase in burden hours by around 580 hours per year for licensing, for a new total burden estimate of 39,406 hours.

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

4. Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While Section 1762 of ECRA on its own provides sufficient authority for such an exemption, this action is also independently exempt from the same APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Nonetheless, BIS is accepting comments on this IFR.

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

List of Subjects

15 CFR Parts 740 and 758

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, parts 740, 742, 758, and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 740—LICENSE EXCEPTIONS

■ 1. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Section 740.6 is amended by adding paragraph (a)(1)(iv) to read as follows:

§ 740.6 Technology and software under restriction (TSR).

(a) * * *

(1) * * *

(iv) Reexport to a destination in Country Group D:5, a destination subject to the Regional Stability control under ECCN 3A999, or Macau or release the technology to a national of such destinations, if the technology is controlled under ECCN 3E069.

* * * * *

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 3. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 4. Section 742.4 is amended by revising (b)(11) to read as follows:

PART 742—CONTROL POLICY—CCL BASED CONTROLS

§ 742.4 National security.

* * * * *

(b) * * *

(11) *License review policy for items specified in ECCNs 3A069 and 3E069.* License applications to export, reexport, or transfer (in-country) items specified in ECCNs 3A069 and 3E069 will be reviewed under a presumption of denial when destined for a country that is in both Country Groups D:1 and D:5, Macau, or a country in Country Group E. All other license applications for these items will be reviewed on a case-by-case basis to determine if the items would make a significant contribution to the military potential of any other destination or combination of destinations that would prove detrimental to the national security of the United States.

* * * * *

■ 5. Section 742.6 is amended by adding paragraphs (a)(13) and (b)(14) to read as follows:

§ 742.6 Regional stability.

(a) * * *

(13) *RS requirement that applies for items specified in ECCNs 3A069 and 3E069.* A license is required for the

export, reexport, or transfer (in-country) of any item specified in ECCNs 3A069 and 3E069 when destined to a Country Group D:5 destination or Macau. See supplement no. 1 to part 740 of the EAR for Country Groups.

(b) * * *

(14) *License review policy for items specified in paragraph (a)(13).* License applications to export, reexport, or transfer (in-country) items described in paragraph (a)(13) of this section will be reviewed under a presumption of denial when destined for a country that is in both Country Groups D:1 and D:5, Macau, or a country in Country Group E. All other license applications for these items will be reviewed on a case-by-case basis.

PART 758—EXPORT CLEARANCE REQUIREMENTS AND AUTHORITIES

■ 6. The authority citation for part 758 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 7. Section 758.1 is amended by adding paragraph (b)(11) to read as follows:

§ 758.1 The Electronic Export Information (EEI) filing to the Automated Export System (AES).

* * * * *

(b) * * *

(11) For all exports of items in ECCN 3A069 when destined to a destination in Country Group D.

PART 774—THE COMMERCE CONTROL LIST

■ 8. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

Supplement No. 1 to Part 774—The Commerce Control List

■ 9. Supplement no.1 to part 774 is revised by adding ECCN 3A069, modifying ECCNs 3A999 and 3E001, and adding ECCN 3E069.

The addition and revision read as follows:

* * * * *

Category 3—Electronics**A. “End Items,” “Equipment,” “Accessories,” “Attachments,” “Parts,” “Components,” and “Systems”**

* * * * *

ECCN 3A069 Specific Laboratory Equipment as Follows (See List of Items Controlled)**License Requirements***Reason for Control:* NS, RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
NS applies to entire entry.	NS Column 2.
RS applies to entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(12) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)*LVS:* N/A*GBS:* Yes, except N/A for destinations subject to the RS control in 3A999.**List of Items Controlled**

Related Controls: See also 3A999 for specific processing equipment, n.e.s.. See also 3E069 for technology for the “development” and “production” of items detailed in 3A069.

License Requirement Note: *Excluded from the scope of this entry are flow cytometers and mass spectrometers that are devices, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(h), that have been authorized for marketing by the Food and Drug Administration under section 510(k), section 513, or section 515 of the FD&C Act, 21 U.S.C. 360(k), 21 U.S.C. 360c, 21 U.S.C. 360e, or are exempt from the requirement of premarket notification under section 510(k) of the FD&C Act, 21 U.S.C. 360(k), and that are included in a list required by section 510(j) of the FD&C Act, 21 U.S.C. 360(j).*

Related Definitions: N/A**Items:**

- Flow cytometers and cell sorters that are “specially designed” for spectral analysis or contain 26 or greater detectors or channels.
- Liquid chromatography mass spectrometry instruments (LC/MS and LC-MS/MS) “specially designed” for top-down proteomic analysis.

* * * * *

3A999 Specific Processing Equipment, n.e.s., as Follows (See List of Items Controlled).**License Requirements***Reason for Control:* RS, AT*Control(s)*

RS applies to entire entry.

AT applies to entire entry

Country chart (see Supp. No. 1 to part 738)

A license is required for items controlled by this entry for export or re-export to Iraq or Pakistan or transfer within Iraq or Pakistan for regional stability reasons. The Commerce Country Chart is not designed to determine RS license requirements for this entry. See §§ 742.6 and 746.3 of the EAR for additional information.

A license is required for items controlled by this entry to North Korea for anti-terrorism reasons. The Commerce Country Chart is not designed to determine AT licensing requirements for this entry. See § 742.19 of the EAR for additional information.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)*LVS:* N/A*GBS:* N/A**List of Items Controlled**

Related Controls: (1) See also 3A225 (for frequency changers capable of operating in the frequency range of 600 Hz and above) and 3A233. (2) Certain auxiliary systems, equipment, “parts” and “components” for isotope separation plants made of or protected by UF₆ resistant materials are subject to the export licensing authority of the Nuclear Regulatory Commission (see 10 CFR part 110). (3) See also 3A069 for flow cytometers and cell sorters that are “specially designed” for spectral analysis or contain 26 or greater detectors or channels as well as liquid chromatography mass spectrometry instruments (LC/MS and LC-MS/MS) “specially designed” for top-down proteomic analysis.

Related Definitions: N/A**Items:**

- Frequency changers capable of operating in the frequency range from 300 up to 600 Hz, n.e.s.;
- Mass spectrometers n.e.s.;
- All flash x-ray machines, and “parts” or “components” of pulsed power systems designed thereof, including Marx generators, high power pulse shaping networks, high voltage capacitors, and triggers;
- Pulse amplifiers, n.e.s.;
- Electronic equipment for time delay generation or time interval measurement, as follows:
 - Digital time delay generators with a resolution of 50 nanoseconds or less over time intervals of 1 microsecond or greater; or
 - Multi-channel (three or more) or modular time interval meter and chronometry equipment with resolution of 50 nanoseconds or less over time intervals of 1 microsecond or greater;

f. Chromatography and spectrometry analytical instruments, n.e.s.

* * * * *

E. “Technology”

* * * * *

3E001 “Technology” according to the General Technology Note for the “development” or “production” of commodities controlled by 3A (except 3A069, 3A901, 3A904, 3A980, 3A981, 3A991, 3A992, or 3A999), 3B (except 3B001.a.4, c, d, f.1, f.5, k to n, p.2, p.4, r, 3B002.c, 3B903, 3B904, 3B991, 3B992, 3B993, or 3B994) or 3C (except 3C907, 3C908, 3C909, or 3C992).

License Requirements*Reason for Control:* NS, MT, NP, RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
NS applies to “technology” for commodities controlled by 3A001, 3A002, 3A003, 3B001 (except as noted in the heading), 3B002 (except 3B002.c), or 3C001 to 3C006.	NS Column 1.
MT applies to “technology” for commodities controlled by 3A001 or 3A101 for MT Reasons.	MT Column 1.
NP applies to “technology” for commodities controlled by 3A001, 3A201, or 3A225 to 3A234 for NP reasons.	NP Column 1.
RS applies to “technology” for commodities controlled in 3A090, when exported from Macau or a destination specified in Country Group D:5.	Worldwide (see § 742.6(a)(6)(iii)).
RS applies to “technology” for commodities controlled by 3A001.z, 3A090 (except for 3A090.c).	To or within destinations specified in Country Groups D:1, D:4, and D:5 of supplement no. 1 to part 740 of the EAR, excluding any destination also specified in Country Groups A:5 or A:6. See § 742.6(a)(6)(iii) of the EAR.
RS applies to “technology” for commodities controlled by 3A090.c.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(6)(i)(B) of the EAR.
RS applies to “technology” for commodities controlled by 3A001.a.15 or b.13, 3A004, 3B003, 3C007, 3C008, or 3C009.	RS Column 2.
AT applies to entire entry	AT Column 1.

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those*

incorporating “information security” functionality, and associated “software” and “technology” for the “production” or “development” of such microprocessors.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for MT, and “technology” for the “development” or “production” of: (a) vacuum electronic device amplifiers described in 3A001.b.8, having operating frequencies exceeding 19 GHz; (b) solar cells, coverglass-interconnect-cells or covered-interconnect-cells (CIC) “assemblies,” solar arrays and/or solar panels described in 3A001.e.4; (c) “Monolithic Microwave Integrated Circuit” (“MMIC”) amplifiers in 3A001.b.2; (d) discrete microwave transistors in 3A001.b.3; and (e) commodities described in 3A090.

Note: See § 740.2(a)(9)(ii) of the EAR for license exception restrictions for ECCN 3E001 “technology” for commodities controlled by 3A001.z, 3A090.

IEC: Yes, for “technology” for equipment controlled by 3B001.q, see § 740.2(a)(22) and § 740.24 of the EAR.

Special Conditions for Strategic Trade Authorization (STA)

STA: License Exception STA may not be used to ship or transmit “technology” according to the General Technology Note for the “development” or “production” of equipment specified by ECCNs 3A002.g.1 or 3B001.a.2 to any of the destinations listed in Country Group A:6 (see supplement no.1 to part 740 of the EAR). License Exception STA may not be used to ship or transmit “technology” according to the General Technology Note for the “development” or “production” of components specified by ECCN 3A001.b.2, b.3, commodities specified in 3A090, to any of the destinations listed in Country Group A:5 or A:6 (see supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: (1) “Technology” according to the General Technology Note for the “development” or “production” of certain “space-qualified” atomic frequency standards described in Category XV(e)(9), MMICs described in Category XV(e)(14), and oscillators described in Category XV(e)(15) of the USML are “subject to the ITAR” (see 22 CFR parts 120 through 130). See also ECCNs 3E101, 3E201 and 9E515. (2) “Technology” for “development” or “production” of “Microwave Monolithic Integrated Circuits” (“MMIC”) amplifiers in 3A001.b.2 is controlled in this ECCN 3E001; 5E001.d refers only to that additional “technology” “required” for telecommunications.

Related Definition: N/A.

Items: The list of items controlled is contained in the ECCN heading.

Note 1: 3E001 does not control “technology” for equipment or “components” controlled by 3A003.

Note 2: 3E001 does not control “technology” for integrated circuits controlled by 3A001.a.3 to a.14 or z, having all of the following:

(a) Using “technology” at or above 0.130 μm ; and

(b) Incorporating multi-layer structures with three or fewer metal layers.

* * * * *

3E069 “Technology” according to the General Technology Note for the “development” or “production” of items controlled by 3A069.

License Requirements

Reason for Control: NS, RS, AT

Control(s)	Country chart (see Supp. No. 1 to part 738)
NS applies to entire entry.	NS Column 2.
RS applies to entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(13) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for Macau, destinations in Country Group D:5, or destinations subject to the RS control in 3A999.

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2025–00723 Filed 1–15–25; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 250108–0010]

RIN 0694–AJ76

Addition of Entities to and Revision of Entry on the Entity List

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding 11 entities under 11 entries to the Entity List. These entries

are listed on the Entity List under the destination of China, People’s Republic of (China) (11). These entities have been determined by the U.S. Government to be acting contrary to the national security and/or foreign policy interests of the United States. This rule also revises one existing entry on the Entity List under the destination of India.

DATES: This rule is effective January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730–774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b) of the EAR. The EAR imposes additional license requirements on and limits the availability of most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. The license review policy for each listed entity is identified in the “License Review Policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the entity to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

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

Additions to the Entity List

The ERC determined to add Beijing Zhipu Huazhang Technology Co., Ltd.; Beijing Lingxin Intelligent Technology Co., Ltd.; Beijing Yuanyin Intelligent Technology Co., Ltd.; Beijing Zhipu

Future Technology Co., Ltd.; Beijing Zhipu Linghang Technology Co., Ltd.; Beijing Zhipu Qingyan Technology Co., Ltd.; Hangzhou Zhipu Huazhang Technology Co., Ltd.; Nanjing Zhihu Information Technology Co., Ltd.; Shanghai Zhipu Huanu Technology Co., Ltd.; and Shenzhen Zhipu Future Technology Co., Ltd., to the Entity List, under the destination of China. These additions are being made because these entities advance the People's Republic of China's military modernization through the development and integration of advanced artificial intelligence research. This activity is contrary to the national security and foreign policy interests of the United States under Section 744.11 of the EAR. A license is required for all items subject to the EAR, with a license review policy of a presumption of denial.

The ERC determined to add Beijing Keyi Hongyuan Optoelectronics Co., Ltd. to the Entity List, under the destination of China. Specifically, this entity is co-developing lithography technology for advanced-node fabrication facilities in China. This technology will enable indigenous production in China of advanced integrated circuits for military end-use. This activity is contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. A license is required for all items subject to the EAR, with a license review policy of a presumption of denial.

For the reasons described above, this final rule adds the following 11 entities under 11 entries to the Entity List and includes, where appropriate, aliases:

China

- Beijing Keyi Hongyuan Optoelectronics Co., Ltd.,
- Beijing Lingxin Intelligent Technology Co., Ltd.,
- Beijing Yuanyin Intelligent Technology Co., Ltd.,
- Beijing Zhipu Future Technology Co., Ltd.,
- Beijing Zhipu Huazhang Technology Co., Ltd.,
- Beijing Zhipu Linghang Technology Co., Ltd.,
- Beijing Zhipu Qingyan Technology Co., Ltd.,
- Hangzhou Zhipu Huazhang Technology Co., Ltd.,
- Nanjing Zhihu Information Technology Co., Ltd.,
- Shanghai Zhipu Huanu Technology Co., Ltd., and
- Shenzhen Zhipu Future Technology Co., Ltd.

Modifications to the Entity List

The ERC determined to modify one existing entry on the Entity List, “The following Department of Atomic Energy entities” under the destination of India. Specifically, the ERC determined to remove the three entities listed within the entry (“Indian Rare Earths,” “Indira Gandhi Atomic Research Center (IGCAR),” and “Bhabha Atomic Research Center (BARC)”) but continue to list the relevant facilities (Nuclear reactors (including power plants) not under International Atomic Energy Agency (IAEA) safeguards, (excluding Kundankulam 1 and 2); fuel reprocessing and enrichment facilities; and heavy water production facilities and their collocated ammonia plants) in the entry.

The ERC determined to remove three entities from the entry based on information received pursuant to § 744.16(e) of the EAR and the review that the ERC conducted in accordance with the procedures described in supplement no. 5 to part 744 of the EAR. Modifying the Department of Atomic Energy entry to remove Indian Rare Earths, IGCAR, and BARC will support U.S. foreign policy objectives by reducing barriers to advance energy cooperation, including joint research and development and science and technology cooperation, towards shared energy security needs and goals. It will also enable closer cooperation between the United States and India to secure more resilient critical minerals and clean energy supply chains, following through on a leader-level commitment to hasten bilateral collaboration at a time when these supply chains have grown increasingly fragile. The United States and India share a commitment to advance peaceful nuclear cooperation and associated research and development activities, with strengthened science and technology cooperation over the past several years which has benefitted both countries and their partner countries around the world. The removal of the three entities from the entry aligns with and supports the overall ambition and strategic direction of the U.S.-India partnership.

Prior to their removal, a license was required for all items subject to the EAR to these three entities regardless of the item's end use. With the removal of BARC, IGCAR, and India Rare Earths from the entry on the Entity List, a license is no longer required for exports to these three entities unless the end use is listed in § 744.2 of the EAR. Section 744.2 of the EAR prohibits exports, reexports, and transfers (in-country) of items subject to the EAR to defined

nuclear proliferation activities, to any destination, other than countries in supplement no.3 to part 744. As India is not listed in supplement no.3 to part 744, exporters, re-exporters and transferors (in-country) are reminded that they are required to seek a license if they know or have reason to know that the exported item(s) will be used in any of the activities listed in § 744.2 of the EAR for all end-users in India, regardless of whether they are listed on the Entity List or not.

India has openly tested nuclear weapons and openly declared that it possesses nuclear weapons. India has publicized its nuclear energy and nuclear fuel-cycle plans. Information on India's nuclear activities is readily available from a variety of reputable sources. Furthermore, India has publicized the list of civil nuclear facilities that are subject to IAEA safeguards. This list is available on the IAEA website as INFCIRC/754. Exporters should seek guidance from BIS if they are unsure if the exported item(s) will be used in nuclear explosive activities and/or unsafeguarded nuclear activities.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on January 16, 2025, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before February 18, 2025. Any such items not actually exported, reexported, or transferred (in-country) before midnight, on February 18, 2025, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, Section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, Section

1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, *inter alia*, establishing and maintaining a list of foreign persons and end uses that are determined to be a threat to the national security and foreign policy of the United States pursuant to the policy set forth in Section 1752(2)(A), and restricting exports, reexports, and in-country transfers of any controlled items to any foreign person or end-use so listed; apprising the public of changes in policy, regulations, and procedures; and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can

be accessed at: <https://www.reginfo.gov/public/do/PRAMain>.

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

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While Section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).

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

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

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

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

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

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2024, 89 FR 77011 (September 20, 2024); Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 2. Supplement no. 4 to part 744 is amended by:

■ a. Under CHINA, PEOPLE'S REPUBLIC OF, by adding, in alphabetical order, entries for “Beijing Keyi Hongyuan Optoelectronics Co., Ltd.,” “Beijing Lingxin Intelligent Technology Co., Ltd.,” “Beijing Yuanyin Intelligent Technology Co., Ltd.,” “Beijing Zhipu Future Technology Co., Ltd.,” “Beijing Zhipu Huazhang Technology Co., Ltd.,” “Beijing Zhipu Linghang Technology Co., Ltd.,” “Beijing Zhipu Qingyan Technology Co., Ltd.,” “Hangzhou Zhipu Huazhang Technology Co., Ltd.,” “Nanjing Zhihu Information Technology Co., Ltd.,” “Shanghai Zhipu Huanyu Technology Co., Ltd.,” and “Shenzhen Zhipu Future Technology Co., Ltd.,” and

■ b. Under India, revising the entry for “The following Department of Atomic Energy entities.”

The additions and modification read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
* * *	* * *	* * *	* * *	* * *
CHINA, PEOPLE'S REPUBLIC OF.				
	* * *	* * *	* * *	* * *
	Beijing Keyi Hongyuan Optoelectronics Co., Ltd., a.k.a., the following three aliases: —RSLaser; —Beijing RSLaser Photoelectric Technology; and —Beijing RSLaser Opto-Electronics. No. 19, Rongxing North 1st Street, Daxing District, Beijing, China.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	* * *	* * *	* * *	* * *
	Beijing Lingxin Intelligent Technology Co., Ltd., 7th Floor, Building 9, No. 1, Zhongguancun East Road, Haidian District, Beijing, China; and Room 4–1106, 11th Floor, No. 28 Chengfu Road, Haidian District, Beijing, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	* * *	* * *	* * *	* * *
	Beijing Yuanyin Intelligent Technology Co., Ltd., Room 07–128, 101, 7th Floor, No. 219 Wangfujing Street, Dongcheng District, Beijing, China; and Room 801, 8th Floor, Building 9, No. 1, Zhongguancun East Road, Haidian District, Beijing, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.

Country	Entity	License requirement	License review policy	Federal Register citation
	Beijing Zhipu Future Technology Co., Ltd., Room 801, 8th Floor, Building 9, No. 1, Zhongguancun East Road, Haidian District, Beijing, China. Beijing Zhipu Huazhang Technology Co., Ltd., a.k.a., the following two aliases: —Zhipu AI; and —Beijing Knowledge Atlas Technology Co., Ltd. Floor 10, Building 9, No. 1, Zhongguancun East Road, Haidian District, Beijing, 100080, China. Beijing Zhipu Linghang Technology Co., Ltd., Room 306–4, 3rd Floor, Building 6, No. 10 Kegou 1st Street, Beijing Economic and Technological Development Zone, Beijing, China. Beijing Zhipu Qingyan Technology Co., Ltd., Room 202, 2nd Floor, Building 13, No. 98 Lianshihu West Road, Mentougou District, Beijing, China.	For all items subject to the EAR. (See § 744.11 of the EAR). For all items subject to the EAR. (See § 744.11 of the EAR). For all items subject to the EAR. (See § 744.11 of the EAR). For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial. Presumption of denial. Presumption of denial. Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. 90 FR [INSERT FR PAGE NUMBER] January 16, 2025. 90 FR [INSERT FR PAGE NUMBER] January 16, 2025. 90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	Hangzhou Zhipu Huazhang Technology Co., Ltd., Room 551, No. 857, 859, Shixin North Road, Yingfeng Street, Xiaoshan District, Hangzhou, Zhejiang Province, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	Nanjing Zhihu Information Technology Co., Ltd., Room 605, South Building (Block E), Phase II, Dingye Baitai Biological Building, No. 10 Xinghuo Road, Jiangbei New District, Nanjing, Jiangsu Province, China; and Room 412, Main Building, Zhixin Technology Building, No. 15 Xinghuo Road, Jiangbei New District, Nanjing, Jiangsu Province, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	Shanghai Zhipu Huanyu Technology Co., Ltd., 3rd Floor, Building 1, No. 400, Fangchun Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	Shenzhen Zhipu Future Technology Co., Ltd., Building A701, Vanke Cloud City Phase 6, Dashi 2nd Road, Xili Community, Xili Street, Nanshan District, Shenzhen, Guangdong Province, China; and C1202, Building 2, Shenzhen Software Industry Base, No. 87, 89, and 91, Gaoxin South 10th Road, Nanshan District, Shenzhen, Guangdong Province, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
INDIA	The following Department of Atomic Energy facilities: —Nuclear reactors (including power plants) not under International Atomic Energy Agency (IAEA) safeguards, (excluding Kundankulam 1 and 2); —Fuel reprocessing and enrichment facilities; and —Heavy water production facilities and their collocated ammonia plants.	For all items subject to the EAR	Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items. See § 744.2(d) of the EAR.	63 FR 64322, 11/19/98 65 FR 14444, 3/17/00 66 FR 50090, 10/1/01 69 FR 56694, 9/22/04. 90 FR [INSERT FR PAGE NUMBER] January 16, 2025.

* * * * *

Matthew S. Borman,

Principal Deputy Assistant Secretary for
Strategic Trade and Technology Security.

[FR Doc. 2025–00704 Filed 1–15–25; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 744**

[Docket No. 250106–0001]

RIN 0694–AK01

Additions to the Entity List**AGENCY:** Bureau of Industry and Security, Department of Commerce.**ACTION:** Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding 16 entities to the Entity List, under the destinations of China, People's Republic of (China) (14) and Singapore (2). These entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States.

DATES: This rule is effective January 16, 2025.

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

SUPPLEMENTARY INFORMATION:**Background**

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730–774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in, activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b). The EAR imposes additional license requirements on, and limits the availability of, most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. The license review policy for each listing is identified in the “License Review Policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the listing to the Entity List. BIS amends the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use Based) and 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair),

State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

Entity List Decisions*Additions to the Entity List*

The ERC approved the addition of Chengdu Suanfeng Technology Co., Ltd.; Fujian Sophon Technology Co., Ltd.; Fujian Suanxin Technology Co., Ltd.; Jiangsu Suanxin Technology Co., Ltd.; Qingdao Sophgo Technology Co., Ltd.; Quliang Electronics Co., Ltd.; Shanghai Suanhu Technology Co., Ltd.; Sophon Technologies Ltd.; Sophon Technology (Beijing) Co., Ltd.; Suanli (Fujian) Technology Co., Ltd.; Tianjin Shunhua Technology Co., Ltd.; Wuhan Sophgo Technology Co., Ltd.; Wuxi Sophgo Technology Co., Ltd.; and Xiamen Sophgo Technologies Limited under the destination of China; and Sophgo Technologies Pte. Ltd. and PowerAir Pte. Ltd. under the destination of Singapore to the Entity List. These entities are being added to the Entity List due to their involvement in supporting or directly contributing to the development of advanced computing integrated circuits (ICs) that further China's development of advanced weapons systems, weapons of mass destruction, and high-tech surveillance applications, and because these entities supply Chinese public security end users and pose a risk of diversion to Huawei, an entity on the Entity List. This activity is contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. These entities will be added to the Entity List with a footnote 4 designation for their role in supporting or directly contributing to the development of advanced computing ICs that further China's development of advanced weapons systems, weapons of mass destruction, and high-tech surveillance applications. For all of these entities, BIS imposes a license requirement for all items subject to the EAR, and a license review policy of a presumption of denial. The footnote 4 designation means that “items subject to the EAR,” for the purpose of the license requirements for these entries, includes foreign-produced items that are subject to the EAR pursuant to § 734.9(e)(2) of the EAR.

For the reasons described above, this final rule adds the following 16 entities,

including aliases where appropriate, to the Entity List:

China

- Chengdu Suanze Technology Co., Ltd.,
- Fujian Sophon Technology Co., Ltd.,
- Fujian Suanxin Technology Co., Ltd.,
- Jiangsu Suanxin Technology Co., Ltd.,
- Qingdao Sophgo Technology Co., Ltd.,
- Quliang Electronics Co., Ltd.,
- Shanghai Suanhu Technology Co., Ltd.,
- Sophgo Technologies Ltd.,
- Sophon Technology (Beijing) Co., Ltd.,
- Suanli (Fujian) Technology Co., Ltd.,
- Tianjin Shunhua Technology Co., Ltd.,
- Wuhan Suanneng Technology Co., Ltd.,
- Wuxi Suanneng Technology Co., Ltd., and
- Xiamen Sophgo Technologies Limited.

Singapore

- Sophgo Technologies Pte. Ltd., and
- PowerAir Pte. Ltd.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on January 16, 2025, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before February 18, 2025. Any such items not actually exported, reexported or transferred (in-country) before midnight, on February 18, 2025, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, Section 1753 of

ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, Section 1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, inter alia, establishing and maintaining a list of foreign persons and end-uses that are determined to be a threat to the national security and foreign policy of the United States pursuant to the policy set forth in Section 1752(2)(A), and restricting exports, reexports, and in-country transfers of any controlled items to any foreign person or end-use so listed; apprising the public of changes in policy, regulations, and procedures, and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

Rulemaking Requirements

- 1. This rule has been determined to be not significant for purposes of Executive Order 12866.
- 2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this

collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at: <https://www.reginfo.gov/public/do/PRAMain>.

- 3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.
- 4. Pursuant to Section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While Section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).
- 5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.
Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—END-USE AND END-USER CONTROLS

- 1. The authority citation for part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2024, 89 FR 77011 (September 20, 2024); Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

- 2. Supplement no. 4 is amended by:
 - a. Under CHINA, PEOPLE'S REPUBLIC OF, adding in alphabetical order entries for Chengdu Suanze Technology Co., Ltd.; “Fujian Sophon Technology Co., Ltd.”; “Fujian Suanxin Technology Co., Ltd.”; “Jiangsu Suanxin Technology Co., Ltd.”; “Qingdao Sophgo Technology Co., Ltd.”; “Quliang Electronics Co., Ltd.”; “Shanghai Suanhu Technology Co., Ltd.”; “Sophgo Technologies Ltd.”; “Sophon Technology (Beijing) Co., Ltd.”; “Suanli (Fujian) Technology Co., Ltd.”; “Tianjin Shunhua Technology Co., Ltd.”; “Wuhan Suanneng Technology Co., Ltd.”; “Wuxi Suanneng Technology Co., Ltd.”; and “Xiamen Sophgo Technologies Limited;” and
 - b. Under SINGAPORE, adding in alphabetical order entries for “Sophgo Technologies Pte. Ltd.” and “PowerAir Pte. Ltd.”

The additions read as follows:
Supplement No. 4 to Part 744—Entity List

Country	Entity	License requirement	License review policy	Federal Register citation
CHINA, PEOPLE'S REPUBLIC OF.	Chengdu Suanze Technology Co., Ltd., No. 401 (attached to No. A54), 4th Floor, Unit 1, Building 4, No. 1700, North Section of Tianfu Avenue, Chengdu High-tech Zone, China (Sichuan) Pilot Free Trade Zone, Sichuan Province, China.	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ .	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER AND January 16, 2025].
	Fujian Sophon Technology Co., Ltd., a.k.a., and the following one alias: —Fujian Suanfeng Technology Co., Ltd. Room 916, Yangguang Building North, Fuzhou University Science and Technology Park, No. 2, Xueyuan Road, Shangjie Town, Minhou County, Fuzhou, Fujian Province, China.	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ .	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	Fujian Suanxin Technology Co., Ltd., 02 1st Floor, #2–1 Building, Qiaoxingjun Area 2, North Baima Road, Nanjie Neighborhood, Gulou District, Fuzhou, Fujian Province, China.	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ .	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER] January 16, 2025.

Country	Entity	License requirement	License review policy	Federal Register citation
	Jiangsu Suanxin Technology Co., Ltd., Room 1501, Building 1, No. 8 Zhujiawan Street, Gusu District, Suzhou, Jiangsu Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	89 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Qingdao Sophgo Technology Co., Ltd., a.k.a., the following two aliases: —Qingdao Suanneng; <i>and</i> —Qingdao Sophon. Room 501, Building 20, Zone C, Kechuang Huigu (Qingdao) Science and Technology Park, No. 2 Xiuyuan Road, High-tech Zone, Qingdao, Shandong Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	89 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Quliang Electronics Co., Ltd., No. 368 Jianxing Road, Integrated Circuit Science Park, Jinjiang City, Quanzhou, Fujian Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Shanghai Suanhu Technology Co., Ltd., 3rd Floor, Building 2, No. 200 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Sophgo Technologies Ltd., a.k.a., the following four aliases: —Beijing Sophgo; —Beijing Suanneng Technology Co., Ltd; —Sophgo; <i>and</i> —SOPHON. 901, 9th Floor, Building 8, No. 8 Kegou 1st Street, Beijing Economic and Technological Development Zone, Yizhuang Group High-end Industrial Zone, Beijing Pilot Free Trade Zone, Beijing, China; <i>and</i> Building 6, Yard 9, Fenghao East Road, Haidian District, Beijing, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Sophon Technology (Beijing) Co., Ltd., Room 106–2, Floor 1, Building 1, No. 9 Fenghao East Road, Haidian District, Beijing, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Suanli (Fujian) Technology Co., Ltd., Building 2, Phase 2, China Southeast Big Data Industrial Park, No. 2 Hujiang Road, Wenwusha Neighborhood, Changle District, Fuzhou, Fujian Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Tianjin Shunhua Technology Co., Ltd., Area 3, Floor 1, Area C, Dongman Building, No. 126 Dongman Middle Road, Sino-Singapore Tianjin Eco-city (No. TG0004), Binhai, Tianjin, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Wuhan Suanneng Technology Co., Ltd., a.k.a., the following one alias: —Wuhan Sophgo. Room 2902, Fanyuecheng Office Building T2, Guanshan Avenue, East Lake New Technology Development Zone, Wuhan, Hubei Province, China; <i>and</i> Room 2902, Fanyuecheng Office Building T2, Guanshan Avenue, Donghu New Technology Development Zone, Wuhan, Hubei Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Wuxi Suanneng Technology Co., Ltd., a.k.a., the following one alias: —Wuxi Sophgo. Room 7028, Comprehensive Building, No. 298 Xicheng Road, Liangxi District, Wuxi, Jiangsu Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *
	Xiamen Sophgo Technologies Limited, a.k.a., the following two aliases: —Xiamen Suanneng Technology Co., Ltd.; <i>and</i> —Xiamen Sophgo. Room 702–01, Xinghui Building, No. 9, Zengcuoan North Road, Software Park, Xiamen Torch Hi-Tech Zone, Xiamen, Fujian Province, China. *	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ . *	Presumption of denial. *	90 FR [INSERT FR PAGE NUMBER] January 16, 2025. *

Country	Entity	License requirement	License review policy	Federal Register citation
SINGAPORE	Sophgo Technologies Pte. Ltd., #13-01/02/03, 9 Temasek Boulevard, Singapore; and 38 Beach Road, #29-11, South Beach Tower, 189767, Singapore.	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ .	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	PowerAir Pte. Ltd., 1 Raffles Place, #36-01 One Raffles Place, 048616, Singapore.	For all items subject to the EAR (See §§ 734.9(e)(2) and 744.11 of the EAR) ⁴ .	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER] January 16, 2025.
	*	*	*	*

⁴ For this entity, "items subject to the EAR" includes foreign-produced items that are subject to the EAR under § 734.9(e)(2) of the EAR. See § 744.11(a)(2)(iv) for related license requirements and license review policy.

* * * * *

Matthew S. Borman,
Principal Deputy Assistant Secretary for Export Administration.
[FR Doc. 2025-00480 Filed 1-15-25; 8:45 am]
BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

15 CFR Part 791

[Docket No. 250107-0003]

RIN 0605-AA51

Securing the Information and Communications Technology and Services Supply Chain; Corrections

AGENCY: U.S. Department of Commerce.
ACTION: Final rule; correction.

SUMMARY: The Department of Commerce is correcting a final rule that appeared in the **Federal Register** on December 6, 2024. This final rule revises the regulations on the Department of Commerce's review of transactions involving information and communications technology and services designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary that may pose undue or unacceptable risk to the United States or U.S. persons. That rule inadvertently omitted instructions to update certain regulatory language included in the rule. This document corrects the omissions in the December 6, 2024 rule.

DATES: Effective February 4, 2025.

FOR FURTHER INFORMATION CONTACT: Rachel O'Meara, U.S. Department of Commerce, Telephone: (202) 482-4124, email: ICTsupplychain@doc.gov.

SUPPLEMENTARY INFORMATION: On December 6, 2024, the Department of Commerce (Department) published in the **Federal Register** a final rule, "Securing the Information and Communications Technology and

Services Supply Chain" (89 FR 96872). This final rule revised the regulations at 15 CFR part 791 on the Department's review of transactions involving information and communications technology and services (ICTS) designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary that may pose undue or unacceptable risk to the United States or U.S. persons. The revisions to 15 CFR part 791 inadvertently omitted instructions to update certain regulatory language included in the final rule. This document corrects the omissions inadvertently published in the **Federal Register** on December 6, 2024, specifically the omission of instructions to update certain paragraphs of §§ 791.3 and 791.100. While the related regulatory text was included in the final rule, the final rule unintentionally omitted the instructions to update introductory text for paragraph (a) in § 791.3 and to add paragraph (a)(9) to § 791.100. This document corrects the inadvertent omissions introduced by the December 6, 2024, final rule by instructing the Code of Federal Regulations to update introductory text for paragraph (a) in § 791.3 and to add paragraph (a)(9) to § 791.100.

Federal Register Correction

In FR Doc. 2024-28335, appearing on page 96872 in the **Federal Register** of Friday, December 6, 2024, the following corrections are made:

§ 791.3 [Corrected]

- 1. On page 96893, in the first column, in part 791, instruction 6 amending § 791.3 is corrected to read as follows:
- 6. Amend § 791.3 by revising paragraphs (a) introductory text, (a)(2) and (4), and (b) and removing paragraph (c).

The revisions read as follows:

§ 791.100 [Corrected]

- 2. On page 96893, in the third column, in part 791, instruction 8 amending § 791.100 is corrected to read as follows:

- 8. Amend § 791.100 by:
 - a. Revising paragraphs (a) introductory text and (a)(6) through (8);
 - b. Adding paragraph (a)(9); and
 - c. Revising paragraphs (c) introductory text, (d) introductory text, (d)(5), and (e).
- The revisions and addition read as follows:

Dated: January 7, 2025.
Elizabeth L.D. Cannon,
Executive Director, Office of Information and Communications Technology and Services.
[FR Doc. 2025-00542 Filed 1-15-25; 8:45 am]
BILLING CODE 3510-20-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 376

[Docket No. RM25-6-000; Order No. 905]

Continuity of Operations Plan

AGENCY: Federal Energy Regulatory Commission, DOE.
ACTION: Final rule.

SUMMARY: In this final rule, the Commission revises its Continuity of Operations Plan regulations to include, in its hierarchy of delegation of Commission authority, the Director and other staff of the Office of Energy Infrastructure Security, who were not included when the regulations were earlier revised.

DATES: This rule will become effective January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Mark Hershfield, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First St. NE, Washington, DC 20426, (202) 502-8597, mark.hershfield@ferc.gov.

Christopher Macfarlane, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First St. NE, Washington, DC 20426, (202) 502-6761, christopher.macfarlane@ferc.gov.

SUPPLEMENTARY INFORMATION:

1. This final rule revises the Commission's Continuity of Operations Plan (COOP) regulations¹ to incorporate the Director and other staff of the Office of Energy Infrastructure Security (OEIS) into the hierarchy of delegation of Commission authority during emergency conditions, and also to revise that hierarchy.

Discussion

2. In September 2012, the Commission announced the creation of OEIS, which both then and today focuses on identifying, communicating and seeking comprehensive solutions to significant potential cyber and physical security risks to the energy infrastructure under the Commission's jurisdiction and coordinating and collaborating with federal, state and industry representatives.

3. The Commission's COOP regulations were last updated in April 2013. Although OEIS was established as a front-facing office in September 2012, it was not included in the hierarchy of delegation of Commission authority during emergency conditions in Order No. 778.² Since this time, both natural and human-caused threats against energy infrastructure have significantly increased in frequency and severity. In addition, COOP may be initiated by circumstances that fall within OEIS' responsibilities, and where the office is responsible for leading and/or assisting with FERC's Mission Essential Functions.³

4. This final rule revises the Commission's COOP regulations to expand the hierarchy list to incorporate the Director and other staff of OEIS who were not included when the regulations were last revised in April 2013.

Regulatory Flexibility Act

5. The Regulatory Flexibility Act of 1980 (RFA)⁴ generally requires a description and analysis of final rules that will have a significant economic

impact on a substantial number of small entities. This final rule concerns a matter of internal agency procedure, and it will not have such an impact. An analysis under the RFA is not required. The Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Information Collection Statement

6. Office of Management and Budget (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.⁵ This final rule contains no new information collections. Therefore, OMB review of this final rule is not required.

Environmental Analysis

7. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.⁶ Rules that are procedural, ministerial, or internal administrative and management actions are categorically excluded from this requirement.⁷ This final rule is procedural in nature and therefore falls within this categorical exclusion in the Commission's regulations.

Document Availability

8. 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>).

9. 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 (*i.e.*, the subdocket number—*e.g.*, 000, 001, 002, etc.) in the docket number field.

10. User assistance is available for eLibrary and the Commission's website during normal business hours. For assistance, please contact Online Support at 1-866-208-3676 (email at FERCOnlineSupport@ferc.gov), or the Public Reference Room at (202) 502-

8371, TTY (202) 502-8659 (email at public.reference@ferc.gov).

Effective Date and Congressional Notification

11. The provisions of 5 U.S.C. 801 regarding Congressional review of final rules do not apply to this final rule because the rule concerns agency procedure and practice and will not substantially affect the rights of non-agency parties.

12. These regulations are effective on January 16, 2025. The Commission finds that notice and public comments are unnecessary because this rule concerns only agency procedure or practice. Therefore, the Commission finds good cause to waive the notice period otherwise required before the effective date of a final rule.

List of Subjects in 18 CFR Part 376

Civil defense, Organization and functions (Government agencies).

By the Commission.

Issued: January 3, 2025.

Debbie-Anne A. Reese,
Secretary.

In consideration of the foregoing, the Commission amends part 376, chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 376—ORGANIZATION, MISSION, AND FUNCTIONS; OPERATIONS DURING EMERGENCY CONDITIONS

■ 1. The authority citation for part 376 continues to read as follows:

Authority: 5 U.S.C. 553; 42 U.S.C. 7101-7352; E.O. 12009, 3 CFR 1978 Comp., p. 142.

■ 2. Section 376.204 is revised to read as follows:

§ 376.204 Delegation of Commission authority during emergency conditions

(a) *Delegation of authority to one or two Commissioners.* During emergency conditions, the Commission shall function as usual, if a quorum of the Commission is available and capable of acting. If by reason of such conditions a quorum of the Commission is not available and capable of acting, all functions of the Commission are delegated to the Commissioner or Commissioners who are available and capable of acting.

(b) *Delegation of authority to Commission staff.* (1) When, by reason of emergency conditions, there is no Commissioner available and capable of acting, the functions of the Commission are delegated to the first seven members of the Commission staff on the list set forth in paragraph (b)(2) of this section who are available and capable of acting.

¹ 18 CFR 376.204.

² *Continuity of Operations Plan*, Order No. 778, 78 FR 21245, (Apr. 10, 2013), 143 FERC ¶ 61,014 (2013).

³ DHS/FEMA, Federal Continuity Directive 2, Federal Executive Branch Mission Essential Functions and Candidate Primary Mission Essential Functions Identification and Submission Process (Washington, DC: DHS/FEMA, June 2017), Annex I-1 & n.12, quoting PPD-40, p. 2. Accessed Oct. 10, 2024. https://www.fema.gov/sites/default/files/2020-07/Federal_Continuity_Directive2_June132017.pdf. See also DHS/FEMA, Federal Continuity Directive, Continuity Planning Framework for the Federal Executive Branch (Washington, DC: DHS/FEMA, Dec. 2023). Accessed Oct. 10, 2024. https://www.fema.gov/sites/default/files/documents/fema_federal-continuity-directive-planning-framework.pdf.

⁴ 5 U.S.C. 601-12.

⁵ 5 CFR 1320.12.

⁶ *Reguls. Implementing the Nat'l Env't Policy Act*, Order No. 486, 52 FR 47897 (Dec. 10, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

⁷ 18 CFR 380.4(a)(1); see also Order No. 486, FERC Stats. & Regs. ¶ 30,783.

(2) The list referred to in paragraph (b)(1) of this section is:

- (i) General Counsel;
- (ii) Executive Director;
- (iii) Director of the Office of Energy Market Regulation;
- (iv) Director of the Office of Energy Projects;
- (v) Director of the Office of Electric Reliability;
- (vi) Director of the Office of Enforcement;
- (vii) Director of the Office of Energy Infrastructure Security;
- (viii) Deputy General Counsels, in order of seniority;
- (ix) Deputy Directors, Office of Energy Market Regulation, in order of seniority;
- (x) Deputy Directors, Office of Energy Projects, in order of seniority;
- (xi) Deputy Directors, Office of Electric Reliability, in order of seniority;
- (xii) Deputy Directors, Office of Enforcement, in order of seniority;
- (xiii) Deputy Directors, Office of Energy Infrastructure Security, in order of seniority;
- (xiv) Associate General Counsels and Solicitor, in order of seniority;
- (xv) In order of seniority, Assistant Directors and Division heads, Office of Energy Market Regulation; Assistant Directors and Division heads, Office of Energy Projects; Assistant Directors and Division heads, Office of Electric Reliability; Deputy Associate General Counsels; Assistant Directors and Division heads, Office of Enforcement; Assistant Directors and Division heads, Office of Energy Infrastructure Security;
- (xvi) In order of seniority, Regional Engineers and Branch Chiefs of the Office of Energy Projects' regional offices; and Deputy Division Directors and Group Managers of the Office of Electric Reliability's regional offices.

(3) For purposes of paragraph (b)(2)(viii)–(xvi) of this section, order of seniority shall be based on the highest grade and longest period of service in that grade and, furthermore, for purposes of paragraph (b)(2)(xv)–(xvi) of this section, order of seniority shall be without regard to the particular Office or Division or Branch or Group to which the member of staff is assigned.

(c) *Devolution of authority to Commission staff during emergencies affecting the National Capital Region.*

(1) To the extent not otherwise provided by this section, during emergency conditions when the Chairman is not available and capable of acting, when no Commissioner is available and capable of acting, and when no person listed in paragraph (b)(2)(i)–(xvi) of this section who is located in the National Capital Region is available and capable of acting, the functions of the Commission

are delegated, in order of seniority (as described in paragraph (b)(3) of this section), to Regional Engineers and Branch Chiefs of the Office of Energy Projects' regional offices and Deputy Division Directors and Group Managers of the Office of Electric Reliability's regional offices.

(2) Such delegation shall continue until such time as the Chairman is available and capable of acting, one or more Commissioners are available and capable of acting, or persons listed in paragraph (b)(2)(i)–(xvi) of this section who are located in the National Capital Region are available and capable of acting.

(d) *Reconsideration of staff action taken under delegations.* Action taken pursuant to the delegations provided for in this section shall be subject to reconsideration by the Commission, acting with a quorum, within thirty days after the date upon which public notice is given that a quorum of the Commission has been reconstituted and is functioning.

[FR Doc. 2025–00888 Filed 1–15–25; 8:45 am]

BILLING CODE 6717–01–P

RAILROAD RETIREMENT BOARD

20 CFR Part 220

RIN 3220–AB71

Evidence of Disability

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (RRB) amends its regulations to designate additional acceptable medical sources in disability claims under the Railroad Retirement Act. This change recognizes the evolution of how medical care and treatment are delivered and aligns the RRB's acceptable medical sources with recently amended regulations of the Social Security Administration (SSA). Additionally, the changes clarify existing RRB policy regarding how evidence from medical sources, other than those designated as acceptable medical sources, will be evaluated.

DATES: This rule is effective March 17, 2025.

FOR FURTHER INFORMATION CONTACT: Peter J. Orlowicz, Senior Counsel, (312) 751–4922, Peter.Orlowicz@rrb.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information

The RRB published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on June 21, 2024 (89

FR 51990). The preamble to the NPRM discussed the changes from our current rules and our reasons for proposing those changes. In the NPRM, we proposed to designate additional acceptable medical sources (AMS) in disability claims under the Railroad Retirement Act. Although the RRB will accept and evaluate evidence from any relevant source, including medical sources not designated as an AMS, the RRB requires evidence about a claimant's impairment from an AMS to adjudicate a claim of disability.

The additional AMS we proposed to add are:

(1) Licensed or certified school psychologists, or other licensed or certified individuals with another title who perform the same function as a school psychologist in a school setting, for impairments of intellectual disability, learning disabilities, and borderline intellectual functioning only;

(2) Licensed podiatrists, for impairments of the foot or of the foot and ankle, depending on the scope of practice in the State in which the podiatrist practices;

(3) Qualified speech-language pathologists, for speech and language impairments only, and when either licensed by a State professional licensing agency, fully certified by a State education agency where the individual practices, or holding a Certificate of Clinical Competence in Speech-Language Pathology from the American Speech-Language-Hearing Association;

(4) Licensed audiologists, for impairments of hearing loss, auditory processing disorders, and balance disorders when such disorders are within the individual's licensed scope of practice;

(5) Licensed Advanced Practice Registered Nurses or other licensed advance practice nurses with another title, within the individual's scope of practice (this category includes, but is not limited to, Certified Nurse Midwives, Nurse Practitioners, Certified Registered Nurse Anesthetists, and Clinical Nurse Specialists); and

(6) Licensed Physician Assistants, for impairments within the individual's licensed scope of practice.

We provided 60 days for the public to comment on the NPRM. We received three comments: two comments were submitted by professional organizations representing medical providers who would be added as AMS under the proposed rule, and one comment was submitted by a public policy research group. All three comments were supportive of the proposed changes, with two commenters providing

additional suggestions as described below. We also identified and fixed two minor grammatical errors that do not affect the substance of the rule.

II. Public Comments

Comment: The American Academy of Physician Associates (AAPA) recommended that the regulation include “physician assistant” and “physician associate” as equivalent titles and list both in the regulation to avoid confusion. The AAPA explained the titles both refer to individuals who graduate from programs accredited by the same accrediting body, are certified by the same certifying organization, and have the same scope of practice. Individuals in this profession have historically been identified as “physician assistants,” but the official title is now recognized as “physician associate” as reflected in the title of the AAPA, other professional organizations, professional training programs, and state laws regarding licensure. Because the title change will take time to be formalized in all jurisdictions, the AAPA recommends that both “physician assistant” and “physician associate” be listed.

Response: We agree with this comment, and we revised the final regulatory text accordingly. Specifically, we revised the proposed regulatory text for PAs as AMS in final 220.46(a)(9) to read, “Licensed Physician Assistants/Physician Associates (for impairments within the individual’s licensed scope of practice).” We do not view this as a substantive change in the scope of individuals the rule is intended to cover, nor do we understand the AAPA to be suggesting such a change in scope.

Comment: One commenter recommended clarifying who may qualify as an “other licensed or certified individual . . . who perform the same function as a school psychologist in a school setting.” The commenter expressed concern that special education teachers may possess certain state certifications to teach children with learning disabilities, but that state certification standards for special education teachers vary from state to state and a significant proportion of special education teachers may be teaching with a provisional or emergency appointment without having the necessary certification or experience to provide medical reports of intellectual disability, learning disabilities, or borderline intellectual functioning.

Response: We did not adopt this comment. Special education teachers and school psychologists are different and distinct professions with different

certification standards. Section 8002(19) of the Every Student Succeeds Act, Public Law 114–95 (Dec. 10, 2015) identifies school psychologists as “specialized instructional support personnel” along with school counselors, school social workers, school nurses, speech language pathologists, and school librarians. In Organizational Principle 3 of its 2020 Professional Standards, the National Association of School Psychologists recommends the ratio of school psychologists to students should not exceed 1 school psychologist for every 500 students. While school psychologists work with other school personnel, including special education teachers, to perform their function, a special education teacher would not normally be performing the same function as a school psychologist in the school setting. We believe the residual clause for other licensed or certified individuals with different titles who are performing the same function in a school setting is sufficiently clear. An individual who lacks a certification or license equivalent to a school psychologist and who does not perform the same function as a school psychologist would not qualify as an AMS under this paragraph.

Comment: One commenter agreed with the addition of licensed podiatrists as AMS for impairments of the foot or foot and ankle, but advocated for the inclusion of other orthopedic specialists who are certified and trained to address issues of other skeletal structures.

Response: We did not adopt this comment. Many orthopedic specialists will qualify as an AMS because they are licensed medical or osteopathic doctors. To the extent that skeletal structure-related impairments are within the scope of practice for an Advanced Practice Registered Nurse or a Physician Assistant/Physician Associate, those individuals would also be qualified as an AMS without the need for separate discussion. In the case of other individuals who hold themselves out as orthopedic specialists but would not otherwise qualify as an AMS under those other categories, § 220.46(b) in the final rule acknowledges we will accept and consider evidence from such a medical source about the claimant’s impairment(s) and the effect on the claimant’s ability to work, but the presence of a medically determinable physical or mental impairment must be established with objective medical evidence from an AMS.

Regulatory Analysis

Executive Order 12866, as Supplemented by Executive Order 13563

The RRB, with the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, no regulatory impact analysis is required.

Executive Order 13132 (Federalism)

This proposed rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, the RRB believes that this proposed rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Regulatory Flexibility Act

The RRB certifies that this rule will not have a significant economic impact on a substantial number of small entities because the rulemaking affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

List of Subjects in 20 CFR Part 220

Disability benefits, Railroad employees, Railroad retirement.

For the reasons set out in the preamble, the Railroad Retirement Board amends 20 CFR part 220 as follows:

PART 220—DETERMINING DISABILITY

■ 1. The authority citation for part 220 continues to read as follows:

Authority: 45 U.S.C. 231a; 45 U.S.C. 231f.

■ 2. Amend § 220.46 by:

- a. Revising paragraph (a);
- b. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f) respectively;
- c. Adding new paragraph (b); and
- d. Revising newly redesignated paragraphs (c)(6)(i), (c)(6)(ii) introductory text, (d) introductory text, (e), and (f).

The revisions and addition read as follows:

§ 220.46 Medical evidence.

(a) *Acceptable medical sources.* The Board needs reports about the claimant's impairment(s) from acceptable medical sources. Acceptable medical sources are—

- (1) Licensed physicians (medical or osteopathic doctors);
- (2) Licensed or certified psychologists at the independent practice level;
- (3) Licensed or certified school psychologists, or other licensed or certified individuals with another title who perform the same function as a school psychologist in a school setting (for impairments of intellectual disability, learning disabilities, and borderline intellectual functioning only);
- (4) Licensed optometrists (for impairments of visual disorders, or for the measurement of visual acuity and visual fields only, depending on the scope of practice in the State in which the optometrist practices);
- (5) Licensed podiatrists (for impairments of the foot only, or foot and ankle only, depending on the scope of practice in the State in which the podiatrist practices);
- (6) Qualified speech-language pathologists (for speech or language impairments only.) For this source, *qualified* means that the speech-language pathologist must be licensed by the State professional licensing agency, or be fully certified by the State education agency in the State in which the speech-language pathologist practices, or hold a Certificate of Clinical Competence in Speech-Language Pathology from the American Speech-Language-Hearing Association;
- (7) Licensed audiologists (for impairments of hearing loss, auditory processing disorders, and balance disorders within the licensed scope of practice only);
- (8) Licensed Advanced Practice Registered Nurses or other licensed advance practice nurses with another title (for impairments within the individual's licensed scope of practice only);
- (9) Licensed Physician Assistants/Physician Associates (for impairments within the individual's licensed scope of practice); or
- (10) Persons authorized to furnish a copy or summary of the records of a medical facility. Generally, the copy or summary should be certified as accurate by the custodian or by any authorized employee of the Railroad Retirement Board, Social Security Administration,

Department of Veterans Affairs, or State agency.

(b) *Other medical sources.* Individuals who are licensed as healthcare workers by a State and are working within the scope of practice permitted under State or Federal law, other than acceptable medical sources identified in paragraph (a) of this section, are other medical sources. Examples include licensed clinical social workers, naturopaths, and chiropractors. The Board will accept and consider evidence from other medical sources about the claimant's impairment(s) and the effect on the claimant's ability to work, but the presence of a medically determinable physical or mental impairment must be established with objective medical evidence from an acceptable medical source as defined in paragraph (a) of this section.

(c) * * *

(6) * * *

(i) Statements about what the claimant can still do despite his or her impairment(s) based on the medical source's findings on factors in paragraphs (c)(1) through (5) of this section (except in disability claims for remarried widow's and surviving divorced spouses). (See § 220.112).

(ii) Statements about what the claimant can still do (based on the medical source's findings on factors in paragraphs (c)(1) through (5) of this section) should describe—

* * * * *

(d) *Completeness.* The medical evidence, including the clinical and laboratory findings, must be complete and detailed enough for the Board to determine whether the claimant is disabled. Specifically, it must allow the Board to determine—

* * * * *

(e) *Evidence from treating medical sources.* A statement by or the opinion of the claimant's treating medical source will not determine whether the claimant is disabled. However, the medical evidence provided by a treating medical source will be considered by the Board in making a disability decision. A treating medical source is a medical source to whom the claimant has been going for treatment on a continuing basis. The claimant may have more than one treating medical source. The Board may use consulting physicians or other medical consultants for specialized examinations or tests, to obtain more complete evidence, and to resolve any conflicts. A consulting physician is a doctor (often a specialist) to whom the claimant is referred for an examination once or on a limited basis. (See § 220.50 for an explanation of when the Board

may request a consultative examination.)

(f) *Information from non-medical sources.* Information from other sources may also help the Board understand how an impairment affects the claimant's ability to work. Other sources include—

- (1) Public and private social welfare agency personnel;
- (2) Family members, caregivers, friends, and neighbors of the claimant;
- (3) Educational personnel such as teachers, counselors, and daycare center workers;
- (4) Railroad and nonrailroad employers; and,
- (5) The claimants themselves.

Dated: January 7, 2025.

By Authority of the Board.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2025–00515 Filed 1–15–25; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2023–N–0437]

Color Additive Petition From Center for Science in the Public Interest, et al.; Request To Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is granting a color additive petition submitted by Center for Science in the Public Interest, et al., by repealing the color additive regulations that permit the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs. The petitioners provided data demonstrating that this additive induces cancer in male rats. Therefore, FDA is revoking the authorized uses in food and ingested drugs of FD&C Red No. 3 in the color additive regulations.

DATES: This order is effective January 15, 2027, except for amendatory instruction 4, which is effective January 18, 2028. If any provisions are delayed or stayed by the filing of proper objections, FDA will publish such notification in the **Federal Register**. Submit either electronic or written objections and requests for a hearing on the order by February 18, 2025. See

section X for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections 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 February 18, 2025. Objections 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 objections in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0437 for "Color Additive Petition from Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs."

Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of objections. 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 objections 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: Shayla West-Barnette, Office of Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1262; or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In the **Federal Register** of February 17, 2023 (88 FR 10245), we announced that we filed a color additive petition (CAP 3C0323) jointly submitted by the Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Chef Ann Foundation, Children's Advocacy Institute, Consumer Federation of America, Consumer Reports, Defend Our Health, Environmental Defense Fund, Environmental Working Group, Feingold Association of the United States, Food & Water Watch, Healthy Babies Bright Futures, Life Time Foundation, Momsrising, Prevention Institute, Public Citizen, Public Health Institute, Public Interest Research Group, Real Food for Kids, Lisa Y. Lefferts, Linda S. Birnbaum, and Philip J. Landrigan, c/o Mr. Jensen Jose, 1250 I Street NW, Ste 500, Washington, DC 20005 (the petitioners).

The petition proposed that we repeal the color additive regulations for FD&C Red No. 3 in § 74.303 (21 CFR 74.303), which permits the use of FD&C Red No. 3 in foods (including dietary supplements), and § 74.1303 (21 CFR 74.1303), which permits the use of FD&C Red No. 3 in ingested drugs. The notice of petition gave interested parties until April 18, 2023, to submit comments on the filed color additive petition. In response to a written request submitted to the docket, we extended the comment period to May 18, 2023 (88 FR 19026, March 30, 2023). This order granting the request to revise the regulations to no longer provide for these uses of FD&C Red No. 3 responds to the petition.

II. Background

A. Statutory and Regulatory Background of Color Additive Regulation

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes us to regulate "color additives" (see section 721(b) of

the FD&C Act (21 U.S.C. 379e(b))). The FD&C Act defines “color additive” as “a material which . . . is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and . . . [that] when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with [an] other substance) of imparting color thereto” The term “color” includes black, white, and intermediate grays” (see section 201(t) of the FD&C Act (21 U.S.C. 321(t))). Color additives used in or on a food, drug, cosmetic, or certain medical devices are deemed unsafe and prohibited except to the extent that we approve their use (see section 721(a) of the FD&C Act). Certain color additives must be certified by FDA (see section 721(c) of the FD&C Act).

The FD&C Act provides a process through which any person who wishes to use a color additive in or on food, drugs, certain devices, or cosmetics, may submit a petition proposing the issuance of a color additive regulation listing such use with supporting information. A color additive petition may also be submitted to propose the amendment or repeal of any existing color additive regulation (see section 721(b)(5)(C) and (d) of the FD&C Act). In response to a color additive petition, FDA may issue a regulation listing a color additive for use in or on food, drugs, devices, or cosmetics only if it determines that the additive is suitable and safe for such use (see section 721(b)(2)(A) of the FD&C Act). FDA’s determination that a color additive is safe means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended condition of use of the color additive (21 CFR 70.3(i)), which we refer to as “a reasonable certainty of no harm.” This safety standard is referred to as the “general safety clause” for color additives. To determine whether a color additive is safe under the general safety clause, the FD&C Act requires FDA to consider, among other relevant factors: (1) probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or device, or cosmetics because of the use of the additive; (2) cumulative effect, if any, of such additive “in the diet of man or animals,” taking into account the same or any chemically or pharmacologically related substance or substances in such diet; and (3) safety

factors recognized by experts “as appropriate for the use of animal experimentation data” (see section 721(b)(5)(A) of the FD&C Act).

In addition, section 721(b)(5)(B) of the FD&C Act, often referred to as the Delaney Clause, deems color additives unsafe under certain circumstances. The Delaney Clause consists of two parts. The first part (section 721(b)(5)(B)(i) of the FD&C Act) pertains specifically to ingested color additives. The second part (section 721(b)(5)(B)(ii) of the FD&C Act) applies to noningested color additives. For purposes of our review of this petition, we reviewed these uses of FD&C Red No. 3 under the first part because these uses result in ingestion. Section 721(b)(5)(B)(i) of the FD&C Act states that a color additive shall be deemed unsafe for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal. Courts have concluded that the Delaney Clause completely bans additives found to induce cancer in humans or animals. In *Public Citizen v. Young*, 831 F.2d 1108, 1122 (D.C. Cir. 1987), the court held that Congress intended for the Delaney Clause to be “extraordinarily rigid,” to protect the public from cancer-causing substances without exception, rejecting FDA’s argument that a particular color additive should be approved because it did not pose more than a de minimis cancer risk; see also *Les v. Reilly*, 968 F.2d 985, 986 (9th Cir. 1992) (holding that the Environmental Protection Agency’s refusal to revoke regulations permitting the use of certain pesticides, which were regulated as food additives at the time of the court decision and subject to a similarly worded Delaney Clause for food additives, on the grounds that they pose a de minimis cancer risk, is contrary to the provisions of the Delaney Clause).

There is a similar Delaney Clause provision for food additives under section 409(c)(3) of the FD&C Act (21 U.S.C. 348(c)(3)), which states that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. In revoking certain authorizations for food additives under the Delaney Clause, FDA stated that the Delaney Clause limits FDA’s discretion to determine the safety of food additives. FDA stated that the Delaney Clause prevents FDA from finding a food additive to be safe if it has been found to induce cancer when ingested by humans or animals, “regardless of

the probability, or risk, of cancer associated with exposure to the additive or of the extent to which the experimental conditions of the animal study or the carcinogenic mode of action provide insight into the health effects of human consumption and use of the additive in question” (83 FR 50490 at 50492, October 9, 2018).

Section 721(d) of the FD&C Act provides for the issuance, amendment, or repeal of regulations authorizing the use of a color additive, and, among other things, it specifies that the safety provisions of section 721(b)(5) apply to such actions. For FDA to grant a petition that seeks repeal of a color additive regulation based upon new data concerning the safety of the color additive, such data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm for the intended use of the color additive or that it must be deemed unsafe under the Delaney Clause.

B. Chemical Identity and Nomenclature of FD&C Red No. 3

Our regulation, at § 74.303, describes FD&C Red No. 3 as principally the monohydrate of 9 (*o*-carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins. The color is also called erythrosine or other names, including Colour Index (C.I.) Acid Red 51; C.I. No. 45430; and C.I. Food Red 14. FD&C Red No. 3 is required to be certified by FDA that it complies with §§ 74.303 and 74.1303. The designation “FD&C Red No. 3” is permitted only for those batches of the color additive that have been certified by FDA.

C. History of FDA’s Regulatory Actions for FD&C Red No. 3

FD&C Red No. 3, as erythrosine, was first listed in 1907 under the provisions of the Food and Drugs Act of 1906 (Food Inspection Decision 76), and later provisionally listed in 1960 as Red No. 3 for food, drug, and cosmetic use (25 FR 9759, October 12, 1960) (see also Ref. 1). In 1969, FD&C Red No. 3 was permanently listed for use in food and ingested drugs (34 FR 7446, May 8, 1969), now codified in §§ 74.303 and 74.1303. In 1990, FDA did not extend the provisional listing of FD&C Red No. 3 for use in cosmetics and externally applied drugs (55 FR 3516, February 1, 1990) based on thyroid neoplasia in rat carcinogenicity studies, which terminated this listing. The decision did not revoke the existing permanent listing for food and ingested drugs from 1969.

III. Summary and Context of Determination

We have evaluated the data and information submitted in the petition as well as other relevant data. FDA finds that FD&C Red No. 3 can induce cancer in male rats, through a rat specific hormonal mechanism. Therefore, we are revoking the listings providing for these uses of this color additive under section 721(b)(5)(B) of the FD&C Act as a matter of law, as described further below.

IV. Evaluation of Petition

The petitioners state that FD&C Red No. 3 has been shown to induce cancer in male laboratory rats. The petitioners discuss multiple regulatory conclusions that FD&C Red No. 3 is carcinogenic in male rats, which are based on some in vivo studies. Specifically, data reported in the publication entitled "Lifetime Toxicity/Carcinogenicity Study of FD&C Red No. 3 (erythrosine) in Rats" by Borzelleca et al., a compilation of two separate chronic toxicity and carcinogenicity studies, was published in 1987. These conclusions include a 1990 conclusion from FDA (55 FR 3520, February 1, 1990); a 1983 National Toxicology Program (NTP) subcommittee conclusion; a 1989 European Commission's Scientific Committee for Food report (Ref. 2); and Joint Food and Agricultural Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) conclusions (Refs. 3 and 4).

FDA evaluated the data cited by the petitioner, as well as other available data. Based on our review of this data and information, we conclude that the Delaney Clause applies because FD&C Red No. 3 has been found to "induce cancer when ingested by . . . animal." Specifically, some in vivo studies have shown FD&C Red No. 3 can induce thyroid tumors in male rats. Thyroid tumors in male rats appear to result from perturbation in the hypothalamic-pituitary-thyroid hormonal axis (Refs. 5 and 6). These perturbations are initiated by an increase in circulating thyroid stimulating hormone (TSH), causing follicular hyperplasia, which has the potential to develop into thyroid tumors (Refs. 5 and 6). Thus, increased TSH levels appears to be a key event for thyroid tumor development from FD&C Red No. 3 exposure in male rats (Refs. 5 and 6).

Based on the available data and information, FD&C Red No. 3-induced thyroid tumors in male rats are of limited relevance to humans. FDA's Center for Food Safety and Applied Nutrition (CFSAN)'s Cancer Assessment

Committee (CAC) concluded that while studies show FD&C Red No. 3 induces thyroid tumors in male rats, the risk of developing such tumors in humans at low exposure levels from the current uses is unlikely (Ref. 5). FD&C Red No. 3 is likely not genotoxic (in other words, it is not directly DNA reactive) (Refs. 5 and 6). FD&C Red No. 3 appears to induce thyroid tumors in male rats through a key event—an increase in circulating TSH—and rodents show much higher sensitivity to such perturbations compared to humans (Refs. 5 and 6). There is no conclusive available clinical evidence that demonstrates increased TSH levels either promote or actively cause thyroid carcinogenesis in humans (Refs. 5 and 6). Further, studies in humans to date have failed to show convincing evidence that FD&C Red No. 3 exposure results in consistent perturbations in any thyroid hormone levels, including TSH (Refs. 5 and 6). FDA estimated the highest exposure for FD&C Red No. 3 from the approved uses as a color additive in conventional food, dietary supplements, and ingested drugs to be 0.25 milligrams per kilogram of bodyweight per day (mg/kg bw/day) (Ref. 7). When compared against the No Observed Adverse Effect Level for thyroid hormone effects associated with thyroid tumors in male rats of 35.8 mg/kg bw/day, a 210-fold margin of exposure was derived (Ref. 5). Based on the available data and information, FDA and other regulatory agencies including JECFA, the European Food Safety Authority (EFSA), and the Food Standards Australia New Zealand (FSANZ) have concluded that FD&C Red No. 3-induced thyroid tumors in rats are of limited relevance to humans (Refs. 5 and 6). In addition, the carcinogenicity of FD&C Red No. 3 was not observed when tested in other animals including female rats and either sex of mice, gerbils, or dogs (Refs. 5 and 6).

Despite its limited relevance to humans, the cumulative data and information show that high exposure to FD&C Red No. 3 induces thyroid tumors in male rats (Refs. 5 and 6).

V. Comments on the Notice of Petition

FDA received a number of comments in response to the notice of filing of the petition. Most comments expressed general support for revocation of the regulations for FD&C Red No. 3, without providing any additional information.

We summarize and respond to relevant portions of comments in this order. To make it easier to identify comments and FDA's responses to the comments, the word "Comment" will

appear in parenthesis before the description of the comment, and the word "Response" will appear in parentheses before FDA's response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was submitted.

(Comment 1) Several comments argued that the Delaney Clause does not apply because the scientific community's understanding of the carcinogenicity potential of FD&C Red No. 3 has evolved since inclusion of the Delaney Clause in the FD&C Act and since FDA's conclusion (55 FR 3520) that FD&C Red No. 3 induces cancer in male rats. Some comments argue that FDA has discretion to exercise scientific judgment in determining whether FD&C Red No. 3 induces cancer for purposes of the Delaney Clause.

(Response 1) We agree that a large body of literature has been published since FDA's conclusion that FD&C Red No. 3 induces cancer in male rats. We have reviewed the currently available data and information pertaining to the safety of FD&C Red No. 3 as a color additive and concluded that the FD&C Red No. 3-induced thyroid tumors in male rats are of limited relevance to humans (Refs. 5 and 6). However, the current literature continues to support the finding that high exposure to FD&C Red No. 3 induces cancer in male rats (Ref. 6). Because of this finding, we disagree that FDA has discretion to determine that FD&C Red No. 3 does not induce cancer under the Delaney Clause. The language of the Delaney Clause is straightforward. Under the general safety clause for color additives, FDA has discretion to review a number of factors to determine whether a color additive is safe (section 721(b)(5)(A) of the FD&C Act). However, for ingested color additives that are shown "to induce cancer in man or animal," the Delaney Clause limits FDA's discretion and requires that FDA conclude that the color additive is not safe as a matter of law.

(Comment 2) Several comments argued that the Delaney Clause does not apply because FD&C Red No. 3 is non-genotoxic and induces tumors through a secondary mechanism. The comments assert that FDA's action to terminate the provisional listing FD&C Red No. 3 in 1990 was because there was inadequate evidence at the time to demonstrate that FD&C Red No. 3 was non-genotoxic, and now that there is evidence demonstrating that FD&C Red No. 3 is non-genotoxic, FDA has discretion to

determine that FD&C Red No. 3 does not cause cancer.

(Response 2) We agree that FD&C Red No. 3 is non-genotoxic based on the available data and information. FD&C Red No. 3 induces tumors in male rats through a key event (increased TSH production) (Ref. 6). We refer to the increase in TSH levels as a “key event” and not as a secondary mechanism because the exact mechanism of FD&C Red No. 3-induced carcinogenesis in male rats has not been determined. Nonetheless, we disagree with the comments’ assertion that the Delaney Clause does not apply. As we concluded in our 2018 action revoking the authorizations of certain food additives under a similarly worded Delaney Clause, the Delaney Clause does not differentiate between non-genotoxic and genotoxic carcinogens (83 FR 50490 at 50501). Nor does the Delaney Clause permit FDA to find an ingested color additive safe for human consumption if the color additive has been found to induce cancer in animals. Consistent with our conclusion in revoking certain food additive approvals based on the Delaney Clause (83 FR 50490), FDA concludes that the Delaney Clause limits FDA’s discretion to determine the safety of color additives that are intended to be ingested (such as the use of FD&C Red No. 3 in food and ingested drugs) in that it prevents FDA from finding such a color additive to be safe if it has been found to induce cancer when ingested by humans or animals, regardless of the probability, or risk, of cancer associated with exposure to the additive or of the extent to which the experimental conditions of the animal study or the carcinogenic mode of action provide insight into the health effects of human consumption and use of the additive in question.

(Comment 3) One comment argued that the evidence demonstrating that FD&C Red No. 3 induces thyroid tumors in male rats is insufficient to invoke the Delaney Clause.

(Response 3) We disagree. Again, we acknowledge the large body of published literature that does not show FD&C Red No. 3 inducing cancer in female rats, or multiple other animal species, including humans (Refs. 5 and 6). However, under the Delaney Clause, these negative findings do not outweigh or negate the positive findings of the two chronic feeding studies. Because FD&C Red No. 3 has been found to induce tumors in male rats, FDA must revoke the regulations providing for these uses of the color additive as a matter of law.

(Comment 4) One comment argued that the Delaney Clause does not apply

because the dose range used for the two chronic feeding studies in rats render the positive findings unreliable.

Specifically, the comment asserts that in its 1990 order, the study FDA relied on was unreliable because the dose of FD&C Red No. 3 exceeded the maximum tolerated dose. The comment asserts that this violates the testing guidelines of the National Cancer Institute.

(Response 4) We disagree. The two chronic feeding studies in rats were appropriately designed and considered to be positive bioassays (Ref. 5). These two studies reported within a single manuscript were considered appropriate and not to have exceeded the maximum tolerated dose (MTD) per current guidance (Redbook 2000, Chapters II.C.5.A. and IV.C.7. or IV.C.8) (Ref. 5). Redbook 2000 uses the NTP’s definition of MTD, which states that the MTD is “that dose which, when given for the duration of the chronic study as the highest dose, will not shorten the treated animals’ longevity from any toxic effects other than the induction of neoplasms.” The data that was deemed to demonstrate FD&C Red No. 3 is carcinogenic in male rats used a maximum dose of 4 percent (Borzelleca et al., 1987), which did not impact the longevity of the treated animals’ life spans, resulted in no systemic toxic effects other than the induction of neoplasms, and did not cause unacceptable side effects. Thus, the dose scheme used by Borzelleca et al. (1987) fits the FDA Redbook 2000 definition of MTD. Furthermore, while rats may not be an ideal model to assess the carcinogenicity potential of FD&C Red No. 3 in humans, these chronic feeding studies do reasonably demonstrate that FD&C Red No. 3 induces thyroid tumors in male rats. These studies are sufficient to invoke the Delaney Clause because the Delaney Clause is not limited to inducing cancer in humans.

(Comment 5) One comment requested that FDA convene a Color Additive Advisory Committee if FDA delists FD&C Red No. 3 on the basis of the Delaney Clause.

(Response 5) We decline to convene the meeting requested by the comment. Section 721(b)(5)(c)(i) of the FD&C Act states that any person who will be adversely affected by a proposal if placed into effect may request, within the specified time period, that the petition or order be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) (here, the Delaney clause, (B)(i)) that is involved in the proposal) and that requires the exercise of scientific

judgment. Upon such request, the Secretary must appoint an advisory committee. FDA’s determination that FD&C Red No. 3 has been shown to cause cancer in laboratory animals is based on a comprehensive review of all relevant carcinogenicity studies (Ref. 6). After reviewing these studies, FDA did not find there to be a genuine debate regarding the science—specifically, that FD&C Red No. 3 induced cancer in male rats. Thus, FDA’s conclusion that FD&C Red No. 3 has been shown to cause cancer in laboratory animals is not a matter that requires referral to an advisory committee because it did not require the exercise of scientific judgment.

(Comment 6) A couple of comments stated that the highest dietary exposure to FD&C Red No. 3 is below the Acceptable Daily Intake (ADI) and therefore, dietary exposure from its use as a food color additive does not present a safety concern. Another comment stated that because of the relatively low dietary exposure to FD&C Red No. 3, revoking the regulations authorizing its use would not significantly reduce risk to the public.

(Response 6) Based on our evaluation of the dietary exposure to FD&C Red No. 3 and the available scientific evidence, we conclude that FD&C Red No. 3 meets the safety standard of a reasonable certainty of no harm required for a color additive (see Refs. 6 and 7). We derived a 210-fold margin of exposure between the highest dietary exposure to FD&C Red No. 3 (0.25 mg/kg bw/d) and the No Observed Adverse Effect Level chosen by the CAC (35.8 mg/kg bw/d) (Ref. 6). We agree that the highest dietary exposure to FD&C Red No. 3 is below the ADI established by JECFA in 2018 (6 mg/kg bw/d). We also agree with JECFA’s conclusion that the possibility of developing thyroid tumors in humans at low dietary exposure levels from the current uses of FD&C Red No. 3 is unlikely (Ref. 6). However, as a matter of law (see section 721(b)(5)(B) of the FD&C Act), we must revoke the regulations authorizing the uses of FD&C Red No. 3 because it has been shown to induce cancer in male rats.

(Comment 7) Several comments stated that the findings that FD&C Red No. 3 induces cancer in male rats are not applicable to humans and, therefore, do not indicate that the color additive would induce tumors in humans. These comments asserted that the conclusions of other regulatory agencies and authoritative risk assessment bodies support that the use of FD&C Red No. 3 is unlikely to cause tumors in humans.

(Response 7) We agree that there are physiological differences between rats

and humans that require contextualization when extrapolating the relevance of animal studies to humans. There is no conclusive evidence that increased TSH production—a key event for tumor induction in male rats—causes thyroid carcinogenesis in humans (see Ref. 6). Furthermore, studies in humans have not demonstrated that dietary exposure to FD&C Red No. 3 causes consistent perturbations of TSH or other hormones. In fact, studies in humans demonstrate a lack of effects on the thyroid. Based on the scientific evidence, we agree that the thyroid tumors observed in male rats are of limited relevance to humans, and we note that JECFA, EFSA, and the FSANZ have also reached this same conclusion (Ref. 6). However, as stated earlier, we must revoke the regulations authorizing the uses of FD&C Red No. 3 because it has been shown to induce cancer in male rats (see section 721(b)(5)(B) of the FD&C Act). The Delaney Clause prevents us from finding its use to be safe, regardless of the extent to which the experimental conditions of the animal study provide insight into the health effects of human consumption and use of the color additive in question.

(Comment 8) One comment asserts that FDA is required to consider reasonable alternatives to revoking the color additive listings for FD&C Red No. 3. The comment also asserts that the “proposed rule does not indicate whether FDA investigated this issue of reasonably viable alternatives to FD&C Red. 3.”

(Response 8) Under section 721(b) of the FD&C Act, a color additive may not be marketed unless FDA determines that the additive is suitable and safe for such use. Under section 721(b)(5)(B) of the FD&C Act, also referred to as the Delaney Clause, a color additive shall be deemed unsafe, and shall not be listed, if certain conditions are met. As FDA has determined that the Delaney Clause applies to the authorized uses of FD&C Red No. 3, FDA does not have discretion to consider alternatives to revoking the color additive listing, and that is true regardless of whether there are “reasonably viable alternatives” for this color additive.

(Comment 9) One comment asserts that FDA did not disclose the relevant studies in the filing notice.

(Response 9) We disagree. As required under section 721(d)(1), FDA is required to publish “notice of the proposal made by the petition . . . in general terms.” Furthermore, we note that the petition, which was included in the public docket, included citations to the relevant studies.

VI. Conclusion

Upon review of the available information, we have determined that the information provided in the petition and other publicly available relevant data demonstrate that FD&C Red No. 3 has been shown to cause cancer in laboratory animals. Under the Delaney Clause this finding of carcinogenicity renders the color additive “unsafe” as a matter of law. FDA is revoking the authorizations for this substance as a color additive to no longer provide for the use of FD&C Red No. 3 in food and ingested drugs. Therefore, we are amending 21 CFR part 74 as set forth in this document. We consider this action to also partially respond to CSPI’s 2008 citizen petition (Docket No. FDA–2008–P–0349).

Because the effective date for the removal of § 74.303 will occur before the effective date for the removal of § 74.1303, we are also amending § 74.1303 to add the identity and specifications from § 74.303(a)(1) and (b), which are currently referenced in § 74.1303(a). This amendment will become effective on the effective date for the removal of § 74.303.

Upon the removal of these color additive listings, FDA will no longer provide certificates for FD&C Red No. 3. In accordance with 21 CFR 80.32(h), all certificates for existing batches and portions of batches of FD&C Red No. 3 will cease to be effective for use in food on the effective date for the removal of § 74.303 and for use in ingested drugs on the effective date for the removal of § 74.1303, and any lots of FD&C Red No. 3 will be regarded as uncertified after the relevant date(s). Use of FD&C Red No. 3 after its certificate ceases to be effective will result in such food or ingested drugs being adulterated. When FD&C Red No. 3 has been used in food or ingested drugs while its certificate is still effective, such food or ingested drugs will not be regarded as adulterated by reason of the use of such color additive.

VII. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impacts

We have determined under 21 CFR 25.32(m) 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 order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Objections

This order is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections under sections 701(e)(2) and 721(d) of the FD&C Act (21 U.S.C. 371(e)(2) and 379e(d)). If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

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 restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

- * 1. Memorandum from S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, to M. Honigfort, Division of Food Ingredients, Regulatory Review Branch, June 6, 2024.
2. SCF. Reports of the Scientific Committee for Food (21st series), 1989. Available at: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_21.pdf (accessed January 16, 2024).
3. JECFA, Evaluation of Certain Food Additives and Contaminants: Thirty-seventh Report, 1991. Available at: <https://www.who.int/publications/i/item/9241208066> (accessed January 16, 2024).
4. JECFA, Safety Evaluation of Certain Food Additives: Eighty-sixth Report, 2020. Available at: <https://www.who.int/publications/i/item/9789240004580> (accessed January 16, 2024).
- * 5. CFSAN CAC Full Committee Review, Memorandum of Meeting, October 15, 2019.
- * 6. Memorandum from J. Gingrich, Division of Food Ingredients, Toxicology Review Branch, to S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, June 18, 2024.
- * 7. Memorandum from D. Doell, Chemistry Review Group, Division of Petition Review (DPR), Office of Food Additive Safety (OFAS), CFSAN, FDA, to J. Kidwell, Regulatory Review Group I, DPR, OFAS, CFSAN, FDA, September 18, 2015.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

- 1. The authority citation for part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.303 [Removed]

- 2. Remove § 74.303.

- 3. Revise § 74.1303 to read as follows:

§ 74.1303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*-carboxyphenyl)-6-

hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins.

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Volatile matter (at 135 °C) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

(2) Water-insoluble matter, not more than 0.2 percent.

(3) Unhalogenated intermediates, total not more than 0.1 percent.

(4) Sodium iodide, not more than 0.4 percent.

(5) Triiodoresorcinol, not more than 0.2 percent.

(6) 2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

(7) Monoiodofluoresceins not more than 1.0 percent.

(8) Other lower iodinated fluoresceins, not more than 9.0 percent.

(9) Lead (as Pb), not more than 10 parts per million.

(10) Arsenic (as As), not more than 3 parts per million.

(11) Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1303 [Removed]

- 4. Effective January 18, 2028 remove § 74.1303.

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00830 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 16

[Docket No. TTB–2025–0001; Notice No. 236]

Civil Monetary Penalty Inflation Adjustment—Alcoholic Beverage Labeling Act

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notification of civil monetary penalty adjustment.

SUMMARY: This document informs the public that the maximum penalty for violations of the Alcoholic Beverage Labeling Act (ABLA) is being adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended. Prior to the publication of this document, any person who violated the provisions of the ABLA was subject to a civil penalty of not more than \$25,561, with each day constituting a separate offense. This document announces that this maximum penalty is being increased to \$26,225.

DATES: The new maximum civil penalty for violations of the ABLA takes effect on January 16, 2025 and applies to penalties that are assessed after that date.

FOR FURTHER INFORMATION CONTACT: Vonzella C. Johnson, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; (202) 508–0413.

Background

Statutory Authority for Federal Civil Monetary Penalty Inflation Adjustments

The Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), Public Law 101–410, 104 Stat. 890, 28 U.S.C. 2461 note, as Act of 2015, Public Law 114–74, section 701, 129 Stat. 584, requires the regular adjustment and evaluation of civil monetary penalties to maintain their deterrent effect and helps to ensure that penalty amounts imposed by the Federal Government are properly accounted for and collected. A “civil monetary penalty” is defined in the Inflation Adjustment Act as any penalty, fine, or other such sanction that is: (1) For a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and

(3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

The Inflation Adjustment Act, as amended, requires agencies to adjust civil monetary penalties by the inflation adjustment described in section 5 of the Inflation Adjustment Act. The Act also provides that any increase in a civil monetary penalty shall apply only to civil monetary penalties, including those whose associated violation predated such an increase, which are assessed after the date the increase takes effect.

The Inflation Adjustment Act, as amended, provides that the inflation adjustment does not apply to civil monetary penalties under the Internal Revenue Code of 1986 or the Tariff Act of 1930.

Alcoholic Beverage Labeling Act

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the Federal Alcohol Administration Act (FAA Act) pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120-01.

The FAA Act contains the Alcoholic Beverage Labeling Act (ABLA) of 1988, Public Law 100-690, 27 U.S.C. 213-219a, which was enacted on November 18, 1988. Section 204 of the ABLA, codified in 27 U.S.C. 215, requires that a health warning statement appear on the labels of all containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States, as well as on containers of alcoholic beverages that are manufactured, imported, bottled, or labeled for sale, distribution, or shipment to members or units of the U.S. Armed Forces, including those located outside the United States.

The health warning statement requirement applies to containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States on or after November 18, 1989. The statement reads as follows:

Government Warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery and may cause health problems.

Section 204 of the ABLA also specifies that the Secretary of the Treasury shall have the power to ensure the enforcement of the provisions of the ABLA and issue regulations to carry

them out. In addition, section 207 of the ABLA, codified in 27 U.S.C. 218, provides that any person who violates the provisions of the ABLA is subject to a civil penalty of not more than \$10,000, with each day constituting a separate offense.

Most of the civil monetary penalties administered by TTB are imposed by the Internal Revenue Code of 1986, and thus are not subject to the inflation adjustment mandated by the Inflation Adjustment Act. The only civil monetary penalty enforced by TTB that is subject to the inflation adjustment is the penalty imposed by the ABLA at 27 U.S.C. 218.

TTB Regulations

The TTB regulations implementing the ABLA are found in 27 CFR part 16, and the regulations implementing the Inflation Adjustment Act with respect to the ABLA penalty are found in 27 CFR 16.33. This section indicates that, in accordance with the ABLA, any person who violates the provisions of this part is subject to a civil penalty of not more than \$10,000. Further, pursuant to the provisions of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, this civil penalty is subject to periodic cost-of-living adjustments. Accordingly, any person who violates the provisions of 27 CFR part 16 is subject to a civil penalty of not more than the amount listed at <https://www.ttb.gov/laws-regulations-and-public-guidance/other/penalties>. Each day constitutes a separate offense.

To adjust the penalty, § 16.33(b) indicates that TTB will provide notice in the **Federal Register** and at the website mentioned above of cost-of-living adjustments to the civil penalty for violations of 27 CFR part 16.

Penalty Adjustment

In this document, TTB is publishing its yearly adjustment to the maximum ABLA penalty, as required by the amended Inflation Adjustment Act.

As mentioned earlier, the ABLA contains a maximum civil monetary penalty. For such penalties, section 5 of the Inflation Adjustment Act indicates that the inflation adjustment is determined by increasing the maximum penalty by the cost-of-living adjustment. The cost-of-living adjustment means the percentage increase (if any) between the Consumer Price Index for All Urban Consumers (CPI-U) for the October preceding the date of the adjustment and the prior year's October CPI-U.

The CPI-U in October 2023 was 307.671, and the CPI-U in October 2024 was 315.664. The rate of inflation between October 2023 and October 2024

was therefore 2.598 percent. When applied to the current ABLA penalty of \$25,561 this rate of inflation yields a raw (unrounded) inflation adjustment of \$664.0748. Rounded to the nearest dollar, the inflation adjustment is \$664, meaning that the new maximum civil penalty for violations of the ABLA will be \$26,225.

The new maximum civil penalty will apply to all penalties that are assessed after January 16, 2025. TTB has also updated its web page at <https://www.ttb.gov/laws-regulations-and-public-guidance/other/penalties> to reflect the adjusted penalty.

Dated: January 10, 2025.

Amy R. Greenberg,

Acting Assistant Administrator, Headquarters Operations.

[FR Doc. 2025-00912 Filed 1-15-25; 8:45 am]

BILLING CODE 4810-31-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 257

[EPA-HQ-OLEM-2020-0107; FRL-7814.1-04-OLEM]

RIN 2050-AH34

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Legacy CCR Surface Impoundments; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is taking direct final action to correct errors and clarify several provisions published in the **Federal Register** on May 8, 2024. This May 8, 2024 rule (Legacy Final Rule) established regulatory requirements for legacy coal combustion residuals (CCR) surface impoundments and CCR management units, among other things, under the Resource Conservation and Recovery Act (RCRA).

DATES: This final rule is effective on May 16, 2025 without further notice unless EPA receives adverse comment by March 17, 2025. If EPA receives adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public about the specific regulatory paragraph or amendment that will not take effect.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OLEM-2020-0107. All documents in the docket are listed on

the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., 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 <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Why is the EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because EPA views this as a noncontroversial action and anticipates no adverse comment since the amendments merely correct errors in the regulatory text and conform the regulatory text to the decisions articulated in the Legacy Final Rule preamble. However, in the “Proposed Rules” section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposed rule to adopt the provisions in this direct final rule if adverse comments are received on this direct final rule. The Agency will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of the proposed rule document.

If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public about the specific regulatory paragraph(s) or amendment(s) that will not take effect. The corrections that are not withdrawn will become effective on the date set out above. EPA would address all public comments in any subsequent final rule based on the

comments and new information submitted in response to the proposed rule.

In light of the narrow purpose of this rule to conform the regulatory text to the final actions described in the Legacy Final Rule, EPA is only soliciting comment on whether the changes in this direct final rule conform the text to EPA’s stated intent in the Legacy Final Rule preamble. EPA is not reconsidering, proposing to reopen, or otherwise soliciting comment on any provisions of the Legacy Final Rule itself. For the reader’s convenience, EPA has provided a background description of individual provisions in the Legacy Final Rule in several places throughout this preamble. These descriptions do not reopen the underlying described provisions, but merely explain the context to inform the public of the basis for this action’s technical corrections. In addition, for the convenience of the reader, EPA is revising and republishing §§ 257.75 and 257.100 in their entirety, which means that the regulatory text presented in this action is a combination of revised content (discussed in this preamble) and unchanged, republished content. The Agency is not reconsidering, proposing to reopen, or otherwise soliciting comment on the unchanged, republished content of these sections of the regulatory text. EPA will not respond to comments submitted on any issues other than those specifically identified in this action, and such comments will not be considered part of the rulemaking record.

II. General Information

A. Does this action apply to me?

This rule may be of interest to electric utilities and independent power producers that fall within the North American Industry Classification System (NAICS) code 221112. The reference to NAICS code 221112 is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This discussion lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not described here could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in § 257.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

EPA is correcting errors and conforming the regulatory text to the decisions articulated in the Legacy Final Rule published in the **Federal Register** on May 8, 2024, which established regulatory requirements for legacy CCR surface impoundments and CCR management units (CCRMU). In addition, EPA is making a number of revisions to clarify the final requirements, such as consolidating the compliance deadlines for CCRMU into a single section and providing a deadline for the initial fugitive dust plan for CCRMU at facilities without a regulated unit.

C. What is the Agency’s authority for taking this action?

EPA is publishing this rule under the authority of sections 1008(a)(3), 2002(a), 4004, and 4005(a), (d) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, 42 U.S.C. 6907(a), 6912(a), 6944, 6945(a) and (d).

III. Background

On April 17, 2015, EPA issued national minimum criteria for the disposal of CCR as solid waste under subtitle D of RCRA (80 FR 21302) (2015 CCR Rule or CCR regulations). The 2015 CCR Rule, codified in subpart D of part 257 of Title 40 of the Code of Federal Regulations, established regulations for existing and new CCR landfills, existing and new CCR surface impoundments, and all lateral expansions of these CCR units. The 2015 CCR Rule also imposed requirements on inactive surface impoundments at active facilities but exempted inactive surface impoundments at inactive facilities. On August 21, 2018, the U.S. Court of Appeals for the District of Columbia Circuit vacated and remanded the provision that exempted inactive impoundments at inactive facilities from the CCR regulations. *Utility Solid Waste Activities Group, et al. v. EPA* (USWAG) 901 F.3d 414 (D.C. Cir. 2018).

On May 8, 2024, EPA published the Legacy Final Rule regulating inactive surface impoundments at inactive facilities (legacy CCR surface impoundments or legacy impoundments) under 40 CFR part 257, subpart D. (89 FR 38950). In addition, the final rule established requirements to address the risks from solid waste management activities involving the direct placement of CCR on the land

that was exempt from regulation under the 2015 CCR Rule. This included inactive CCR landfills, and CCR surface impoundments and landfills that closed prior to the effective date of the 2015 CCR Rule; the final rule refers to these newly regulated units as CCRMU. The Legacy Final Rule added a definition for legacy CCR surface impoundments, CCRMU, among other terms. It also established the regulatory requirements applicable to legacy CCR surface impoundments and CCRMU, which largely consist of requiring compliance with certain existing CCR regulations, along with tailored compliance deadlines.

On November 8, 2024, EPA published a direct final rule to correct three errors in the Legacy Final Rule. In addition to taking action to correct inadvertent deletions of existing regulatory text in part 257, subpart D, the direct final rule made clear that the effective date of the Legacy Final Rule is November 8, 2024. These corrections are effective on February 6, 2025 (89 FR 88650).

IV. Revisions to Part 257, Subpart D

Since publication of the Legacy Final Rule, EPA has identified a number of errors in the final regulatory text. Some of these are typographical errors, while others are regulatory text that does not conform to the Agency's stated positions in the Legacy Final Rule preamble. EPA has also identified regulatory provisions that, as drafted, have the potential to be ambiguous or confusing. Some of these issues were raised to the Agency's attention by members of the public including industry, non-governmental organizations, and State regulatory agencies. EPA is addressing these errors, inconsistencies, and ambiguities in this direct final rule and companion proposed rule. These changes include: (1) Fixing incorrect regulatory text citations; (2) Clarifying and adding provisions in the regulatory text to match what is clearly described in the preamble; and (3) Improving rule implementation by adding a new section consolidating compliance deadlines for CCRMU.

A. Revisions to § 257.50(d) (Scope and Purpose)

In the preamble to the Legacy Final Rule, EPA explained its decision to extend regulation to certain other facilities currently generating power for the electrical grid that only have CCRMU onsite. 89 FR 39053. EPA explained that it was concerned that CCRMU (e.g., inactive CCR landfills, closed CCR landfills, or closed CCR surface impoundments) are located at these facilities. EPA estimated that this

category would consist of nine units at five facilities. Id., n. 141 (referencing "Universe of CCR Management Units. April 2024.").¹ The preamble described these facilities as "other active facilities" and defined them as those that: (1) On or after October 19, 2015, were producing electricity for the grid; (2) Had ceased placement of CCR in their onsite CCR units before the effective date of the 2015 CCR Rule (October 19, 2015); and (3) Had no inactive CCR surface impoundments. This was codified in the final regulatory text at § 257.50(d), which provides that "This subpart applies to CCR management units . . . , located at active facilities."

After the final rule was published EPA received several questions regarding the scope of the active facilities covered under § 257.50(d). Several entities noted that the final regulatory text could be read to extend beyond the scope described in the final rule preamble, to include all facilities producing power for the grid on or after October 19, 2015 regardless of whether there was any history of onsite CCR disposal or coal combustion for power generation at the facility, such as a nuclear electric power generation plant at which coal was never burned, or a wind electric power generation site developed on an agricultural field.

For example, one entity requested that EPA confirm that power generation sites that have never been "used for treating, storing, disposing, or otherwise conducting solid waste management of CCR" are not considered "active facilities" (e.g., greenfield solar electric power generation sites or other electric generation facilities that have not combusted coal) and would not have to undertake a CCRMU facility evaluation. Another asked whether a facility that generates power that has beneficially used CCR onsite (e.g., structural fill beneath a building structure) is required to comply with the facility evaluation requirements even if the location never burned coal.

EPA acknowledges that as currently written the regulation could result in the inclusion of electric utilities or independent power producers that have not placed CCR onsite or operated an onsite coal-fired electric generating unit (EGU), including, for example, the scenarios described in the previous paragraph. As the preamble made clear, this was never EPA's intent. Rather EPA intended the CCRMU regulations to only apply to facilities with a regulated CCR unit and to the small subset of

active facilities described in the Legacy Final Rule preamble. Indeed, EPA specifically declined requests to extend coverage more broadly. See 89 FR 39053–39054. Consistent with that intent, today's technical correction rule amends the regulatory text at § 257.50(d), by replacing the phrase "active facilities" with the phrase "other active facilities." EPA is also defining "other active facility" in § 257.53, to mean ". . . a facility that meets all of the following conditions: (1) On or after October 19, 2015, the facility has produced electricity for the grid using fossil fuel; (2) By October 19, 2015, the facility had ceased placing at the facility any CCR generated by the onsite electric generating unit; and (3) There are no regulated CCR units at the facility."

Consistent with that revision, a nuclear electric power generation facility at which coal was not burned, a wind electric power generation facility developed on an agricultural field or other electric generation facilities that have not combusted coal onsite would not be subject to the CCRMU regulations. The nuclear facility described above would not be subject to the CCRMU regulations because all three criteria of the definition of "other active facility" are not met. The wind facility described above also does not meet any of these criteria and consequently would not be subject to the CCRMU regulations. Similarly, other electric generation facilities (e.g., solar facilities) that have never combusted coal onsite do not meet all of the "other active facility" criteria; even if the facility had produced electricity for the grid using fossil fuel, criteria 2 and 3 still have not been met. The same is generally true where the only activity at the electric generation facility involving CCR was its use as structural fill beneath a structure because the facility would not meet all three criteria. However, where CCR has been placed on the ground onsite, the facility owner or operator needs to be careful in conducting any redevelopment activities. If CCR is moved from its original placement as part of redeveloping the site, and is (re)placed directly on the land, this would constitute active disposal, subject to the CCR regulations in part 257 applicable to active disposal units.

In addition, EPA is revising § 257.100 to conform to the new definition of "other active facility." Specifically, the term "fuel" in the regulatory text of § 257.100(a)(1) is revised to read "fossil fuel." A similar conforming change is reflected in new paragraph (b)(4)(ii) of § 257.90.

¹ Docket item EPA–HQ–OLEM–2020–0107–1031 identifies the CCRMU at other active facilities.

Finally, the introductory paragraphs of § 257.75(a), (b), (c)(1), and (d)(1) of the Legacy Final Rule incorporated the same language from § 257.50(d) that EPA is now revising. Therefore, EPA is revising the introductory paragraphs of those provisions to add references to “other active facilities” so that those provisions conform with the description of regulated facilities in § 257.50(d). EPA is also correcting other errors in § 257.75(c) and (d), which are discussed in Unit IV.C of this preamble.

B. Revisions to § 257.53 (Definitions)

Since publication of the Legacy Final Rule, EPA has identified a number of errors in certain regulatory definitions. Some of these involve an inconsistency between the preamble and the regulatory text. Others are provisions that, as drafted, have the potential to be ambiguous or confusing. Several of these issues were raised to the Agency’s attention by members of the public including industry, non-governmental organizations, and State regulatory agencies. To address these issues, EPA is amending three definitions so that they are consistent with the final actions described in the Legacy Final Rule preamble. Additionally, EPA is adding a definition of “other active facility” to § 257.53, which is discussed in Unit IV.A of this preamble.

1. Closed Prior to October 19, 2015

In the Legacy Final Rule, EPA established requirements for CCRMU and for legacy CCR surface impoundments. In the process, EPA explained several key classifications of CCR units. Importantly, EPA noted that since promulgation of the 2015 CCR Rule, any CCR surface impoundment that had ceased receiving CCR but still contained liquid and CCR on or after October 19, 2015, is classified as an “inactive” impoundment. 89 FR 38986–94. See also, *Electric Energy v. EPA*, 106 F.4th 31, 42 (D.C. Cir 2024); *USWAG*, 941 F.3d at 432. Inactive impoundments located at active utilities have been regulated since issuance of the 2015 CCR Rule. 40 CFR 257.50(c). By contrast, inactive impoundments at inactive facilities are considered legacy impoundments. 89 FR 39100. However, EPA has realized that its new definition of a CCRMU conflicts with these provisions. Specifically, the definition’s phrase “closed prior to October 19, 2015” could be read to cover both inactive impoundments currently regulated under the 2015 CCR regulations and legacy impoundments. Therefore, a correction is necessary.

The Legacy Final Rule defines a CCR management unit to “include [] . . .

CCR units that closed prior to October 19, 2015.” 40 CFR 257.53. That phrase is defined in turn to include a “CCR surface impoundment [that] completed closure . . . in accordance with state law prior to October 19, 2015.” *Id.* But at the same time, the 2015 CCR regulations distinguish between “closed” and “inactive” impoundments based on whether free “liquids” are present. See 40 CFR 257.53 (definitions of “closed” and “inactive CCR impoundment.”). As EPA explained in 2015, “[i]nactive” surface impoundments are those that contain both CCR and water, but no longer receive additional wastes. By contrast, a “closed” surface impoundment would no longer contain water, . . . and would be capped or otherwise maintained.” 80 FR 21343. See also, 89 FR 38992–38993. EPA accordingly defined “closed” in 2015 to mean that “placement of CCR in a CCR unit has ceased, and the owner or operator has completed closure of the CCR unit in accordance with § 257.102 and has initiated post-closure care in accordance with § 257.104.” 40 CFR 257.53. An impoundment closed in accordance with § 257.102 has eliminated free liquids and consequently would no longer contain liquids.

But this distinction between a closed and inactive impoundment was inadvertently omitted from the definition of a CCRMU, which referred only to a unit that had “completed closure in accordance with state law” without any further qualification. And as a factual matter, most inactive impoundments in existence in 2015 could be considered to have “closed in accordance with state law.” This is because as EPA has previously explained—and numerous commenters confirmed during the rulemaking—many State laws prior to 2015 either exempted CCR surface impoundments from State solid waste closure requirements or otherwise allowed free liquids to remain in a closed impoundment. See, 89 FR 38983–38984, 38990, 39029–39030; 80 FR 21322–21325.

Thus, that phrase in the CCRMU definition could be interpreted to reclassify every inactive CCR surface impoundment as a CCRMU, simply because of its status under State law, even if the impoundment meets the definition of an inactive or legacy CCR surface impoundment as defined elsewhere in the CCR regulations. This interpretation is, however, clearly inconsistent with the proposed Legacy Rule and the Legacy Final Rule, in which EPA explicitly considered—and rejected—the approach of classifying an

impoundment based on its status under State law rather than on the existing definitions in § 257.53.

The proposed Legacy Rule explained that under the existing definitions in § 257.53, to the extent an impoundment still contains liquid, it would be an inactive impoundment, and that when located at an inactive facility, such a unit would be considered a legacy impoundment. 88 FR 31992. This is because under the existing definitions an “inactive CCR surface impoundment” means “a CCR surface impoundment that no longer receives CCR on or after October 19, 2015[,] and still contains both CCR and liquids on or after October 19, 2015.” 40 CFR 257.53. EPA further proposed that “[t]his would apply whether the unit is considered ‘closed’ under state law.” *Id.* 89 FR 38986.

The Legacy Final Rule retained this approach. In response to comments, the Legacy Final Rule discussed at length that under the existing definition, *any* impoundment that was no longer receiving CCR but contained CCR and liquids after 2015 is an inactive CCR surface impoundment, not a CCRMU, regardless of any other consideration, including its status under State law. See, 89 FR 38986–38996. As part of that discussion, EPA reiterated that, consistent with the original 2015 Rule, the presence of liquid remaining in an impoundment is a significant part of what distinguishes an “inactive” impoundment from a “closed” impoundment. *Id.* at 38992–38994. See also *id.* at 38996, specifically identifying “[a]ny impoundment that still contains free liquids: (a) even if it is considered ‘closed’ under State law” as a legacy impoundment.

The Legacy Final Rule preamble thus expressly maintained EPA’s interpretations from 2015. It also contains no indication that EPA intended to reclassify as a CCRMU either any unit currently regulated under the 2015 Rule or any unit that EPA had proposed to regulate as a legacy impoundment. To the contrary, EPA disagreed with a commenter who characterized an impoundment that had closed under State law in 2008, but still contained CCR and liquids, as either a legacy CCR surface impoundment or a CCRMU. EPA explained the unit was actually an “inactive CCR surface impoundment” regulated under the 2015 Rule rather than either a legacy impoundment or a CCRMU. 89 FR 39027.

To correct this mistake, EPA is amending the definition of “closed prior to October 19, 2015” at 40 CFR 257.53 to include an express statement that any

unit that “meets the definition of an inactive CCR surface impoundment or legacy CCR surface impoundment in § 257.53 is not a CCR management unit.”

2. CCR Landfill or Landfill

For reasons explained in the Legacy Final Rule preamble, EPA amended the definition of “CCR landfill or landfill” by changing the word “receive” to “contain.” See 89 FR 39043–39044, 39053. However, in the regulatory text, EPA inadvertently only changed the first instance of the word “receives.” This action corrects that error by amending the definition of “CCR landfill or landfill” so that all instances of “receive” are changed to “contain.”

3. Facility

In the Legacy Final Rule, EPA adopted provisions that allow an owner or operator to complete the closure by removal of a CCR unit in two stages. See 89 FR 39082–39088. In the first stage, the owner or operator must complete the removal of all CCR from the unit and the removal or decontamination of all areas affected by releases from the CCR unit during the active life of the CCR unit (e.g., soil contaminated by CCR), except for groundwater. In the second stage, the owner or operator must complete the groundwater corrective action during a separate post-closure care period that commences only after the first stage has been completed (i.e., all CCR has been removed from the unit and affected areas have been decontaminated). Therefore, at some sites, during this post closure care period, the only solid waste remaining at the facility would be the contamination in the groundwater that is in the process of being remediated.

In order to effectuate this, conforming changes needed to be made to other provisions. EPA included some of these revisions in the final rule, (e.g., EPA amended the definition of an operator to clarify that the term includes those person(s) or parties responsible for directing or overseeing groundwater monitoring, closure, or post-closure activities at a CCR unit). 89 FR 39052, 39100–39101. But the Agency failed to make similar revisions to the definition of a facility to account for this situation. As currently drafted, the term is defined to mean the land, and structures, other appurtenances, and improvements on the land, used for treating, storing, disposing, or otherwise conducting solid waste management of CCR. Although the provision could fairly be interpreted to include the CCR constituents contaminating the groundwater, to avoid any ambiguity

EPA is amending the definition to expressly address this situation. Specifically, EPA is making two revisions. The first is to replace the phrase “used for treating, storing, disposing, or otherwise conducting solid waste management of CCR” with a phrase that mirrors the statutory formulations: “where CCR is treated, is stored, or is disposed, or where solid waste management of CCR is otherwise conducted.” In addition, EPA is adding the following sentence to the definition: “A facility includes any onsite soil or groundwater that contains CCR or leachate, or where one or more constituent listed in appendix IV of this part is detected at a statistically significant level above the groundwater protection standard.”

C. Revisions to § 257.75 (Requirements for CCR Management Units)

1. Conforming Revisions to § 257.75(a), (b), (c), and (d)

As discussed in Unit IV.A of this preamble, EPA is making conforming changes to § 257.75(a) through (d), consistent with the revisions to § 257.50(d).

2. Typographical Error in § 257.75(c)(1)(xiv)

Section 257.75(c) specifies requirements for the Facility Evaluation Report Part 1. One of the paragraphs of § 257.75(c) includes a typographical error and this final rule corrects the error. The typographical error is in the first sentence of § 257.75(c)(1)(xiv) as shown in the Legacy Final Rule. Specifically, the cross-reference to paragraph (c)(i) is missing the second paragraph designation level and should instead read (c)(1)(i). Therefore, this final rule corrects the first sentence of paragraph § 257.75(c)(1)(xiv) to read: “A narrative description of any data gaps for information in paragraphs (c)(1)(i) through (xiii) of this section . . .”

3. Typographical Errors in § 257.75(d)

Section 257.75(d) specifies requirements for the Facility Evaluation Report Part 2. One of the paragraphs of § 257.75(d) includes a typographical error and this final rule corrects the error. The typographical error is in the first sentence of § 257.75(d)(1) as shown in the Legacy Final Rule. Specifically, the cross-reference to paragraph (d)(i)(xiii) is incorrect and should instead read (d)(1)(xiv). Therefore, this final rule corrects this part of the first sentence of paragraph § 257.75(d)(1) to read: “information specified in paragraphs (d)(1)(i) through (xiv) of this section . . .”

In addition, § 257.75(d) also includes two references to the Facility Evaluation Report Part 2; however, the text included in the Legacy Final Rule is uncapitalized. This final rule capitalizes these terms to read “Facility Evaluation Report Part 2” to be consistent with other uses of the term.

4. Consolidation of CCR Management Unit Deadlines in § 257.75(e) and Addition of § 257.75(f)

The Legacy Final Rule established various deadlines for CCRMU to comply with the regulatory requirements. These compliance deadlines are specified in multiple sections of part 257, subpart D, including, for example, §§ 257.75, 257.90, 257.101, 257.102, and 257.104. Since publication of the Legacy Final Rule, EPA has heard from entities that navigating multiple sections to identify the compliance deadlines for CCRMU is cumbersome. For clarity, EPA is adding a new paragraph at § 257.75(e) to the CCRMU Facility Evaluation provisions that consolidates all of the compliance dates for CCRMU. EPA is not revising any of these dates or removing the provisions from other sections of part 257, such as in the groundwater monitoring and corrective action sections. As a result of adding a new paragraph to § 257.75, the Agency is revising the section heading of § 257.75 to read “Requirements for identifying CCR management units and deadlines.” Finally, EPA is also redesignating the existing paragraph (e) as (f).

D. Revisions to § 257.80 (Fugitive Dust Requirements)

In the Legacy Final Rule, EPA required owners or operators of CCR units to comply with the fugitive dust requirements in § 257.80. In the final rule preamble, EPA explains that EPA expects facilities with CCRMU to already have a fugitive dust control plan because: (1) Fugitive dust requirements apply to the entire facility and (2) CCRMU are located at facilities with a regulated CCR unit. 89 FR 39061. Therefore, instead of creating a deadline for the creation of fugitive dust plans for CCRMU, EPA finalized a deadline of no later than 30 days following a triggering event, such as the closure of a CCRMU or change in facility or CCR unit operations, for owners or operators to amend their existing fugitive dust plans. However, not all facilities regulated under the CCRMU provisions will be required to have a fugitive dust plan prior to identifying a CCRMU (i.e., “other active facilities”). As such, the owners or operators of these facilities do not have regulatory certainty regarding when they must develop their initial

fugitive dust plan. This action corrects this oversight by finalizing a deadline of no later than August 9, 2027 (*i.e.*, six months after the Facility Evaluation Report Part 2 pursuant to § 257.75(d) is due) for the initial fugitive dust plan for CCRMU located at other active facilities. This compliance timeframe (*i.e.*, six months after determining applicability of the fugitive dust requirements) is consistent with timeframes provided in the 2015 CCR Rule and for legacy CCR surface impoundments in the Legacy Final Rule. See revisions to § 257.80(b)(5).

E. Revisions to § 257.90 (Groundwater Monitoring and Corrective Action Applicability)

The Legacy Final Rule preamble clearly stated CCRMU must conduct assessment monitoring simultaneously with detection monitoring. 89 FR 39065–39066. However, the corresponding regulatory text was inadvertently omitted from the final rule. Therefore, consistent with the Legacy Final Rule preamble, this action is amending § 257.90(b)(3)(iii) to include the requirement for owners or operators of CCRMU to comply with the assessment monitoring requirements.

Additionally, the Legacy Final Rule established various deadlines for CCR units to comply with the groundwater monitoring and corrective action requirements in §§ 257.90–98. The compliance deadlines for different CCR units (*i.e.*, landfills, CCRMU, inactive surface impoundments, legacy surface impoundments) are specified in multiple sections of part 257, subpart D, including, §§ 257.90, 257.100(a), 257.100(e), and 257.100(f). Since publication of the Legacy Final Rule, EPA has heard from entities that navigating multiple sections to determine initial groundwater monitoring compliance deadlines is cumbersome. Therefore, for clarity, EPA is adding a new paragraph at § 257.90(b)(4) that will duplicate and consolidate the initial timeframes for the groundwater monitoring requirements applicable to inactive CCR surface impoundments and legacy CCR surface impoundments. With the addition of this new paragraph, readers of § 257.90(b) will be able to locate the initial groundwater monitoring timeframes for all CCR units. With this action EPA is not revising the initial timeframes, nor removing, or otherwise modifying the provisions in § 257.100(a)(1), (e)(5) and (f)(4) that are now referenced in the new § 257.90(b)(4).

F. Revision to § 257.95 (Assessment Monitoring Program)

As stated above and in Unit IV.E of this preamble, in contradiction with the Legacy Final Rule preamble, the provisions requiring owners and operators of legacy CCR surface impoundments and CCRMU to conduct simultaneous detection and assessment monitoring were inadvertently omitted from the regulatory text. Additionally, the provisions that contain the groundwater monitoring compliance deadlines are in different locations within the Legacy Final Rule regulatory text; EPA expects this may cause confusion about the compliance deadline. Therefore, consistent with the Legacy Final Rule preamble and to improve implementation, this action is amending § 257.95(a) and (b) to clarify the applicability of the assessment monitoring requirements to legacy CCR surface impoundments and CCRMU and the associated compliance deadlines.

G. Revisions to § 257.100 (Inactive CCR Surface Impoundments and Legacy CCR Surface Impoundments)

1. Requirements and Deadlines for Certain Facilities With an Inactive CCR Surface Impoundment in § 257.100(a)(1)

The preamble to the Legacy Final Rule states that EPA adopted a pathway to compliance for facilities that believed they were inactive facilities and did not have units subject to the requirements of the 2015 CCR Rule, despite these facilities producing electricity through renewables. The Legacy Final Rule further states that such facilities producing electricity through renewables (*i.e.*, non-fossil fuels) are subject to the same applicable compliance deadlines as inactive impoundments at inactive facilities (*i.e.*, legacy CCR surface impoundments). 89 FR 39001. EPA is revising the regulatory text in § 257.100(a)(1) to clarify that the requirements and compliance timeframes applicable to these facilities are specified in § 257.100(f)(1).

2. Facility Evaluation Report Requirements for Facilities With a Legacy CCR Surface Impoundment in § 257.100(f)(1)(iii)

The Legacy Final Rule preamble states that an owner or operator of a legacy CCR surface impoundment who utilizes the applicability report extension(s) available through § 257.100(f)(1)(iii) will have the subsequent deadlines delayed by the length of the extension(s). 89 FR 39007–39008. The regulatory text includes provisions to extend those deadlines for legacy CCR surface impoundments. However, the provision

that cross-referenced the extensions for the CCRMU requirement deadlines was inadvertently omitted from the final rule. This action is amending § 257.100(f)(1)(iii) to include the deadline extensions for the CCRMU requirements for these owners or operators, consistent with the final rule preamble.

3. Typographical Error in § 257.100(f)(1)(iii)(A)(3)

EPA identified a typographical error in § 257.100(f)(1)(iii)(A)(3) as the regulatory text does not include the word “all.” Therefore, EPA is correcting this error so the regulatory text now reads: “The details of a written field investigation work plan, including all of the following.”

4. Groundwater Monitoring and Corrective Action Under § 257.100(f)(4)

The Legacy Final Rule preamble clearly stated legacy CCR surface impoundments must conduct assessment monitoring simultaneously with detection monitoring. 89 FR 39020. However, the corresponding regulatory text was inadvertently omitted from the final rule. Therefore, consistent with the Legacy Final Rule preamble, this action is amending § 257.100(f)(4)(iii)(A) to include the requirement for owners or operators of legacy CCR surface impoundments to comply with the assessment monitoring requirements.

5. Typographical Error in § 257.100(f)(4)(iv)

EPA identified a typographical error in § 257.100(f)(4)(iv), which is the paragraph that contains the deadline when the first annual groundwater monitoring and corrective action report is due for legacy CCR surface impoundments. The regulatory text established a deadline for this report of January 31, 2027. However, after publication, EPA realized that this deadline was one year too soon, as the actions required to be included in this report are not required to be completed by that date. Therefore, EPA is correcting the date when the first annual groundwater monitoring and corrective action report is due for legacy CCR surface impoundments to be January 31, 2028 to ensure the report contains all the required information set forth in § 257.90(e).

6. Certification of Closure by Removal for Legacy CCR Surface Impoundments in § 257.100(g)

The Legacy Final Rule preamble clearly states an owner or operator of a legacy CCR surface impoundments who is able to complete the certification of

closure by removal pursuant to § 257.100(g) is not subject to any further requirements under the Legacy Final Rule, including the CCRMU requirements. 89 FR 39008–39010. The corresponding regulatory text was inadvertently omitted from the final rule. Therefore, in this action, EPA is amending § 257.100(g) to include a provision that exempts owners and operators of legacy CCR surface impoundments that complete the certification of closure by removal from any further requirements under part 257, consistent with the Legacy Final Rule preamble.

7. Typographical Error in § 257.100(g)(6)(vii)

EPA identified a typographical error in § 257.100(g)(6)(vii) that mistakenly references “paragraph (g)(3) of this section,” rather than (g)(6). Section 257.100(g)(3) requires documentation that all CCR and other contaminated materials were removed from the unit. This is different from what § 257.100(g)(6) requires, which is all the documentation that groundwater monitoring concentrations do not exceed the groundwater protection standards established pursuant to § 257.95(h) for constituents listed in Appendix IV to part 257. Therefore, for accuracy, EPA is correcting this citation to reference “paragraph (g)(6) of this section”.

8. Simplification of § 257.100(h)

To simplify the final regulation, EPA is replacing a cross-reference with the actual compliance date found in the referenced provision. Section 257.100(h) in the Legacy Final Rule sets the compliance deadline for the owner or operator of a legacy impoundment to complete a certification as November 8, 2024 by referencing “the date listed in paragraph (f)(1)(i) of this section.” In this action, EPA is simplifying the regulation by replacing that phrase with the referenced date, November 8, 2024.

9. Compliance Date Clarification in § 257.100(i)

In § 257.100(i), EPA finalized a set of requirements for legacy CCR surface impoundments that have completed closure in accordance with § 257.102(d) no later than November 8, 2024 or a closure that meets the criteria in § 257.101(g). As finalized in the Legacy Final Rule, the introductory paragraph could be mistakenly read as setting a November 8, 2024 deadline for all the requirements in the paragraph instead of the date by which closure must have been completed for the requirements listed subsequently to be applicable.

Additionally, § 257.100(i) of the Legacy Final Rule included the wrong compliance deadlines for certain requirements (e.g., to compile a unit history of construction). For some requirements § 257.100(i) refers to the deadlines in the 2015 CCR rule, rather than the deadlines applicable to legacy impoundments. To clarify these deadlines for the regulated community, EPA is amending the introductory paragraph and adding dates to § 257.100(i)(1) through (11), as appropriate.

Finally, for the reasons explained in Unit IV.E of this preamble and consistent with the changes in § 257.100(f)(4) and the Legacy Final Rule preamble, this action is amending § 257.100(i)(7)(iii)(A) to include the requirement for owners or operators of these legacy CCR surface impoundments to comply with the assessment monitoring requirements.

H. Revisions to § 257.102 (Criteria for Conducting the Closure or Retrofit of CCR Units)

1. Closure for Cause for Legacy CCR Surface Impoundments and CCR Management Units in § 257.102(e)(4)

The regulations require certain CCR units to close for cause. In the 2015 CCR Rule, this included CCR surface impoundments that are unlined (§ 257.71), fail location restrictions (§§ 257.60 through 257.64), or fail factors of safety (§ 257.73), and landfills that fail the location restriction for unstable areas (§ 257.64). The 2015 CCR Rule implements this with regulatory text in § 257.101 (mandatory closure deadlines) and § 257.102 (closure standards). The 2015 CCR Rule also included specific regulatory text in § 257.102(e) stating that CCR units closing for cause are not eligible for the provisions in § 257.102(e)(2) that allow units to idle. The Legacy Final Rule also mandated the closure of legacy CCR surface impoundments and CCRMU. 89 FR 39026–39027, 39070–39071, 39108. However, EPA inadvertently failed to similarly amend § 257.102(e) to make clear that these units are not eligible for the idling provisions under § 257.102. Therefore, EPA is amending § 257.102(e)(4) to clarify that legacy CCR surface impoundments and CCRMU are not eligible for the idling provisions by adding paragraphs (vi) and (vii) referencing the closure for cause provisions in § 257.101.

2. Completion of Closure Deadlines in § 257.102(f)(1)(ii)

The Legacy Final Rule establishes a deadline of five years to complete

closure of a legacy CCR surface impoundment, which is the same time provided to CCR surface impoundments regulated by the 2015 CCR Rule. 89 FR 39033. However, the regulatory text was not amended to add legacy CCR surface impoundments to the list of CCR units that are provided five years to complete closure. Therefore, EPA is amending § 257.102(f)(1)(ii) to add legacy impoundments to the list of CCR units that are provided five years to complete closure.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. An ICR covering the information collection activities contained in the existing Legacy Final Rule has been submitted for OMBs approval under the temporary OMB control number 2050–0231. The corrections and clarifications to the CCR Legacy Final Rule contained in this action do not have an effect on the established information collection requirements.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities (SISNOSE) under the RFA. This final rule clarifies and corrects errors in the regulatory text of the CCR Legacy Final Rule. This rule does not impose any additional requirements on any entities, including small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The rule clarifies and corrects errors in the regulatory text of the CCR Legacy Final Rule. This rule does not impose any additional requirements, and thus the costs involved in this action are estimated not to exceed \$183 million in 2023\$ (\$100 million in 1995\$ adjusted for inflation

using the GDP implicit price deflator) or more in any one year.

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. The rule clarifies and corrects errors in the regulatory text of the CCR Legacy final rule. This rule does not impose any additional requirements. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order.

Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA’s Policy on Children’s Health also does not apply.

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 and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

The EPA believes that this action does not concern human health or environmental conditions and therefore

cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns. This rule clarifies and corrects errors in the regulatory text of the CCR Legacy Final Rule. This rule does not impose any additional requirements. EPA conducted an extensive Environmental Justice analysis for the Legacy CCR rule. The results of that analysis can be found in the preamble for that final rule. 89 FR 39098.

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).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Jane Nishida,
Acting Administrator.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6927, 6944, 6945(a) and (d); 33 U.S.C. 1345(d) and (e).

■ 2. Amend § 257.50 by revising paragraph (d) to read as follows:

§ 257.50 Scope and purpose.

(d)(1) This subpart applies to CCR management units containing 1,000 tons or greater of CCR, located at facilities with a regulated CCR unit or other active facilities.

(2) CCR management units containing greater than or equal to 1 ton and less than 1,000 tons of CCR, located at facilities with a regulated CCR unit or other active facilities are subject only to the requirements of the facility evaluation report in § 257.75 until a permitting authority determines that

regulation of these units, either individually or in the aggregate, is warranted and determines the applicable requirements.

- 3. Amend § 257.53 by:
 - a. Revising the definitions of “Closed prior to October 19, 2015”, “CCR landfill or landfill” and “Facility”; and
 - b. Adding in alphabetical order the definition of “Other Active Facility”.

The revisions and addition read as follows:

§ 257.53 Definitions.

Closed prior to October 19, 2015 means the closure of the CCR landfill or surface impoundment was completed in accordance with State law prior to October 19, 2015. However, a CCR surface impoundment that meets the definition of an inactive CCR surface impoundment or legacy CCR surface impoundment in § 257.53 is not a CCR management unit.

CCR landfill or landfill means an area of land or an excavation that contains CCR and which is not a surface impoundment, an underground injection well, a salt dome formation, a salt bed formation, an underground or surface coal mine, or a cave. For purposes of this subpart, a CCR landfill also includes sand and gravel pits and quarries that contain CCR, CCR piles, and any practice that does not meet the definition of a beneficial use of CCR.

Facility means all contiguous land, and structures, other appurtenances, and improvements on the land, where CCR is treated, is stored, or is disposed; or where solid waste management of CCR is otherwise conducted. A facility may consist of several treatment, storage, or disposal operational units (e.g., one or more landfills, surface impoundments, or combinations of them). A facility includes any onsite soil or groundwater that contains CCR or leachate, or where one or more constituent listed in appendix IV of this part is detected at a statistically significant level above the groundwater protection standard.

Other Active Facility means a facility that meets all of the following conditions:

- (1) On or after October 19, 2015, the facility has produced electricity for the grid using fossil fuel;
- (2) By October 19, 2015, the facility had ceased placing at the facility any CCR generated by the onsite electric generating unit; and

(3) There are no regulated CCR units at the facility.

* * * * *

■ 4. Revise and republish § 257.75 to read as follows:

§ 257.75 Requirements for identifying CCR management units and deadlines.

(a) *Applicability.* The requirements of this section apply to owners and operators of facilities with a regulated CCR unit or other active facilities.

(b) *Facility evaluation.* The owner or operator of a facility with a regulated CCR unit or other active facility must conduct a facility evaluation to identify all CCR management units at the facility in accordance with paragraphs (c) through (e) of this section. At a minimum, the presence or absence of CCR management units at the facility must be confirmed and documented through a thorough evaluation of reasonably and readily available records that contain the information needed to prepare the Facility Evaluation Reports Part 1 and Part 2 required by paragraphs (c) and (d) of this section. The facility evaluation must also include a physical inspection of the facility. Where necessary, the physical inspection must include field investigation activities to fill data gaps, such as conducting exploratory soil borings, geophysical assessments, or any other similar physical investigation activities to establish the location and boundaries of potential or likely CCR management units, and to affirmatively rule out other areas of potential CCR placement at the facility that were identified during the information review or physical inspection. The facility evaluation must identify all CCR management units at the facility regardless of when the CCR management unit came into existence.

(c) *Facility Evaluation Report Part 1.* (1) No later than Monday, February 9, 2026, the owner or operator of a facility with a regulated CCR unit or other active facility must prepare a Facility Evaluation Report Part 1, which shall contain, to the extent reasonably and readily available, the information specified in paragraphs (c)(1)(i) through (xiv) of this section. The owner or operator has prepared the Facility Evaluation Report Part 1 when the report has been placed in the facility's operating record as required by § 257.105(f)(25).

(i) The name and address of the person(s) owning and operating the facility; the unit name associated with each regulated CCR unit and CCR management unit at the facility; and the identification number of each regulated CCR unit and CCR management unit if

any have been assigned by the State or by the owner.

(ii) The location of any CCR management unit identified on the most recent U.S. Geological Survey (USGS) 2 minute or 15-minute topographic quadrangle map, or a topographic map of equivalent scale if a USGS map is not available. The location of each regulated CCR unit at the facility must also be identified in the same manner.

(iii) A statement of the purpose(s) for which each CCR management unit at the facility is or was used.

(iv) A description of the physical and engineering properties of the foundation and abutment materials on which each CCR management unit is constructed.

(v) A discussion of any known spills or releases of CCR, including any associated remediation activities, from each CCR management unit and whether the spills or releases were reported to State or Federal agencies.

(vi) Any record or knowledge of structural instability of each CCR management unit.

(vii) Any record or knowledge of groundwater contamination associated or potentially associated with each CCR management unit.

(viii) The size of each CCR management unit, including the general lateral and vertical dimensions and an estimate of the volume of waste contained within the unit.

(ix) Dates when each CCR management unit first received CCR and when each CCR management unit ceased receiving CCR.

(x) Identification of all types of CCR in each CCR management unit at the facility.

(xi) A narrative description of any closure activities that have occurred, including any applicable engineering drawings or reports.

(xii) A narrative that documents the data reviewed as part of the facility evaluation process, and that lists all data and information indicating the presence or absence of CCR management units at the facility.

(xiii) Any supporting information used to identify and evaluate CCR management units at the facility, including but not limited to any construction diagrams, engineering drawings, permit documents, wastewater flow diagrams, aerial photographs, satellite images, historical facility maps, any field or analytical data, groundwater monitoring data or reports, inspection reports, documentation of interviews with current or former facility workers, and other documents used to identify and evaluate CCR management units at the facility.

(xiv) A narrative description of any data gaps for information in paragraphs (c)(1)(i) through (xiii) of this section, not available in existing information collection records and a plan for remedying identified data gaps through a physical examination of the facility, including any field or laboratory work needed to remedy data gaps in the Facility Evaluation Report Part 1 record. The plan must include the major milestones needed to fill the identified data gaps (e.g., a physical examination of the facility, sampling of media, measurements of CCR concentrations in and around the unit or physical presence, delineation of CCR management unit(s)) and dates to complete such needed tasks. Also, as necessary and timely, any updates to data gap remedy plans must be added to the public record during the Facility Evaluation Report Part 1.

(2) The owner or operator of any facility regulated under this subpart must obtain a certification from a qualified professional engineer stating that the Facility Evaluation Report Part 1 meets the requirements of paragraph (c)(1) of this section.

(3) The owner or operator of any facility regulated under this subpart must certify the Facility Evaluation Report Part 1 required by paragraph (c)(1) of this section with the following statement signed by the owner or operator or an authorized representative:

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this demonstration and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

(4) No later than Monday, February 9, 2026, the owner or operator must notify the Agency of the establishment of a CCR website using the procedures in § 257.107(a) via the "contact us" form on EPA's CCR website.

(5) The owner or operator of any facility regulated under this subpart that does not contain any CCR management unit must submit Facility Evaluation Report Part 1 documenting the steps taken during the facility evaluation to determine the absence of any CCR management unit. The Facility Evaluation Report Part 1 must include the certifications required under paragraph (c)(3) of this section.

(d) *Facility Evaluation Report Part 2.* (1) No later than Monday, February 8,

2027, the owner or operator of a facility with a regulated CCR unit or other active facility must prepare a Facility Evaluation Report Part 2, which shall contain, to the extent not provided in the Facility Evaluation Report Part 1 under paragraph (c) of this section, the information specified in paragraphs (d)(1)(i) through (xiv) of this section obtained from a physical evaluation of the facility, including where necessary field sampling. The owner or operator has prepared the Facility Evaluation Report Part 2 when the report has been placed in the facility's operating record as required by § 257.105(f)(26).

(i) The name and address of the person(s) owning and operating the facility; the unit name associated with each regulated CCR unit and CCR management unit at the facility; and the identification number of each regulated CCR unit and CCR management unit if any have been assigned by the State or by the owner.

(ii) The location of any CCR management unit identified on the most recent U.S. Geological Survey (USGS) 2 minute or 15-minute topographic quadrangle map, or a topographic map of equivalent scale if a USGS map is not available. The location of each regulated CCR unit at the facility must also be identified in the same manner.

(iii) A statement of the purpose(s) for which each CCR management unit at the facility is or was used.

(iv) A description of the physical and engineering properties of the foundation and abutment materials on which each CCR management unit was constructed.

(v) Any further evidence of known spills or releases, including any associated remediation activities, of CCR from each CCR management unit and whether the spills or releases were reported to State or Federal agencies.

(vi) Any further evidence of structural instability of each CCR management unit.

(vii) Any further evidence of groundwater contamination associated or potentially associated with each CCR management unit.

(viii) The size of each CCR management unit, including the general lateral and vertical dimensions and an estimate of the volume of CCR contained within the unit.

(ix) Identification of the types of CCR in each CCR management unit.

(x) A narrative description of any closure activities that have occurred, including any applicable engineering drawings or reports.

(xi) A narrative that documents the nature and extent of field oversight activities and data reviewed as part of the facility evaluation process, and that

lists all data and information that was reviewed indicating the presence or absence of CCR management units at the facility.

(xii) Any additional supporting information used to identify and evaluate CCR management units at the facility, including but not limited to any construction diagrams, engineering drawings, permit documents, wastestream flow diagrams, aerial photographs, satellite images, historical facility maps, any field or analytical data, groundwater monitoring data or reports, inspection reports, and other documents used to identify and assess CCR management units at the facility. Additionally, as necessary and timely, any updates to the part 1 data gap remedy plan must be added to the record during the facility evaluation report part 2 timeframe.

(xiii) The Facility Evaluation Report Part 2 must explain how each data gap identified in Facility Evaluation Report Part 1 was addressed.

(xiv) A description of each CCR management unit for which regulation under this subpart is deferred for allowable reasons as specified in § 257.101(g) or (h). The owner or operator must provide documentation in the Facility Evaluation Report Part 2 to substantiate that the requirements § 257.101(g) or (h) have been met.

(2) The owner or operator of any facility regulated under this subpart must obtain a certification from a qualified professional engineer stating that the Facility Evaluation Report Part 2 meets the requirements of paragraph (d)(1) of this section.

(3) The owner or operator of any facility regulated under this subpart must certify the Facility Evaluation Report Part 2 required by paragraph (d)(1) of this section with the following statement signed by the owner or operator or an authorized representative:

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this demonstration and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

(4) The owner or operator of any facility regulated under this subpart that does not contain any CCR management unit must submit Facility Evaluation Report Part 2 documenting the steps taken during the facility evaluation to determine the absence of any CCR

management unit. The Facility Evaluation Report Part 2 must include the certifications required under paragraph (d)(3) of this section.

(e) Except as provided in paragraphs (e)(6) and (7) of this section, the owner or operator of a CCR management unit must comply with all of the following:

(1) *Facility evaluation.* (i) No later than February 9, 2026, prepare a Facility Evaluation Report Part 1 as specified in § 257.75(c);

(ii) No later than February 9, 2026, notify the Agency of the establishment of a CCR website as specified in § 257.75(c)(4);

(iii) No later than February 8, 2027, prepare a Facility Evaluation Report Part 2 as specified in § 257.75(d);

(2) *Fugitive dust requirements.* The owner or operator of a CCR management unit must amend the written facility fugitive dust plan no later than 30 days whenever there is a change in conditions that would substantially affect the written plan in effect, such as the construction and operation of a new CCR unit, as specified in § 257.80(b)(6).

(i) The owner or operator of a CCR management unit at an other active facility must prepare the initial fugitive dust plan no later than August 9, 2027 as specified in § 257.80(b)(5)(ii).

(ii) The owner or operator of a CCR management unit at an other active facility must, prepare the initial annual fugitive dust control report no later than October 9, 2028 as specified in § 257.80(c).

(3) *Groundwater monitoring and corrective action.* (i) No later than May 8, 2028, be in compliance with the requirements of § 257.90(b)(3);

(ii) No later than January 31, 2029, prepare the initial groundwater monitoring and corrective action report as set forth in § 257.90(e).

(4) *Closure and post-closure care.* Except as provided in (e)(8) of this section:

(i) No later than November 8, 2028, prepare an initial written closure plan as specified in § 257.102(b);

(ii) No later than November 8, 2028, prepare an initial written post-closure care plan as specified in § 257.104(d); and

(iii) No later than May 8, 2029, initiate the closure of the CCR management unit as specified in § 257.101(f)(1).

(iv) No later than the date closure of the CCR management unit is initiated, complete the notification of intent to close as specified in § 257.102(g).

(v) No later than the deadlines specified under § 257.102(f), complete closure of the CCR management unit.

(vi) Within 30 days of completing closure of the CCR management unit,

complete the notification of completion of closure as specified in § 257.102(h).

(vii) For owners and operators of CCR management units operating under the deferral provisions in § 257.101(g) and (h), the closure deadlines of this paragraph (e)(4) are deferred until permitting as described in § 257.101(g) or (h);

(5) *Recordkeeping, Notification, and internet Posting.* Comply with all applicable recordkeeping, notification, and internet posting requirements as specified in §§ 257.105 through 257.107.

(6) For owners and operators of CCR management units that have utilized the legacy CCR surface impoundment applicability report extension(s) in § 257.100(f)(1)(iii), the deadlines in paragraphs (e)(1) through (5) of this section are adjusted by the length of the extension(s) as described in § 257.100(f)(1)(iii)(E).

(7) For owners and operators of CCR management units that are operating under the provisions in § 257.100(h)(2), the deadlines in paragraphs (e)(1) through (5) of this section are adjusted as described in § 257.100(h)(2)

(f) The owner or operator of the facility must comply with the recordkeeping requirements specified in § 257.105(f), the notification requirements specified in § 257.106(f), and the internet requirements specified in § 257.107(f).

■ 5. Amend § 257.80 by revising paragraph (b)(5) to read as follows:

§ 257.80 Air criteria.

* * * * *

(b) * * *

(5) (i) Except as provided in § 257.100(a)(1), (e)(4)(i), and (f)(3)(i), the owner or operator of a regulated CCR unit must prepare an initial CCR fugitive dust control plan for the facility no later than October 19, 2015, or by initial receipt of CCR in any CCR unit at the facility if the owner or operator becomes subject to this subpart after October 19, 2015.

(ii) The owner or operator of a CCR management unit at an other active facility must prepare an initial CCR fugitive dust control plan for the facility no later than August 9, 2027.

(iii) The owner or operator has completed the initial CCR fugitive dust control plan when the plan has been placed in the facility's operating record as required by § 257.105(g)(1).

* * * * *

■ 6. Amend § 257.90 by revising paragraph (b)(3)(iii) and adding (b)(4) to read as follows:

§ 257.90 Applicability.

* * * * *

(b) * * *

(3) * * *

(iii) Initiate the detection monitoring and assessment monitoring programs to include obtaining a minimum of eight independent samples for each background and downgradient well, as required by §§ 257.94(b) and 257.95.

* * * * *

(4) *Inactive CCR surface impoundments and legacy CCR surface impoundments.* (i) Except for as provided in paragraph (b)(4)(ii) of this section, owners and operators of inactive CCR surface impoundments must comply with the initial groundwater monitoring and corrective action requirements no later than April 17, 2019, as specified in § 257.100(e)(5)(i).

(ii) Owners and operators of inactive CCR surface impoundments at active electric utilities and independent power producers that generate electricity without the use of fossil fuel, provided the facility has not generated electricity using fossil fuels on or after October 19, 2015, must comply with the initial groundwater monitoring and corrective action requirements no later than May 10, 2027, as specified in § 257.100(a)(1) and (f)(4)(i) through (iii).

(iii) Owners and operators of legacy CCR surface impoundments must comply with the initial groundwater monitoring and corrective action requirements no later than May 10, 2027, as specified in § 257.100(f)(4)(i) through (iii).

* * * * *

■ 7. Amend § 257.95 by revising paragraphs (a) and (b) to read as follows:

§ 257.95 Assessment monitoring program.

(a) Assessment monitoring is required for all of the following:

(1) Whenever a statistically significant increase over background levels has been detected for one or more of the constituents listed in appendix III to this part;

(2) For legacy CCR surface impoundments, assessment monitoring must be initiated no later than Monday, May 10, 2027; and

(3) For CCR management units, assessment monitoring must be initiated no later than Monday, May 8, 2028.

(b) Within 90 days of triggering an assessment monitoring program, or as provided in §§ 257.90(b)(3) and 257.100(f)(4), and annually thereafter, the owner or operator of the CCR unit must sample and analyze the groundwater for all constituents listed in appendix IV to this part. The number of samples collected and analyzed for each well during each sampling event

must be consistent with § 257.93(e), and must account for any unique characteristics of the site, but must be at least one sample from each well.

* * * * *

■ 8. Revise and republish § 257.100 to read as follows:

§ 257.100 Inactive CCR surface impoundments and Legacy CCR surface impoundments.

(a) *General.* (1) Inactive CCR surface impoundments are subject to all of the requirements of this subpart applicable to existing CCR surface impoundments, except that an active electric utility or independent power producer that generates electricity without the use of fossil fuel is subject to the compliance requirements and associated deadlines applicable to legacy CCR surface impoundments in paragraph (f)(1) of this section, provided the facility has not generated electricity using fossil fuels on or after October 19, 2015.

(2) Legacy CCR surface impoundments are subject to all of the requirements of this subpart applicable to existing CCR surface impoundments, except for the requirements in §§ 257.60 through 257.64 and 257.71.

(b) through (d) [Reserved]

(e) *Timeframes for certain inactive CCR surface impoundments.* (1) An inactive CCR surface impoundment for which the owner or operator has completed the actions by the deadlines specified in paragraphs (e)(1)(i) through (iii) of this section is eligible for the alternative timeframes specified in paragraphs (e)(2) through (6) of this section. The owner or operator of the CCR unit must comply with the applicable recordkeeping, notification, and internet requirements associated with these provisions. For the inactive CCR surface impoundment:

(i) The owner or operator must have prepared and placed in the facility's operating record by December 17, 2015, a notification of intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.105(i)(1);

(ii) The owner or operator must have provided notification to the State Director and/or appropriate Tribal authority by January 19, 2016, of the intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.106(i)(1); and

(iii) The owner or operator must have placed on its CCR website by January 19, 2016, the notification of intent to initiate closure of the inactive CCR surface impoundment pursuant to § 257.107(i)(1).

(2) *Location restrictions.* (i) No later than April 16, 2020, the owner or

operator of the inactive CCR surface impoundment must:

(A) Complete the demonstration for placement above the uppermost aquifer as set forth by § 257.60(a), (b), and (c)(3);

(B) Complete the demonstration for wetlands as set forth by § 257.61(a), (b), and (c)(3);

(C) Complete the demonstration for fault areas as set forth by § 257.62(a), (b), and (c)(3);

(D) Complete the demonstration for seismic impact zones as set forth by § 257.63(a), (b), and (c)(3); and

(E) Complete the demonstration for unstable areas as set forth by § 257.64(a), (b), (c), and (d)(3).

(ii) An owner or operator of an inactive CCR surface impoundment who fails to demonstrate compliance with the requirements of paragraph (e)(2)(i) of this section is subject to the closure requirements of § 257.101(b)(1).

(3) *Design criteria.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2018, complete the documentation of liner type as set forth by § 257.71(a) and (b).

(ii) No later than June 16, 2017, place on or immediately adjacent to the CCR unit the permanent identification marker as set forth by § 257.73(a)(1).

(iii) No later than October 16, 2018, prepare and maintain an Emergency Action Plan as set forth by § 257.73(a)(3).

(iv) No later than April 17, 2018, compile a history of construction as set forth by § 257.73(b) and (c).

(v) No later than April 17, 2018, complete the initial hazard potential classification, structural stability, and safety factor assessments as set forth by § 257.73(a)(2), (b), (d), (e), and (f).

(4) *Operating criteria.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 18, 2017, prepare the initial CCR fugitive dust control plan as set forth in § 257.80(b).

(ii) No later than April 17, 2018, prepare the initial inflow design flood control system plan as set forth in § 257.82(c).

(iii) No later than April 18, 2017, initiate the inspections by a qualified person as set forth by § 257.83(a).

(iv) No later than July 19, 2017, complete the initial annual inspection by a qualified professional engineer as set forth by § 257.83(b).

(5) *Groundwater monitoring and corrective action.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2019, comply with groundwater monitoring requirements set forth in §§ 257.90(b) and 257.94(b); and

(ii) No later than August 1, 2019, prepare the initial groundwater monitoring and corrective action report as set forth in § 257.90(e).

(6) *Closure and post-closure care.* The owner or operator of the inactive CCR surface impoundment must:

(i) No later than April 17, 2018, prepare an initial written closure plan as set forth in § 257.102(b); and

(ii) No later than April 17, 2018, prepare an initial written post-closure care plan as set forth in § 257.104(d).

(f) *Timeframes for legacy CCR surface impoundments.* Owners and operators of legacy CCR surface impoundments are subject to the requirements of paragraphs (f)(1) through (5) of this section, except as provided in paragraphs (g) through (i) of this section.

(1) *Legacy CCR surface impoundment applicability report.* (i) Except as provided in paragraph (f)(1)(iii) of this section, owners and operators of legacy CCR surface impoundments must prepare a report for each legacy CCR surface impoundment no later than Friday, November 8, 2024. The owner or operator has prepared the applicability report when the report has been placed in the facility's operating record as required by § 257.105(k)(1). At a minimum, the report for each legacy CCR surface impoundment must contain:

(A) The name and address of the person(s) owning and operating the legacy CCR surface impoundment with their business phone number and email address.

(B) The name associated with the legacy CCR surface impoundment.

(C) Information to identify the legacy CCR surface impoundment, including a figure of the facility and where the unit is located at the facility, facility address, and the latitude and longitude of the facility.

(D) The identification number of the legacy CCR surface impoundment if one has been assigned by the state.

(E) A description of the current site conditions, including the current use of the inactive facility.

(ii) (A) The owner or operator of any legacy CCR surface impoundment must certify the applicability report required by paragraph (f)(1)(i) of this section with the following statement signed by the owner or operator or an authorized representative:

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this demonstration and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the

submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

(B) The owner or operator must notify the Agency of the establishment of the facility's CCR website and the applicability of the rule, using the procedures in § 257.107(a) via the "contact us" form on EPA's CCR website.

(iii)(A) Notwithstanding the deadline to complete the applicability report under paragraph (f)(1)(i) of this section, an owner or operator may secure additional time to complete the report for the sole reason of determining through a field investigation whether the unit contains both CCR and liquids. The amount of additional time that can be secured is limited as specified in paragraph (f)(1)(iii)(B) of this section. For owners and operators following the procedures of this paragraph (f)(1)(iii), the compliance timeframes for all other applicable requirements under this subpart are adjusted by the length of the extension(s) justified under this paragraph (f)(1)(iii). To qualify for additional time, the owner or operator must prepare an applicability extension report consisting of the following:

(1) The information specified in paragraph (f)(1)(i)(A) through (C) of this section;

(2) A statement by the owner or operator that to the best of their knowledge or belief, existing and available information does not provide a sufficient basis to determine that the unit contained free liquids on or after October 19, 2015; and

(3) The details of a written field investigation work plan, including all of the following:

(i) A detailed description of the approach to characterize the physical, topographic, geologic, hydrogeologic, and hydraulic properties of the CCR in the unit and native geologic materials beneath and surrounding the unit, and how those properties will be used to investigate for the presence of free liquids in the CCR unit.

(ii) A detailed description of the methods and tools that will be employed to determine whether the unit contains free liquids, the rationale for choosing these methods and tools, how these methods and tools will be implemented, and at what level of spatial resolution at the CCR unit to identify and monitor for the presence of free liquids.

(iii) A detailed description of how groundwater elevations will be determined, and at what level of spatial resolution, in relation to the sides and

bottom of the CCR unit and how any intersection of the groundwater table with the CCR unit will be evaluated, and at what level of spatial resolution.

(iv) A plan for evaluating stormwater flow over the surface of the unit, stormwater drainage from the unit, and stormwater infiltration into the unit and how those processes may result in the formation of free liquids in the CCR unit. This plan must include a current topographic map showing surface water flow and any pertinent natural or man-made features present relevant to stormwater drainage, infiltration and related processes.

(v) An estimated timeline to complete the workplan and make a determination if the CCR unit contains free liquids.

(vi) A narrative discussion of how the results from implementing the workplan will determine whether the unit contains free liquids specified.

(vii) A narrative discussion describing any anticipated problems that may be encountered during implementation of the workplan and what actions will be taken to resolve the problems, and anticipated timeframes necessary for such a contingency.

(viii) The owner or operator of the CCR unit must obtain a written certification from a qualified professional engineer stating that the field investigation work plan meets the requirements of paragraph (f)(1)(iii)(A)(3) of this section.

(B) The maximum amount of additional time that can be secured under paragraph (f)(1)(iii) of this section is 18 months, secured in 6-month increments, provided each 6-month increment is supported by an applicability extension report.

(C) Owners and operator must prepare the initial applicability extension report no later than Friday, November 8, 2024. Subsequent applicability extension reports must be prepared no later than 6 months after completing the preceding applicability extension report. The owner or operator has prepared the applicability extension report when the report is placed in the facility's operating record as required by § 257.105(k)(2).

(D) No later than Friday, November 8, 2024, the owner or operator must notify the Agency of the establishment of a CCR website using the procedures in § 257.107(a) via the "contact us" form on EPA's CCR website.

(E) If the owner or operator determines that the unit contains free liquids during implementation of the written field investigation workplan, the owner or operator must cease operating under these extension provisions and prepare the applicability report required

by paragraph (f)(1) of this section within 14 days of determining that the unit contains free liquids. The owner or operator must comply with all other applicable requirements under this subpart under new timeframes. The new timeframes are determined by adding the total length of the extension(s) justified under paragraph (f)(1)(iii) of this section to each of the applicable requirement deadlines specified under this subpart.

(F) If the owner or operator determines that the unit does not contain both CCR and liquids during implementation of the written field investigation work plan, the owner or operator must prepare a notification stating that the field investigation has concluded and that the owner or operator has determined that the unit does not contain both CCR and liquids and does not meet the definition of a legacy CCR surface impoundment. The owner or operator has prepared the notification when the report is placed in the facility's operating record as required by § 257.105(k)(3).

(G) If the owner or operator does not complete the field investigation work within the timeframes specified in paragraph (f)(1)(iii)(B) of this section, the unit shall be considered a legacy CCR surface impoundment and must comply with all other applicable requirements under this subpart pursuant to the timeframes specified under paragraph (f)(1)(iii)(E) of this section.

(2) *Design criteria.* The owner or operator of a legacy CCR surface impoundment must:

(i) Except for legacy CCR surface impoundments that are incised, no later than Wednesday, January 8, 2025, place on or immediately adjacent to the CCR unit the permanent identification marker as set forth by § 257.73(a)(1).

(ii) Except for legacy CCR surface impoundments that do not exceed the height and/or storage volume thresholds under § 257.73(b), no later than Monday, February 9, 2026, compile a history of construction as set forth by § 257.73(c).

(iii) Except for legacy CCR surface impoundments that are incised, no later than Friday, May 8, 2026, complete the initial hazard potential classification assessment as set forth by § 257.73(a)(2) and (f).

(iv) Except for legacy CCR surface impoundments that do not exceed the height and/or storage volume thresholds under § 257.73(b), no later than Friday, May 8, 2026, complete the structural stability and safety factor assessments as set forth by § 257.73(d), (e), and (f).

(v) Except for legacy CCR surface impoundments that are incised, no later than Friday, May 8, 2026, prepare and maintain an Emergency Action Plan as set forth by § 257.73(a)(3).

(3) *Operating criteria.* The owner or operator of the legacy CCR surface impoundment must:

(i) No later than Friday, November 8, 2024, prepare the initial CCR fugitive dust control plan as set forth in § 257.80(b).

(ii) No later than Friday, November 8, 2024, prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the legacy CCR surface impoundment.

(iii) No later than Friday, November 8, 2024, initiate the inspections by a qualified person as set forth by § 257.83(a).

(iv) No later than Monday, February 10, 2025, complete the initial annual inspection by a qualified professional engineer as set forth by § 257.83(b).

(v) No later than Friday, May 8, 2026, prepare the initial inflow design flood control system plan as set forth in § 257.82(c).

(vi) No later than Thursday, January 8, 2026, prepare the initial annual fugitive dust control report as set forth in § 257.80(c).

(4) *Groundwater monitoring and corrective action.* No later than Monday, May 10, 2027, the owner or operator of the legacy CCR surface impoundment must:

(i) Install the groundwater monitoring system as required by § 257.91.

(ii) Develop the groundwater sampling and analysis program, including the selection of the statistical procedures, that will be used for evaluating groundwater monitoring data as required by § 257.93.

(iii) Be in compliance with the following groundwater monitoring requirements:

(A) Initiate the detection monitoring and assessment monitoring programs to include obtaining a minimum of eight independent samples for each background and downgradient well, as required by §§ 257.94(b) and 257.95.

(B) Begin evaluating the groundwater monitoring data for statistically significant increases over background levels for the constituents listed in appendix III of this part, as required by § 257.94.

(C) Begin evaluating the groundwater monitoring data for statistically significant levels over groundwater protection standards for the constituents listed in appendix IV of this part as required by § 257.95.

(iv) No later than January 31, 2028, prepare the initial groundwater monitoring and corrective action report as set forth in § 257.90(e).

(5) *Closure and post-closure care.* Except as provided in § 257.102(g), the owner or operator of the legacy CCR surface impoundment must:

(i) No later than Monday, November 8, 2027, prepare an initial written closure plan as set forth in § 257.102(b); and

(ii) No later than Monday, November 8, 2027, prepare an initial written post-closure care plan as set forth in § 257.104(d).

(g) For owners and operators of legacy CCR surface impoundments that completed closure of the CCR unit by removal of waste prior to Friday, November 8, 2024, no later than Friday, November 8, 2024, complete a closure certification that includes the information in paragraphs (g)(1) through (g)(6) of this section. If the owner or operator meets all the requirements of this paragraph (g), no further requirements under this subpart apply.

(1) The type and volume of CCR and all other materials in the unit prior to closure;

(2) The methods used to verify complete removal of all CCR and other contaminated materials from the unit, including any post-removal sampling and analysis;

(3) Documentation that all CCR and other contaminated materials were removed from the unit, including, the results of any post-removal sampling and analysis that was conducted;

(4) The methods used to verify complete decontamination of all areas affected by releases from the unit, including but not limited to post-decontamination sampling and analysis;

(5) Documentation that all areas affected by releases from the unit were decontaminated and that all groundwater affected by releases has achieved groundwater protection standards; and

(6) Document that groundwater monitoring concentrations do not exceed the groundwater protection standards established pursuant to § 257.95(h) for constituents listed in appendix IV to this part. The documentation must also include a demonstration that the groundwater monitoring system has met all of the following:

(i) Was capable of accurately representing background water quality unaffected by a CCR unit;

(ii) Was capable of accurately representing the quality of water passing the waste boundary of the unit;

(iii) Was capable of detecting contamination in the uppermost aquifer;

(iv) Monitored all potential contaminant pathways;

(v) Established groundwater background concentrations for appendix IV constituents and compared samples to those background concentrations;

(vi) Monitoring wells must have been cased in a manner that maintains the integrity of the monitoring well borehole. This casing must have been screened or perforated and packed with gravel or sand, where necessary, to enable collection of groundwater samples. The annular space (*i.e.*, the space between the borehole and well casing) above the sampling depth must have been sealed to prevent contamination of samples and the groundwater; and

(vii) The last groundwater monitoring sample used to document that the standard in paragraph (g)(6) of this section has been met must have been collected no earlier than one year prior to the initiation of closure.

(h) If the owner or operator of a legacy CCR surface impoundment is unable to complete the closure by removal certification by November 8, 2024, they may elect to conduct groundwater monitoring in accordance with §§ 257.90 through 257.95 to demonstrate there are no exceedances of the groundwater protection standards. If the owner or operator meets all the requirements of paragraph (h)(1) of this section, no further requirements under this subpart apply. If the owner or operator does not meet the requirements of paragraph (h)(1) of this section by Monday, May 8, 2028 or if one or more constituents in appendix IV to this part are detected at statistically significant levels above the groundwater protection standard established under § 257.95(h), they must proceed in accordance with paragraph (h)(2) of this section.

(1) In order to comply with this paragraph (h)(1), the owner or operator must complete all of the following:

(i) Prepare a notification of intent to certify closure no later than Friday, November 8, 2024. The owner or operator has prepared the notification when the report is placed in the facility's operating record as required by § 257.105(k)(4).

(ii) Conduct groundwater monitoring in accordance with §§ 257.90–257.95 for at least two consecutive sampling events to demonstrate that all constituents in appendix IV of this part have concentrations that do not exceed the groundwater protection standards listed in § 257.95(h).

(iii) Complete a closure by removal certification documenting compliance

with paragraphs (g)(1) through (5) and (h)(1)(i) of this section no later than Monday, May 8, 2028.

(2) If the owner or operator does not meet the requirements of paragraph (h)(1) of this section (*e.g.*, by the date or they detect an SSL of an appendix IV constituent), they must comply with all of the following:

(i) If a statistically significant level is detected, the corrective action provisions and proceed in accordance with § 257.102(c)(2).

(ii) The permanent marker requirements in § 257.73(a)(1) no later than 8 months from the date they became subject to this requirement.

(iii) The applicability report requirements of paragraph (f)(1)(i) of this section no later than 6 months from the date they became subject to this requirement.

(iv) The facility evaluation provisions for CCR management units under § 257.75 no later than 33 months from the date they became subject to this requirement.

(v) If any CCR management unit is discovered after completing the facility evaluation report, the fugitive dust requirements of § 257.80(b) no later than 6 months from the date of the facility evaluation report.

(vi) The groundwater monitoring requirements for CCR management units under § 257.90(b)(3)(i) through (iv) no later than 48 months from the date they became subject to this requirement.

(vii) The requirement to prepare an initial written closure plan for CCR management units consistent with the requirements specified in § 257.102(b)(1) no later than 54 months from the date they became subject to this requirement.

(viii) The requirement to prepare an initial post-closure plan for CCR management units consistent with the requirements specified in § 257.104(d)(2)(iii) no later than 54 months from the date they became subject to this requirement.

(ix) The requirement to initiate the closure of CCR management units in accordance with the requirements of § 257.102 no later than 60 months from the date they became subject to this

(i) Owners and operators of legacy CCR surface impoundments that, prior to Friday, November 8, 2024, either completed closure of the unit in accordance with § 257.102(d) or met the requirements in § 257.101(g) must only:

(1) Prepare the applicability report as set forth by § 257.100(f)(1) no later than November 8, 2024;

(2) Prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or

livestock onto the legacy CCR surface impoundment as set forth in § 257.100(f)(3)(ii) no later than November 8, 2024;

(3) Place on or immediately adjacent to the unit the permanent identification marker as set forth by § 257.73(a)(1) no later than January 8, 2025;

(4) Compile a history of construction as set forth by § 257.73(c) no later than February 9, 2026;

(5) Prepare the initial CCR fugitive dust control plan as set forth in § 257.80(b) no later than November 8, 2024;

(6) Prepare the initial annual fugitive dust control report as set forth in § 257.80(c) no later than January 8, 2026;

(7) No later than May 10, 2027, the owner or operator of the legacy CCR surface impoundment must:

(i) Install the groundwater monitoring system as required by § 257.91;

(ii) Develop the groundwater sampling and analysis program, including the selection of the statistical procedures, that will be used for evaluating groundwater monitoring data as required by § 257.93;

(iii) Be in compliance with the following groundwater monitoring requirements:

(A) Initiate the detection monitoring and assessment monitoring programs to include obtaining a minimum of eight independent samples for each background and downgradient well, as required by §§ 257.94(b) and 257.95.

(B) Begin evaluating the groundwater monitoring data for statistically significant increases over background levels for the constituents listed in appendix III of this part, as required by § 257.94;

(C) Begin evaluating the groundwater monitoring data for statistically significant levels over groundwater protection standards for the constituents listed in appendix IV of this part as required by § 257.95;

(8) Include in the applicability report specified in § 257.100(f)(1) information on the completed closure, along with supporting documentation to demonstrate that the closure meets the performance standards in § 257.102(d) or the standards specified in § 257.101(g);

(9) Prepare an initial written post-closure care plan as set forth in § 257.104(d) no later than November 8, 2027;

(10) Conduct post-closure care as set forth in § 257.104(b); and

(11) Comply with applicable recordkeeping, notification, and website posting requirements as set forth by §§ 257.105 through 257.107.

(j) The owner or operator of the legacy CCR surface impoundment must comply with the recordkeeping requirements specified in § 257.105(k), the notification requirements specified in § 257.106(k), and the internet requirements specified in § 257.107(k).

■ 9. Amend § 257.102 by adding paragraphs (e)(4)(vi) and (vii), and revising paragraph (f)(1)(ii) to read as follows:

§ 257.102 Criteria for conducting the closure or retrofit of CCR units and closure of CCR management units.

* * * * *

(e) * * *

(4) * * *

(vi) An owner or operator of a legacy CCR surface impoundment closing the CCR unit as required by § 257.101(e).

(vii) An owner or operator of a CCR management unit closing the CCR unit as required by § 257.101(f).

(f) * * *

(1) * * *

(ii) For existing and new CCR surface impoundments, any lateral expansion of a CCR surface impoundment, and legacy CCR surface impoundments, within five years of commencing closure activities.

* * * * *

[FR Doc. 2025–00848 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2022–0007; FRL 9344.1–01–OAR]

RIN 2060–AV63

Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere (Chemiluminescence Method); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction and correcting amendment.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule published in the **Federal Register** on October 12, 2023, that became effective on November 13, 2023. The final rule updated the current ozone absorption cross-section to the recommended consensus-based value of 1.1329×10^{-17} cm² molecule⁻¹ or 304.39 atm⁻¹ cm⁻¹. After publication, the EPA became aware of an error in the preamble text regarding the date for State, local, and Tribal monitoring agencies to complete implementation of the new ozone cross-

section value, as well as a lack of clarity as to which entities the 2025 and 2026 implementation dates apply. With this action, the EPA is updating the final rule preamble and regulatory text to clarify the applicable implementation dates and the specific entities to which they apply. These corrections do not include any substantive changes to the final rule.

DATES: This final rule is effective on January 16, 2025.

ADDRESSES: The EPA has established a docket for the final rule under Docket ID No. EPA–HQ–OAR–2022–0007. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., CBI or other information 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: Melinda Beaver, Air Quality Assessment Division (C304–06), Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1062; email address: beaver.melinda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Correction to Preamble of October 12, 2023 Final Rule

In the final rule preamble, the EPA incorrectly stated that State, local, and Tribal monitoring agencies will complete cross-section implementation by January 1, 2026. The cross-section will begin implementation at the highest level of the calibration hierarchy, the Standard Reference Photometer (SRP), on January 1, 2025. Because of the time needed to fully implement the cross-section across the national traceability hierarchy for the calibration of the ozone monitoring network, the State, local, and Tribal monitoring agencies are not expected to complete implementation of the cross-section at the monitor level by January 1, 2026; instead, the EPA expects the cross-section implementation will be complete throughout the traceability hierarchy by December 31, 2026.

Also, the accompanying regulatory text in section 2.2 of appendix D to part 50 is inconsistent with the preamble

language that was published in the final rule in that it does not specify to which parties the implementation dates apply. The EPA is correcting both the preamble language and regulatory text in section 2.2 of appendix D to part 50 for consistency.

Correcting Amendments to 40 CFR Part 50 Appendix D

To be consistent with the preamble correction, section 2.2 in appendix D to part 50 is also revised.

II. Rulemaking Procedures

Section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this correction final without prior proposal. In this instance, notice and opportunity for comment is unnecessary because the corrections merely conform the expected implementation dates in the regulatory text to the preamble and clarify the entities to which these dates apply. Therefore, these minor, non-substantive technical corrections do not warrant public comment.

Moreover, the EPA has determined that there is good cause for making this final rule effective less than 30 days after publication in the **Federal Register**. Section 553(d)(3) of the APA, 5 U.S.C. 553(d)(3), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** “except . . . as otherwise provided by the agency for good cause found and published with the rule.” “In determining whether good cause exists, an agency should ‘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.’” *Omnipoint Corp. v. Fed. Comm’n Comm’n*, 78 F.3d 620, 630 (D.C. Cir. 1996) (quoting *United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir. 1977)). Because this rule extends the expected implementation date for specified entities from January 1, 2026, to December 31, 2026, the affected parties do not need time to adjust their behavior before the rule takes effect.

For these reasons, the Agency finds that good cause exists under APA section 553(d)(3) to make this rule effective on January 16, 2025.

III. Statutory and Executive Orders 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 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined by Executive Order 12866, as amended by Executive Order 14094 and was, therefore, not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action revises the ozone absorption cross-section and revise and amend relevant references. It does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action updates the ozone absorption cross-section value for surface ozone monitoring under 40 CFR part 50, and we anticipate that there will be minimal costs associated with this change. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

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. This 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. This action updates a reference measurement principle and

calibration procedure for the measurement of ambient ozone under 40 CFR part 50. 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 only 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)

This rulemaking involves technical standards. The EPA used voluntary consensus standards in the preparation of this measurement principle and procedure; it is the benchmark against which all ambient ozone monitoring methods are compared. This action is simply updating the reference measurement principle in light of updated information.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations 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. This regulatory action is an update to a previously promulgated analytical method and does not have any impact on human health or the environment.

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. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding

that notice and comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in the **SUPPLEMENTARY INFORMATION** section. The EPA has determined that there is good cause for making this correction final without prior proposal. In this instance, notice and opportunity for comment is unnecessary because this action implements a minor, non-substantive technical correction that conforms the regulatory text to the rule's preamble.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Ozone.

Joseph Goffman,

Assistant Administrator, Office of Air and Radiation.

Accordingly, the EPA corrects FR Doc. 2023–22531 and 40 CFR part 50 as follows:

Federal Register Correction

In FR Doc. 2023–22531, at 88 FR 70595 in the **Federal Register** of October 12, 2023, on page 70597, in the first column, the second, third and fourth sentences of the last paragraph are corrected to read as follows:

“The absorption cross-section value stated in this appendix ($304.39 \text{ atm}^{-1} \text{ cm}^{-1} \pm 0.94 \text{ atm}^{-1} \text{ cm}^{-1}$) will be used in all U.S. Standard Reference Photometers (SRPs) beginning January 1, 2025. It is expected that implementation across all other ozone transfer standards and ozone monitors in the field will be completed by December 31, 2026.”

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

- 1. The authority citation for part 50 continues to read as follows:

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

* * * * *

- 2. Amend Appendix D to Part 50 by revising section 2.2 to read as follows:

Appendix D to Part 50—Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere (Chemiluminescence Method)

* * * * *

2.2 The measurement system is calibrated by referencing the instrumental chemiluminescence measurements to certified O_3 standard concentrations generated in a dynamic flow system and assayed by ultraviolet (UV) photometry to be traceable to a National Institute of Standards and Technology (NIST) standard reference

photometer for O_3 (see Section 4, Calibration Procedure, below) with a specified ozone absorption cross-section value. The absorption cross-section value stated in section 4.1 and section 4.5.3.10 of this appendix ($304.39 \text{ atm}^{-1} \text{ cm}^{-1} \pm 0.94 \text{ atm}^{-1} \text{ cm}^{-1}$) will begin use in all U.S. Standard Reference Photometers (SRPs) on January 1, 2025. It is expected that implementation across all other ozone transfer standards and ozone monitors in the field will be completed by December 31, 2026.

* * * * *

[FR Doc. 2025–00946 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2019–0350; FRL–12535–01–R8]

Clean Air Act Operating Permit Program; Notice of Issuance of Title V Federal Operating Permit to Deseret Generation and Transmission Co-operative

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of final action.

SUMMARY: The Environmental Protection Agency (EPA) issued a final permit decision under title V of the Clean Air Act (CAA) to Deseret Bonanza and Transmission Co-operative (Deseret) for the operation of Deseret's Uintah County, Utah, Bonanza Power Plant (Bonanza).

DATES: EPA issued title V Permit to Operate No. V–UO–000004–2019.00 to Deseret on December 4, 2023, under 40 CFR part 71. This permit was appealed to the Environmental Appeals Board by the Ute Tribe of Utah. The Board denied review of the permit on September 10, 2024, and EPA issued the final permit decision on December 17, 2024. Pursuant to section 307(b)(1) of the CAA, judicial review of EPA's final permit decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Tenth Circuit by March 17, 2025.

FOR FURTHER INFORMATION CONTACT: Suman Kunwar, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–AP–P, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, telephone number: (303) 312–6095, email address: kunwar.suman@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document wherever “we,” “us,” or “our” is used, we mean the EPA. This **SUPPLEMENTARY INFORMATION** is arranged as follows:

I. How can I get copies of this document and other related information?

EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2019–0350. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Environmental Protection Agency, Region 8, Air and Radiation Division, 1595 Wynkoop Street, Denver, Colorado 80202. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Suman Kunwar, Environmental Engineer, at (303) 312–6095 with any questions about reviewing the docket material before visiting the Region 8 office.

II. Background

The 1990 amendments to the CAA established a comprehensive air quality permit program under the authority of Title V of the CAA. Title V requires certain facilities that emit large amounts of air pollution, or that meet other specified criteria, to obtain an operating permit, known as a title V permit, after the source has begun to operate. This permit is an enforceable compilation of all enforceable terms, conditions, and limitations applicable to the source, and is designed to improve compliance by clarifying what facilities must do to control air pollution. EPA regulations implementing title V are codified at 40 CFR part 71 for permits issued by EPA or its delegates, and at 40 CFR part 70 for permits issued by states and local agencies pursuant to approved programs. A title V permit is valid for no more than five years and may be renewed in five-year-increments.

Deseret operates a facility, Bonanza, in Uintah County, Utah. Bonanza is a coal-fired power plant located on the Uintah and Ouray Reservation. Coal is delivered to the Facility by train and is crushed and pulverized before being fed into the main boiler. The boiler produces steam, which powers a turbine to generate electricity. On December 5, 2014, EPA Region 8 issued an initial title V Permit to Deseret for Bonanza pursuant to 40 CFR part 71.

On December 4, 2023, EPA Region 8 renewed Deseret's Title V permit for a new five-year term. See title V Permit to Operate No. V–UO–000004–2019.00, Docket ID: EPA–R08–OAR–2019–0350. On January 3, 2024, the Ute Indian Tribe filed an appeal of the title V permit for Bonanza with the Environmental Appeals Board. The Tribe did not petition to review certain terms and conditions of the renewed title V permit but contended that the Region failed to

address the Tribe’s concerns about the health and environmental impacts of the Bonanza plant and acted contrary to Executive Orders and EPA policies regarding environmental justice and Tribal consultation, and contrary to the Federal trust responsibility to federally-recognized Indian Tribes. In addition, the Tribe asserted that EPA abused its discretion and violated the Federal trust responsibility by not providing the results of an investigation identifying potential non-compliance with coal combustion residual requirements under the Resource Conservation and Recovery Act (“RCRA”) until after the CAA title V permit was issued. Consequently, under 40 CFR 71.11(i)(2)(ii), the effective date of the permit was delayed.

III. Effect of this Action

On September 10, 2024, the EAB denied the petition for review. See *In re Deseret Generation and Transmission Co-operative Bonanza Power Plant*, Permit No. V–UO–000004–2019.00, CAA Appeal No. 24–01 (EAB, September 10, 2024) (Order Denying Review). The Tribe requested that the EAB reconsider its Order Denying Review and on November 8, 2024, the EAB denied the Tribe’s Motion for Reconsideration. Following the EAB’s action, pursuant to 40 CFR 124.19(l)(2)(i), the EPA issued a final permit decision on December 17, 2024. The final title V permit is effective immediately and will expire on December 17, 2029.

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

KC Becker,
Regional Administrator, Region 8.
[FR Doc. 2025–00651 Filed 1–15–25; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0607; FRL–10024–03–R9]

Air Plan Approval; Arizona; Maricopa County Air Quality Department

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Maricopa County Air Quality Department (MCAQD or “County”) portions of the Arizona State Implementation Plan (SIP). These revisions concern the County’s reasonably available control technology (RACT) demonstration for the aerospace coating category and negative declarations for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or “standards”) in the portion of the Phoenix-Mesa ozone nonattainment area regulated by the MCAQD, as well as a rule covering emissions of volatile organic compounds (VOCs) from surface coatings and industrial adhesives. We are also approving a local rule that regulates these emission sources under the Clean Air Act (CAA or “the Act”).
DATES: This rule is effective February 18, 2025.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0607. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as

copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.
FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4126 or by email at Law.Nicole@epa.gov.
SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us” and “our” refer to the EPA.

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- I. Proposed Action and Interim Final Determination
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
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I. Proposed Action and Interim Final Determination

On August 4, 2022 (87 FR 47663), the EPA proposed to approve a RACT certification for Aerospace Manufacturing and Rework Operations, Rule 336 “Surface Coating Operations and Industrial Adhesive Application Processes,” and negative declarations for the 2008 8-hour ozone NAAQS. The following table lists the documents that were submitted by the Arizona Department of Environmental Quality (ADEQ) for incorporation into the Arizona SIP and were the subject of our August 4, 2022 proposed rulemaking action.

Local agency	Document	Adopted	Submitted
MCAQD	Maricopa County Reasonably Available Control Technology (RACT) Certification for Volatile Organic Compound (VOC) Emissions from Aerospace Manufacturing and Rework Operations In Maricopa County June 2021.	06/23/21	06/30/21
MCAQD	Rule 336 Surface Coating Operations and Industrial Adhesive Application Processes.	09/01/21	09/17/21
MCAQD	Negative Declarations for Three Coating Categories Listed in the 2008 Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings.	09/01/21	09/17/21

We proposed to approve the RACT certification, rule, and negative declarations because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on the RACT certification, rule, negative declarations,

and our evaluation. On the same day, we also made an interim final determination (87 FR 47630) that the submittal from the ADEQ corrected SIP deficiencies from a previous submittal, allowing us to defer the imposition of sanctions resulting from our previous

disapproval action concerning ozone nonattainment requirements.

II. Public Comments and EPA Responses

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

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving the RACT certification, rule, and negative declarations into the Arizona SIP. The September 1, 2021 version of Rule 336 will replace the previously approved version of this rule in the SIP. This approval permanently stops sanctions and Federal implementation plan clocks started by our January 7, 2021 partial disapproval and partial conditional approval actions on portions of the MCAQD RACT SIP.¹

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of MCAQD Rule 336, "Surface Coating Operations and Industrial Adhesive Application Processes," revised on September 1, 2021, which regulates VOC emissions from surface coating operations and industrial adhesive application processes. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.² The EPA has made, and will continue to make, these documents available through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and permitted by law. Executive Order 14096 (Revitalizing Our Nation's Commitment to Environmental Justice for All, 88 FR 25251, April 26, 2023) builds on and supplements Executive Order 12898 and defines EJ as, among other things, "the just treatment and

meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment."

The State did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Orders 12898 and 14096 of achieving EJ for communities with EJ concerns.

This action is subject to the Congressional Review Act, 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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 17, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 30, 2024.

Martha Guzman Aceves,
Regional Administrator, Region IX.

For the reasons discussed in the preamble, the Environmental Protection Agency amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

¹ 86 FR 971 (January 7, 2021).

² 62 FR 27968 (May 22, 1997).

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

Subpart D—Arizona

§ 52.119 [Amended]

■ 2. In § 52.119, remove and reserve paragraph (c)(3).

■ 3. In § 52.120:

■ a. In paragraph (c), table 4, under the table headings “Post-July 1998 Rule Codification” and “Regulation III—

Control of Air Contaminants”, revise the entry for “Rule 336”; and

■ b. In paragraph (e), table 1, under the subheading “Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas”, and immediately after the entry for “Maricopa Association of Governments (MAG) 1987 Carbon Monoxide (CO) Plan for the Maricopa County Area, MAG CO Plan Commitments for Implementation, and Appendix A through E, Exhibit 4,

Exhibit D”, revise the entry for “Analysis of Reasonably Available Control Technology for the 2008 8-Hour Ozone National Ambient Air Quality Standard (NAAQS) State Implementation Plan (RACT SIP)”.

The revisions read as follows:

§ 52.120 Identification of plan.

* * * * *
(c) * * *

TABLE 4 TO PARAGRAPH (c)—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-July 1998 Rule Codification				
*	*	*	*	*
Regulation III—Control of Air Contaminants				
*	*	*	*	*
Rule 336	Surface Coating Operations and Industrial Adhesive Application Processes.	9/1/2021	1/16/2025, [INSERT FIRST PAGE OF FEDERAL REGISTER CITATION].	Submitted electronically on September 17, 2021, as an attachment to a letter dated September 17, 2021. The September 1, 2021 version of Rule 336 replaces the November 2, 2016 version that was conditionally approved on January 7, 2021.
*	*	*	*	*

* * * * * (e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES
[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively]¹

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
*	*	*	*	*
Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas				
*	*	*	*	*
Analysis of Reasonably Available Control Technology (RACT) for the 2008 8-Hour Ozone National Ambient Air Quality Standard (NAAQS) State Implementation Plan (SIP).	Maricopa County portion of Phoenix-Mesa nonattainment area for 2008 8-hour ozone NAAQS.	June 22, 2017; Supplemented on September 17, 2021.	January 7, 2021, 86 FR 971; and 1/16/2025, [INSERT FIRST PAGE OF FEDERAL REGISTER CITATION].	Except for those portions approved on 2/26/2020. The RACT requirement for major sources of NO _x was approved on February 7, 2023.
*	*	*	*	*

¹ Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

■ 4. In § 52.122, revise paragraph (a)(3)(i) to read as follows:

§ 52.122 Negative declarations.

* * * * *
(a) * * *
(3) * * *

(i) The following negative declarations for the 2008 ozone NAAQS were adopted by the Maricopa County Air Quality Department.

EPA document No.	Title	Adopted: 05/24/2017 Submitted: 6/22/2017 SIP approved: 01/07/2021	Adopted: 09/01/2021 Submitted: 09/17/2021 SIP approved: 1/16/2025
(A) EPA-450/2-77-008	Surface Coating of Coils	X	
(B) EPA-450/2-77-008	Surface Coating of Paper	X	
(C) EPA-450/2-77-008	Surface Coating of Automobiles and Light-Duty Trucks	X	
(D) EPA-450/2-77-025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	X	
(E) EPA-450/2-77-032	Surface Coating of Metal Furniture	X	
(F) EPA-450/2-77-033	Surface Coating of Insulation of Magnet Wire	X	
(G) EPA-450/2-77-034	Surface Coating of Large Appliances	X	
(H) EPA-450/2-77-037	Cutback Asphalt	X	
(I) EPA-450/2-78-029	Manufacture of Synthesized Pharmaceutical Products	X	
(J) EPA-450/2-78-030	Manufacture of Pneumatic Rubber Tires	X	
(K) EPA-450/2-78-032	Factory Surface Coating of Flat Wood Paneling	X	
(L) EPA-450/2-78-036	Leaks from Petroleum Refinery Equipment	X	
(M) EPA-450/3-82-009	Large Petroleum Dry Cleaners	X	
(N) EPA-450/3-83-006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	X	
(O) EPA-450/3-83-007	Leaks from Natural Gas/Gasoline Processing Plants	X	
(P) EPA-450/3-83-008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.	X	
(Q) EPA-450/3-84-015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.	X	
(R) EPA-450/4-91-031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.	X	
(S) EPA-453/R-94-032	ACT Surface Coating at Shipbuilding and Ship Repair Facilities; Shipbuilding and Ship Repair Operations (Surface Coating), <i>see the Federal Register of 08/27/1996.</i>	X	
(T) EPA-453/R-06-003	Flexible Package Printing	X	
(U) EPA-453/R-06-004	Flat Wood Paneling Coatings	X	
(V) EPA 453/R-07-003	Paper, Film, and Foil Coatings	X	
(W) EPA 453/R-07-004	Large Appliance Coatings	X	
(X) EPA 453/R-07-005	Metal Furniture Coatings	X	
(Y) EPA 453/R-08-003	Miscellaneous Metal and Plastic Parts Coatings; Table 4—Automotive/Transportation and Business Machine Plastic Parts.		X
(Z) EPA 453/R-08-003	Miscellaneous Metal and Plastic Parts Coatings; Table 6—Motor Vehicle Materials.		X
(AA) EPA 453/R-08-004	Fiberglass Boat Manufacturing Materials	X	
(BB) EPA 453/R-08-006	Automobile and Light-Duty Truck Assembly Coatings	X	
(CC) EPA 453/B16-001	Oil and Natural Gas Industry	X	

* * * * *

§ 52.124 [Amend]

■ 5. In § 52.124, remove and reserve paragraph (b).

* * * * *

[FR Doc. 2024-31701 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA-R08-OAR-2023-0473; FRL-12257-02-R8]****Air Plan Approval; Montana; Missoula, Montana Oxygenated Fuels Program Removal, Carbon Monoxide, Limited Maintenance Plan**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the Montana Department of Environmental Quality (MDEQ or “the State”), on January 30, 2024, requesting to change the status of gasoline requirements (the “oxygenated fuels” or “oxyfuels” program) in the Missoula, Montana Carbon Monoxide (CO) Limited Maintenance Plan (LMP) from active control measure to a contingency measure. The SIP revision contains a non-interference demonstration under the Clean Air Act (CAA), which concludes that converting the oxygenated gasoline program from a control measure to a contingency measure in the Missoula CO LMP would not interfere with attainment or maintenance of the CO National Ambient Air Quality Standard (NAAQS). The EPA is finalizing approval of Montana’s SIP submittal pursuant the CAA.

DATES: This rule is effective on February 18, 2025.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R08-OAR-2023-0473. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Amrita Singh, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD-IO, 1595 Wynkoop Street,

Denver, Colorado 80202–1129, (303) 312–6103, singh.amrita@epa.gov.

SUPPLEMENTARY INFORMATION:

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

I. Background

The background for this action is discussed in detail in our October 15, 2024, proposal (89 FR 82953). In that document we proposed to approve a SIP revision submitted by Montana on January 30, 2024. The submission included a request to change the status of the oxyfuels program in Missoula CO LMP from an active control measure to a contingency measure, as well as several ministerial and conforming changes to the related State regulations. To support the request, Montana’s January 30, 2024 SIP revision contains technical support materials to demonstrate the removal of the rules as control measures will not interfere with attainment or maintenance of the CO NAAQS or with any other applicable requirement of the CAA. Specifically, the SIP revision addresses State regulations amended in the Missoula City-County Air Pollution Control (MCCAPC) program rules, Chapter 10: *Fuels*, Subchapter 1: *Oxygenated Fuels Program*, rules. 10.102(1), 10.105(1), 10.109(1), 10.110, 10.111, 10.111(2). In our proposed rulemaking, the EPA’s analysis of Montana’s January 30, 2024 SIP revision was organized into two parts under section II of this preamble. Part A provided the background, analysis, and discussion of non-interference demonstration for the change in status of Montana’s oxyfuels program from a control measure to a contingency measure in the federally approved Montana SIP; Part B contained information regarding the rules submitted for revision in the MCCAPC Chapter 10: *Fuels*, Subchapter 1: *Oxygenated Fuels Program*. The EPA is finalizing to act on the revision listed in the action.

We received one comment on the proposed rulemaking. Our response to the comment is found below.

II. Response to Comments

Comment: The commenter stated that they are in favor of the proposed rulemaking and believe it will help reduce pollution by reducing reliance on carbon-based fuels. The commenter also expressed that this rule would move society toward a greener future and reduce the influence of oil companies.

Response: We appreciate the commenter’s support for the proposed rulemaking. However, the comment is outside the scope of this action, as this

rulemaking is limited to approving a SIP revision reclassifying the oxygenated gasoline program in the Missoula CO LMP from a control measure to a contingency measure.

III. Final Action

For the reasons explained in our proposal, the EPA is finalizing its approval of Montana’s January 30, 2024 SIP revision seeking to revise various air quality rules and to remove the oxygenated gasoline program from Montana’s SIP as a control measure and make it a contingency measure instead. The EPA has the authority to approve removal of a State’s oxygenated gasoline program as specified in CAA section 211(m)(6) and has determined that the criteria of CAA section 211(m)(6) has been satisfied. The EPA has determined that Montana has demonstrated that removal of the oxygenated fuels program from the SIP will not interfere with continued attainment or maintenance of any applicable NAAQS or with any other applicable requirement of the CAA, and that the requirements of CAA section 110(l) have been satisfied. As a result, the EPA is finalizing its approval of the changes to the MCCAPC oxyfuels program rules, Chapter 10: *Fuels*, Subchapter 1: *Oxygenated Fuels Program*, rules 10.102(1), 10.105(1), 10.109(1), 10.110, 10.111, 10.111(2) as submitted by Montana on January 30, 2024.

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the revised MCCAPC oxyfuels program rules, Chapter 10: *Fuels*, Subchapter 1: *Oxygenated Fuels Program*, rules 10.102(1), 10.105(1), 10.109(1), 10.110, 10.111, 10.111(2). These rules revise various air quality regulations by correcting spelling and other clerical errors and remove the oxygenated gasoline program from Montana’s SIP. The EPA is finalizing the incorporation by reference of the regulations described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are

fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.¹

V. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have

¹ 62 FR 27968 (May 22, 1997).

Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.” The MDEQ did not evaluate EJ considerations as part of its SIP submittal; the CAA and the applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have neutral impacts on the air quality of the

affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, low-income populations, and Indigenous people.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 17, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: January 2, 2025.

KC Becker,

Regional Administrator, Region 8.

For the reasons set forth in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart BB—Montana

■ 2. In § 52.1370, the table in paragraph (c) under (c)(2)(iv)(“Missoula County”), is amended by:

■ a. Revising the table entries for “10.102,” “10.105,” “10.109,” and “10.110;”

■ b. Adding in numerical order the table entry for “10.111”.

The revisions and addition read as follows:

§ 52.1370 Identification of plan.

* * * * *

(c) * * *

State citation	Rule title	State effective date	EPA final rule date	Final rule citation	Comments
*	*	*	*	*	*
(2) County Specific					
*	*	*	*	*	*
(iv) Missoula County					
10.102	Definitions	1/16/2024	1/16/2025	[insert first page of Federal Register citation].	*
10.105	Oxygenate Blending Facility Requirements	1/16/2024	1/16/2025	[insert first page of Federal Register citation].	*
10.109	Registration Fees	1/16/2024	1/16/2025	[insert first page of Federal Register citation].	*

State citation	Rule title	State effective date	EPA final rule date	Final rule citation	Comments
10.110	When Authorized by the Federal Government—Cessation of Oxygenated Fuels Program.	1/16/2024	1/16/2025	[insert first page of Federal Register citation].	
10.111	Contingency Measure	1/16/2024	1/16/2025	[insert first page of Federal Register citation].	
*	*	*	*	*	*

* * * * *

[FR Doc. 2025–00380 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2024–0603; FRL–12499–01–OW]

Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action announces the Environmental Protection Agency’s (EPA’s) approval of alternative testing methods for use in measuring the levels of contaminants in drinking water to determine compliance with national primary drinking water regulations. The Safe Drinking Water Act authorizes EPA to approve the use of alternative testing methods through publication in the **Federal Register**. EPA is using this streamlined authority to make two additional methods available for analyzing drinking water samples. This expedited approach provides public

water systems, laboratories, and primacy agencies with more timely access to new measurement techniques and greater flexibility in the selection of analytical methods, thereby reducing monitoring costs while maintaining public health protection.

DATES: This action is effective January 16, 2025.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2024–0603. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Teresa Wells, Technical Support Branch, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: (513) 569–7128; email address: wells.teresa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Public water systems are the regulated entities required to measure contaminants in drinking water samples. In addition, EPA Regions as well as States and Tribal governments with authority to administer the regulatory program for public water systems under the Safe Drinking Water Act (SDWA) may measure contaminants in water samples. When EPA sets a monitoring requirement in its national primary drinking water regulations for a given contaminant, the agency also establishes (in the regulations) standardized test procedures for analysis of the contaminant. This action makes alternative testing methods available for particular drinking water contaminants beyond the testing methods currently established in the regulations. EPA is providing public water systems, required to test water samples, with a choice of using either a test procedure already established in the existing regulations or an alternative testing method that has been approved in this action or in prior expedited approval actions. Categories and entities that may ultimately be affected by this action include:

Category	Examples of potentially regulated entities	NAICS ¹
State, local, & Tribal governments	State, local, and Tribal governments that analyze water samples on behalf of public water systems required to conduct such analysis; State, local, and Tribal governments that directly operate community and non-transient non-community water systems required to monitor.	924110
Industry	Private operators of community and non-transient non-community water systems required to monitor.	221310
Municipalities	Municipal operators of community and non-transient non-community water systems required to monitor.	924110

¹ North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. Other types of entities not listed in the table could also have some interest. To determine

whether your facility is affected by this action, you should carefully examine the applicability language in the *Code of Federal Regulations* (CFR) at 40 CFR 141.2 (definition of a public water system). If you have questions regarding

the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Abbreviations and Acronyms Used in This Action

AMCD: Automated Micro Chlorine Detection
 CFR: Code of Federal Regulations
 EPA: United States Environmental Protection Agency
 FRB: Field Reagent Blank
 LC/MS/MS: Liquid Chromatography/Tandem Mass Spectrometry
 NAICS: North American Industry Classification System
 PFAS: Per- and Polyfluorinated Alkyl Substances
 SDWA: The Safe Drinking Water Act

II. Background

A. What is the purpose of this action?

In this action, EPA is approving two analytical methods for determining contaminant concentrations in drinking water samples collected under SDWA. Regulated entities required to sample and monitor may use either the testing methods already established in existing regulations or the alternative testing methods being approved in this action or in prior expedited approval actions. The new methods are listed along with other methods similarly approved through previous expedited actions in 40 CFR part 141, appendix A to subpart C and on EPA's drinking water methods website at <https://www.epa.gov/dwanalyticalmethods>.

B. What is the basis for this action?

When EPA determines that an alternative analytical method is "equally effective" (i.e., as effective as a method that has already been promulgated in the regulations), SDWA allows EPA to approve the use of the alternative testing method through publication in the **Federal Register** (see section 1401(1) of SDWA). EPA is using this streamlined approval authority to make two additional methods available for determining contaminant concentrations in drinking water samples collected under SDWA. EPA has determined that, for each contaminant or group of contaminants listed in section III of this preamble, the additional testing methods being approved in this action are as effective as one or more of the testing methods already approved in the regulations for those contaminants. Section 1401(1) of SDWA states that the newly approved methods "shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation." Accordingly, this action makes these additional two analytical methods legally available as options for meeting EPA's monitoring requirements.

This action does not add regulatory language, but does, for informational

purposes, update an appendix to the regulations at 40 CFR part 141 that lists all methods approved under section 1401(1) of SDWA. Accordingly, while this action is not a rule, it is updating CFR text and therefore is being published in the "Final Rules" section of the **Federal Register**.

III. Summary of Approvals

EPA is approving two methods that are equally effective relative to methods previously promulgated in the regulations. By means of this action, these two methods are added to appendix A to subpart C of 40 CFR part 141.

A. Methods Developed by EPA

1. EPA Method 537.1, Version 1.0. Determination of Selected Per- and Polyfluorinated Alkyl Substances (PFAS) in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) (USEPA 2018). The EPA's April 26, 2024, **Federal Register** publication for the PFAS National Primary Drinking Water Regulation (89 FR 32532) describes EPA Method 533 ("Determination of PFAS in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and LC/MS/MS," November 2019, 815–B–19–020) (USEPA 2019) and EPA Method 537.1, version 2.0 ("Determination of Selected PFAS in Drinking Water by Solid Phase Extraction and LC/MS/MS," March 2020, EPA/600/R–20/006) (USEPA 2020) as acceptable methods for the analyses specified by the National Primary Drinking Water Regulation.

The primary difference between Method 537.1, version 1.0 and Method 537.1, version 2.0 is the field reagent blank (FRB) preparation. Version 2.0 exposes the FRB to the preservative (Trizma) at the time of field sample collection, whereas version 1.0 combines the lab reagent water and the preservative together in the FRB prior to field sampling. Version 2.0 was created to more-closely mimic the FRB process used in Method 533. Additionally, version 2.0 specifies the use of solid phase extraction cartridge sorbents containing a styrene divinylbenzene polymeric sorbent phase that may not be modified with monomers other than SDVB. The method versions are otherwise identical.

EPA has determined that EPA Method 537.1, version 1.0 is equally effective relative to Method 537.1, version 2.0 for the purposes of the analyses specified in 40 CFR 141.902(b)(1) [*Monitoring requirements for PFAS—Initial monitoring*]. The basis for this

determination is discussed in Adams 2024a. Therefore, EPA is approving EPA Method 537.1, version 1.0 for determination of selected PFAS in drinking water to support initial monitoring required by the PFAS National Primary Drinking Water Regulation. EPA Method 537.1, version 1.0 is available at the National Service Center for Environmental Publications at <https://www.epa.gov/nscep>.

B. Methods Developed by Vendors

1. e-sens AMCD Method—e-sens, Inc. Automated Micro Chlorine Detection (AMCD) Method for the Determination of Residual Free and Total Chlorine in Water (e-sens, Inc. 2023a). e-sens AMCD Method uses a three-electrode electrochemical cell, comprised of a reference electrode, a platinum micro array working electrode, and a platinum counter electrode. The working electrode and the counter electrode are batch-produced on a silicon substrate, and the electrical outputs are processed by an onboard potentiostat. For free chlorine, after electrode conditioning, the embedded microfluidic system adds a precise amount of a concentrated phosphate buffer to each sample to adjust its ionic strength and pH. A standard voltammetry procedure is then invoked on the buffered sample and the faradaic current through the electrochemical cell is recorded. The current magnitude is proportional to the concentration of free chlorine in the sample. The recorded current response is fit to a calibration curve obtained upon manufacture of the sensor and the concentration of free chlorine is reported. For total chlorine, the free chlorine measurement is immediately followed by the total chlorine measurement. A new aliquot of sample is mixed with ammonium chloride, which instantly converts various chlorine species to monochloramine. A concentrated phosphate buffer is then added into the sample to disproportionate monochloramine to form dichloramine, which is readily reduced at the surface of the platinum working electrode. A standard voltammetry procedure is then invoked on the buffered sample and the faradaic current through the electrochemical cell is recorded. The current magnitude is proportional to the concentration of total chlorine in the sample. The recorded current response is fit to a calibration curve obtained upon manufacture of the sensor and the concentration of total chlorine is reported.

Approved methods for free and total chlorine are listed at 40 CFR 141.74(a)(2) and 141.131(c)(1). The

performance characteristics of e-sens AMCD Method were compared to the performance characteristics of the approved Standard Methods 4500-Cl G (APHA 2000). The validation study report (e-sens, Inc. 2023b) summarizes the results obtained from three different laboratories using three different ground water matrixes, and three different surface water matrixes collected from six different locations.

EPA has determined that e-sens AMCD Method is equally effective relative to Standard Methods 4500-Cl G. The basis for this determination is discussed in Adams 2024b. Therefore, EPA is approving the e-sens AMCD Method for determining free and total chlorine in drinking water. A copy of the method is available from e-sens, Inc., 630 Komas Dr., Ste 235, Salt Lake City, Utah 84108.

IV. Statutory and Executive Order Reviews

As noted in section II of this preamble, under the terms of SDWA section 1401(1), this streamlined method approval action is not a rule. Accordingly, the Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

Similarly, this action is not subject to the Regulatory Flexibility Act because it is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute. In addition, because this approval action is not a rule, but simply makes alternative testing methods available as options for monitoring under SDWA, EPA has concluded that other statutes and executive orders generally applicable to rulemaking do not apply to this approval action.

V. References

Adams, W. 2024a. Memo to the record describing basis for expedited approval of EPA Method 537.1, Version 1.0. December 5, 2024. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

Adams, W. 2024b. Memo to the record describing basis for expedited approval of e-sens Automated Micro Chlorine Detection Method November 26, 2024. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

American Public Health Association (APHA). 2000. Standard Methods 4500-Cl D, E, F, G, H, I-00. Chlorine (Residual). D. Amperometric Titration Method. E. Low-Level Amperometric Titration Method. F. DPD Ferrous Titrimetric Method. G. DPD Colorimetric Method. H. Syringaldehyde (FACTS) Method. I. Iodometric Electrode Technique. Approved by Standard Methods Committee 2000. Standard Methods Online (Available at <https://www.standardmethods.org>.)

USEPA. 2018. EPA Method 537.1, Version 1.0. Determination of Selected Per- and Polyfluorinated Alkyl Substances (PFAS) in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS). EPA/600/R-18/352. November 2018. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

USEPA. 2019. EPA Method 533. Determination of PFAS in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and LC/MS/MS. EPA 815-B-19-020. November 2019. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

USEPA. 2020. EPA Method 537.1, Version 2.0. Determination of Selected Per- and Polyfluorinated Alkyl Substances (PFAS) in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS). EPA/600/R-20/006. March 2020. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

e-sens, Inc. 2023a. e-sens AMCD Method. e-sens, Inc. Automated Micro Chlorine Detection (AMCD) Method for the Determination of Residual Free and Total Chlorine in Water. December 2023. (Available at <https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

e-sens, Inc. 2023b. Alternate Test Procedure Validation Study Report of e-sens, Inc. Automated Micro Chlorine Detection (AMCD) Method for the Determination of Residual Free and Total Chlorine in Water. December 2023. (Available at

<https://www.regulations.gov>; docket ID No. EPA-HQ-OW-2024-0603.)

List of Subjects in 40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Jennifer L. McLain,
Director, Office of Ground Water and Drinking Water.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 141 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

- 1. The authority citation for part 141 continues to read as follows:
Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.
- 2. Amend Appendix A to subpart C of Part 141 by:
 - a. In the table entitled “Alternative Testing Methods for Contaminants Listed at 40 CFR 141.74(a)(2)” revise the entries for “Free Chlorine” and “Total Chlorine”;
 - b. In the table entitled “Alternative Testing Methods for Contaminants Listed at 40 CFR 141.131(c)(1)” revise the entries for “Free Chlorine” and “Total Chlorine”;
 - c. Add the table entitled “Alternative Testing Methods for Contaminants Listed at 40 CFR 141.901(b)(1)” after the table entitled “Alternative Testing Methods for Contaminants Listed at 40 CFR 141.852(a)(5)” and before the table entitled “Alternative Testing Methods for Contaminants Listed at 40 CFR 143.4(b)”;
 - d. Add footnotes 69 and 70.

The revisions and additions read as follows:

Appendix A to Subpart C of Part 141—Alternative Testing Methods Approved for Analyses Under the Safe Drinking Water Act

* * * * *

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.74(a)(2)

Residual	Methodology	EPA methods	SM 21st edition ¹	SM 22nd edition, ²⁸ SM 23rd Edition, ⁴⁹ SM 24th edition ⁶⁶	ASTM ⁴	Other
Free Chlorine	Amperometric Titration		4500-Cl D	4500-Cl D	D 1253-08, -14.	
	DPD Ferrous Titrimetric		4500-Cl F	4500-Cl F		
	DPD Colorimetric		4500-Cl G	4500-Cl G		Hach Method 10260. ³¹
	Indophenol Colorimetric					Hach Method 10241. ³⁴
	Syringaldazine (FACTS)		4500-Cl H	4500-Cl H		
On-line Chlorine Analyzer		EPA 334.0 ¹⁶ .				

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.74(a)(2)—Continued

Residual	Methodology	EPA methods	SM 21st edition ¹	SM 22nd edition, ²⁸ SM 23rd Edition, ⁴⁹ SM 24th edition ⁶⁶	ASTM ⁴	Other
Total Chlorine	Amperometric Sensor					ChloroSense, ¹⁷ ChloroSense, Rev. 1.1, ⁵⁹ e- sens AMCD Method. ⁶⁹
	Amperometric Titration		4500-Cl D	4500-Cl D	D 1253-08, -14.	
	Amperometric Titration (Low level measurement)		4500-Cl E	4500-Cl E		
	DPD Ferrous Titrimetric		4500-Cl F	4500-Cl F		
	DPD Colorimetric		4500-Cl G	4500-Cl G		
	Indophenol Colorimetric	127 ⁵⁵ .				Hach Method 10260. ³¹
	Iodometric Electrode		4500-Cl I	4500-Cl I		
	On-line Chlorine Analyzer	EPA 334.0 ¹⁶ .				
	Amperometric Sensor					
						ChloroSense, ¹⁷ ChloroSense, Rev. 1.1, ⁵⁹ e- sens AMCD Method. ⁶⁹
*	*	*	*	*	*	*

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.131(c)(1)

Residual	Methodology	SM 21st edition ¹	SM 22nd edition, ²⁸ SM 23rd Edition, ⁴⁹ SM 24th edition ⁶⁶	ASTM ⁴	Other
Free Chlorine	Amperometric Titration ...	4500-Cl D	4500-Cl D	D 1253-08, -14.	
	DPD Ferrous Titrimetric	4500-Cl F	4500-Cl F		
	DPD Colorimetric	4500-Cl G	4500-Cl G		Hach Method 10260. ³¹ Hach Method 10241. ³⁴
	Indophenol Colorimetric				
	Syringaldazine (FACTS)	4500-Cl H	4500-Cl H		ChloroSense, ¹⁷ ChloroSense, Rev. 1.1, ⁵⁹ e-sens AMCD Method. ⁶⁹
	Amperometric Sensor				
	On-line Chlorine Ana- lyzer.				EPA 334.0. ¹⁶
*	*	*	*	*	*
Total Chlorine	Amperometric Titration ...	4500-Cl D	4500-Cl D	D 1253-08, -14.	
	Low level Amperometric Titration.	4500-Cl E	4500-Cl E		
	DPD Ferrous Titrimetric	4500-Cl F	4500-Cl F		Hach Method 10260. ³¹
	DPD Colorimetric	4500-Cl G	4500-Cl G		
	Iodometric Electrode	4500-Cl I	4500-Cl I		ChloroSense, ¹⁷ ChloroSense, Rev. 1.1, ⁵⁹ e-sens AMCD Method. ⁶⁹
	Amperometric Sensor				
	On-line Chlorine Ana- lyzer.				EPA 334.0. ¹⁶
*	*	*	*	*	*

ALTERNATIVE TESTING METHODS FOR INITIAL MONITORING ONLY OF CONTAMINANTS LISTED AT 40 CFR 141.901(b)(1)

Contaminant	Methodology	EPA method
Perfluorobutane Sulfonate (PFBS)	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰
Perfluorohexane Sulfonate (PFHxS)	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰
Perfluorononanoate (PFNA)	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰
Perfluorooctanesulfonic Acid (PFOS)	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰
Perfluorooctanoic Acid (PFOA)	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO-DA or GenX Chemicals).	SPE LC-MS/MS	537.1, version 1.0. ⁷⁰

¹ Standard Methods for the Examination of Water and Wastewater, 21st edition (2005). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001-3710.

⁴ Available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 or <http://astm.org>. The methods listed are the only alternative versions that may be used.

¹⁶ EPA Method 334.0. "Determination of Residual Chlorine in Drinking Water Using an On-line Chlorine Analyzer," September 2009. EPA 815-B-09-013. Available at <https://www.nemi.gov>.

¹⁷ ChloroSense. "Measurement of Free and Total Chlorine in Drinking Water by Palintest ChloroSense," August 2009. Available at <https://www.nemi.gov> or from Palintest Ltd, 1455 Jamike Avenue (Suite 100), Erlanger, KY 41018.

²⁸ *Standard Methods for the Examination of Water and Wastewater*, 22nd edition (2012). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001-3710.

³¹ Hach Company. "Hach Method 10260-Determination of Chlorinated Oxidants (Free and Total) in Water Using Disposable Planar Reagent-filled Cuvettes and Mesofluidic Channel Colorimetry," April 2013. 5600 Lindbergh Drive, P.O. Box 389, Loveland, CO 80539.

³⁴ Hach Company. "Hach Method 10241-Spectrophotometric Measurement of Free Chlorine (Cl₂) in Drinking Water," November 2015. Revision 1.2. 5600 Lindbergh Drive, P.O. Box 389, Loveland, CO 80539.

⁴⁹ *Standard Methods for the Examination of Water and Wastewater*, 23rd edition (2017). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001-3710.

⁵⁵ EPA Method 127. "Determination of Monochloramine Concentration in Drinking Water." January 2021. EPA 815-B-21-004. Available at the National Service Center for Environmental Publications at <https://www.epa.gov/nscep>.

⁵⁹ ChloroSense, Rev. 1.1. "Free and Total Chlorine in Drinking Water by Amperometry using Disposable Sensors." February 2020. Palintest Ltd, 400 Corporate Circle, Suite J, Golden, CO 80401.

⁶⁶ *Standard Methods for the Examination of Water and Wastewater*, 24th edition (2023). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001-3710.

⁶⁹ e-sens, Inc. "e-sens, Inc. Automated Micro Chlorine Detection (AMCD) Method for the Determination of Residual Free and Total Chlorine in Water." December 2023. Available from e-sens, Inc., 630 Komar Dr., Ste 235, Salt Lake City, Utah 84108.

⁷⁰ EPA Method 537.1, Version 1.0. "Determination of Selected Per- and Polyfluorinated Alkyl Substances (PFAS) in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)." November 2018. EPA/600/R-18/352. Approved as alternative testing method to support initial PFAS monitoring (for monitoring-frequency determinations) until April 26, 2027 as described at 40 CFR 141.902(b)(1) [Monitoring requirements for PFAS—Initial monitoring]. Available at the National Service Center for Environmental Publications at <https://www.epa.gov/nscep>.

[FR Doc. 2025-00464 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter 1

Mandatory Guidelines for Federal Workplace Drug Testing Programs—Authorized Testing Panels

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS)

ACTION: Issuance of authorized drug testing panels.

SUMMARY: The Department of Health and Human Services ("HHS" or "Department") herein publishes the panels of Schedule I and II drugs and biomarkers authorized for testing in Federal workplace drug testing programs. The Department has revised the drug testing panels for both urine and oral fluid, and revised required nomenclature for laboratory and Medical Review Officer Reports.

DATES: The authorized drug testing panels and required report nomenclature are effective July 7, 2025.

FOR FURTHER INFORMATION CONTACT: Eugene D. Hayes, Ph.D., MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276-1459 or by email at Eugene.Hayes@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: The drug testing panels in this Notification specify the analytes and cutoffs for Federal agency workplace drug testing specimens and the nomenclature (*i.e.*, analyte names and abbreviations) that must be used to report Federal workplace drug test results, in accordance with Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG, 88 FR 70768) and the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG, 88 FR 70814). Section 3.4 of Subpart C calls upon the Secretary of HHS (Secretary) to "publish the drug and biomarker test analytes and cutoffs (*i.e.*, the 'drug testing panel' and 'biomarker testing panel') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year," and make them available on the internet at <http://www.samhsa.gov/workplace>. Section 3.4 of the UrMG and the OFMG also requires HHS-certified laboratories, instrumented initial test facilities (IITFs, urine only), and Medical Review Officers (MROs) to use the nomenclature (*i.e.*, analyte names and abbreviations) published with the drug and biomarker testing panels to report Federal workplace drug test results.

This **Federal Register** Notification (FRN) contains only the drug testing panel because, to date, HHS has not approved any biomarker tests for use with Federal workplace drug testing specimens. The drug testing panels in Section 3.4 of the UrMG and OFMG will remain in effect until July 7, 2025.

Background

HHS, by the authority of section 503 of Public Law 100-71, 5 U.S.C., and Executive Order 12564, establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies. In addition, the Department specifies the drugs and biomarkers for which Federal employees may be tested. To facilitate timely analyte and cutoff changes based on the state of the science, the Department publishes the HHS authorized drug and biomarker testing panels separately from the Mandatory Guidelines.

Analyte changes are based on a thorough review of relevant information, including drug prevalence estimates, the current state of the science, laboratory capabilities, costs associated with the change, and benefits of the change to Federal agencies. To identify panel changes needed, the Department solicits review and input from subject matter experts such as Responsible Persons (RPs) of HHS-certified laboratories, Medical Review Officers (MROs), research scientists, and manufacturers of collection devices and/or immunoassay kits, as well as Federal partners such as the Department of Transportation (DOT), the Food and Drug Administration (FDA), the Department of Defense (DOD), and the Drug Enforcement Administration (DEA). The Department also seeks public comment to inform decisions related to analyte changes.

Using this process for recommending changes to the analyte table, the Department proposed the removal of methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDMA) and the addition of fentanyl in the notice for the December 5, 2023, Drug Testing Advisory Board (DTAB) meeting published in the November 17, 2023, **Federal Register**. The meeting notice included supporting information for the proposed changes and a request for public comment, along with the January 4, 2024, due date for public comments and the methods for comment submission. During the December 5th, 2023, DTAB meeting, the Department presented the basis for the proposed changes including technical and scientific support.

The Department received and reviewed 176 comments from 118 commenters. All comments were reviewed and taken into consideration in the preparation of draft final drug testing panels. During the DTAB meeting on March 5, 2024, the Department presented a summary of the public comments, along with additional supporting information for the proposed changes including workplace testing prevalence information, cost estimates and areas of agreement and concerns. The comments are available for public view on the SAMHSA website at <https://www.samhsa.gov/meetings/dtab-meeting-december-2023> and <https://www.samhsa.gov/meetings/dtab-meeting-march-2024>. During the June 4–5, 2024, DTAB meeting, the Department provided updated information on fentanyl positivity in workplace testing (urine and oral fluid). DTAB members agreed with the proposed changes.

The Department continued to assess the proposed testing panel changes and as described below, has decided not to remove MDMA and MDA from the urine and oral fluid drug testing panels at this time.

Summary of Public Comments and HHS's Response

The following provides the basis for the changes to nomenclature and the drug testing panel. The issues and concerns raised in public comments and HHS responses are set forth under each topic.

Nomenclature

For consistency and to avoid misinterpretation of test results, the UrMG and OFMG require HHS-certified test facilities and MROs to report results using the nomenclature (*i.e.*, analyte names and abbreviations) in the drug and biomarker testing panels published in the **Federal Register**.

The drug testing panel includes revised abbreviations for marijuana test analytes, consistent with current scientific nomenclature. The Department previously used the abbreviation THC for Δ-9-tetrahydrocannabinol and THCA for Δ-9-tetrahydrocannabinol-9-carboxylic acid. The new abbreviations are Δ9THC in place of THC and Δ9THCC in place of THCA. Including “Δ9” in these abbreviations distinguishes them from other compounds (*e.g.*, Δ-8-tetrahydrocannabinol-9-carboxylic acid and Δ-8-tetrahydrocannabinol). The revised abbreviation Δ9THCC also distinguishes this marijuana metabolite from Δ9-tetrahydrocannabinolic acid, a non-psychoactive cannabinoid in the cannabis plant that is also commonly abbreviated as THCA. This plant compound is an important precursor integral to the growth, definition, and production of legal hemp as defined by the US Department of Agriculture (USDA).^{1 2}

Drug Testing Panel

Note: Oral fluid cutoffs in the authorized drug testing panel are based on undiluted (neat) oral fluid.

Removed Drugs:

Methylenedioxyamphetamine (MDA) and Methylenedioxymethamphetamine (MDMA)

The Department proposed to remove MDA and MDMA from the drug testing panel because the number of positive specimens reported by HHS-certified laboratories did not seem to support testing all specimens for MDA and MDMA in Federal workplace drug testing programs. Information provided to the Department through the National Laboratory Certification Program (NLCP) in 2024 shows the MDMA positivity rate for the past three years (2021–2023) has been at or below 0.002% and a review of the results indicates that >25% of the positive specimens are likely agency blind samples. A further review of the NLCP data shows that almost 40% of MDMA positive urine specimens are also positive for another drug to include amphetamines (7%), benzoylcegonine (9%) and THC (21%), indicating that these specimens would be identified as drug positive by other means. MDMA accounts for only 0.28% of the drugs identified in exhibits submitted to crime laboratories. Tablets sold as MDMA on the street often do not contain MDMA and instead contain another phenethylamine compound such as dipentylone.^{3 4} In addition, the NLCP information shows that MDA has a significantly lower positivity rate

(0.00008% of tested specimens) than MDMA, with only six specimens identified as containing MDA without MDMA in 2023, and both analytes have lower positivity rates than phencyclidine (PCP). While PCP has an overall positivity rate nearly as low as MDMA, there are regional differences in the positivity of PCP in federally regulated and general workplace drug testing populations with some areas of the country having much higher rates, so the Department has determined that PCP remains a regulated test analyte.⁵

A total of 10 commenters addressed the removal of MDMA and MDA from the testing panel. Of these, four agreed with removal of these drugs, while six disagreed.

Four commenters who disagreed noted that, because drug testing deters use, MDMA and MDA use may increase after removal from the panel. Another commenter who disagreed with removal stated that growing interest in MDMA use for post-traumatic stress disorder and anxiety may lead to increased MDMA use. This commenter also noted that the National Survey on Drug Use and Health (NSDUH) showed adults' self-reported use of MDMA (*i.e.*, Ecstasy) was higher than for phencyclidine (PCP).⁶ A commenter who agreed with removal noted that SAMHSA might consider removing MDA and keeping MDMA on the testing panel with amphetamine and methamphetamine, based on current amphetamines immunoassay cross-reactivity to MDMA.

Three commenters stated that MDMA/MDA positivity rates in DOT-regulated programs have remained steady over time. One of these agreed with removal and had no safety concerns, while the other two commenters cited this as a reason for continuing to test these drugs.

The Department considered all comments and has decided that the removal of MDMA and MDA from the urine and oral fluid drug testing panels requires further study, and therefore, MDMA/MDA will not be removed from the drug testing panels at this time. The Department will continue to monitor MDMA/MDA prevalence and will engage with the DTAB and continue to assess the costs and benefits of removing one or both analytes in the future.

Added Drugs: Fentanyl and Norfentanyl

After declaring the opioid crisis, a public health emergency in 2017, former President Trump signed the SUPPORT for Patients and Communities Act (SUPPORT Act) into law on October 24, 2018. Section 8105 of the Fighting Opioid Abuse in Transportation Act,

included in the SUPPORT Act, required the Secretary to determine whether it is justified, based on the reliability and cost-effectiveness of testing, to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include fentanyl.⁷ Section 8105 additionally required the Secretary to consider whether to include any other drugs or other substances listed in Schedule I and II of Controlled Substances Act (CSA).⁸ Norfentanyl is a metabolite of fentanyl. Because it is also an immediate precursor used in the illicit manufacture of fentanyl, it is a Schedule II substance under the CSA.

Fentanyl was considered for inclusion in the proposed Mandatory Guidelines of May 2015. At that time, fentanyl was primarily found as a mixture with heroin. Because the heroin metabolite 6-acetylmorphine was already included in the Mandatory Guidelines, it was decided that the addition of fentanyl was not needed to identify fentanyl use. However, the illicit drug market and epidemiological data on drug use and overdose have changed since that time: fentanyl, primarily illicitly made fentanyl, is involved in a large percentage of overdose deaths in the United States and is therefore an important public safety concern.^{9 10} Furthermore, illicitly made fentanyl is increasingly used as a stand-alone substance among people who use drugs, not in conjunction with heroin and other substances.³ According to the National Forensic Laboratory Information System (NFLIS) 2022 Annual Report, fentanyl was the 3rd most frequently identified drug and accounted for 13.81% of all drugs reported by forensic laboratories.

The Department conducted studies to determine the prevalence of fentanyl in regulated drug testing specimens and examined the current state of the technology available to HHS-certified laboratories for initial and confirmatory testing of fentanyl and norfentanyl. A review of the literature was conducted to identify peer-reviewed publications that reported concentrations of fentanyl and/or norfentanyl in urine and oral fluid, to determine whether the current initial and confirmatory test technologies available in HHS-certified laboratories are appropriate for testing for fentanyl and/or norfentanyl and to assist in decisions regarding appropriate cutoff concentrations.

Fentanyl Prevalence

When the Department assessed fentanyl prevalence, two HHS-certified laboratories offered urine testing for fentanyl upon request of a Federal agency or an MRO. Data from the NLCP

included six laboratory-reported positive test results from 52 requests for fentanyl testing from January 1, 2017, through December 31, 2022. Three of the specimens were also positive for at least one other drug; two specimens were positive for Δ^9 THCC, and one was positive for other opioids (*i.e.*, hydrocodone, hydromorphone) in addition to fentanyl.

The Department also gathered information through a query of HHS-certified laboratories that perform fentanyl and norfentanyl testing (urine and/or oral fluid) for non-regulated clients (*e.g.*, workplace testing, compliance testing of healthcare providers) and through pulse testing studies (*i.e.*, retesting several deidentified federally regulated urine specimens using the laboratory's fentanyl and norfentanyl testing procedures). Based on information from non-regulated workplace drug testing and the pulse testing studies, it is estimated that approximately 0.27–0.37% of submitted Federal workplace urine specimens will screen positive during initial testing and 0.1 to 0.3% will confirm positive for fentanyl and/or its primary metabolite norfentanyl. Additionally, a recent pulse testing study showed that norfentanyl was 36% more prevalent than 6-acetylmorphine in specimens with a positive opiate initial test.

Of the total 118 commenters, 115 supported the addition of fentanyl to the authorized drug testing panels. Most commenters noted the prevalence of fentanyl use and overdoses, based on their professional or personal experience, and the threat to workplace and public safety, particularly in transportation industries. Of the three individuals who disagreed: one incorrectly stated that fentanyl would be detected and reported using current opioid tests for Federal agency urine specimens; one incorrectly indicated that fentanyl would only be detected within a few hours of use; and the third disagreed with any additional Federal regulations for truck drivers.

The Department considered all comments and has added fentanyl to the urine and oral fluid drug testing panels and added its metabolite norfentanyl to the urine drug testing panel. Until the effective date of the new drug testing panel, fentanyl and/or norfentanyl can be analyzed under the Mandatory Guidelines only upon request of a Federal agency for a reasonable suspicion or post-accident specimen or routinely with a waiver from the Secretary (in accordance with Section 3.2 of the UrMG and OFMG). A detailed discussion is provided below.

Fentanyl Analyte Selection and Cutoff Determination—Urine

Information provided by HHS-certified laboratories in 2023 indicated that a majority (84%) of the laboratories analyzed non-regulated workplace specimens for fentanyl and/or norfentanyl, and that all had the ability to analyze urine specimens for fentanyl with sufficiently sensitive detection limits using commercially available immunoassay kits and confirmatory test instrumentation commonly used in HHS-certified laboratories. The laboratories' initial test cutoffs ranged from 0.5 to 2 ng/mL for fentanyl and confirmatory test cutoffs for fentanyl and norfentanyl ranged from 0.5 to 2 ng/mL for fentanyl and 0.5 to 5 ng/mL for norfentanyl.

Fentanyl and norfentanyl prevalence and concentrations appear to vary considerably depending on the population studied and the applied cutoff. Laboratory data from non-regulated workplace drug testing are around 1% fentanyl positivity in urine. The median, mean and max fentanyl concentrations were 12.6 ng/mL, 257.5 ng/mL and 36,199 ng/mL, respectively. Norfentanyl concentrations were reported to be around 4 times higher than those of fentanyl.¹¹ A recent pulse testing study on regulated urine workplace specimens showed that norfentanyl concentrations were 5.5 times higher than fentanyl concentrations (median, Q1–Q3, 2.5–13.3 times higher).¹² The median fentanyl and norfentanyl concentrations were 159 and 1,521 ng/mL, respectively. In a large study of 1 million urine specimens conducted by healthcare professionals for routine care, the positivity rate for fentanyl was 1.4% (13,770 specimens) using cutoffs of 2 ng/mL for fentanyl and 8 ng/mL for norfentanyl.¹³ Using immunoassay screening and a GC–MS confirmatory test cutoff of 1 ng/mL, fentanyl was positive in 4.2% (458 specimens) of specimens among patients being treated for pain conditions.¹⁴ The median, mean, and range of fentanyl concentrations were 23 ng/mL, 87 ng/mL, and 1 to 2382 ng/mL, respectively. Another study of patients with chronic pain demonstrated that norfentanyl can be an important component of identifying people who use fentanyl when urine is the specimen matrix.¹⁵ The authors showed that including norfentanyl increased the number of positive specimens by 42% over analyzing for fentanyl alone. The fentanyl median, mean and range concentrations were 22 ng/mL, 59.2 ng/mL, and 0.5 to 596 ng/mL, respectively.

Norfentanyl median, mean and range concentrations were 25.5 ng/mL, 134 ng/mL, and 0.5 to 1,772 ng/mL, respectively. A study of 77,018 urine specimens from patients treated with fentanyl using a transdermal patch reported median and mean fentanyl concentration of 37 and 88 ng/mL.¹⁶ When comparing doses of 12 and 100 µg/h, the mean fentanyl concentration increased from 32 to 137 ng/mL, and the norfentanyl mean concentration increased from 176 to 695 ng/mL, illustrating the dose-response relationships.

Based on this information, the Department originally proposed a 1 ng/mL initial test cutoff for both fentanyl and norfentanyl in urine, with a 0.5 ng/mL confirmatory test cutoff for both analytes.

Ten commenters disagreed with adding norfentanyl as an initial test analyte for urine. Nine of these specifically disagreed with norfentanyl as an initial test analyte, noting that no current FDA-cleared immunoassay has sufficient cross-reactivity for fentanyl and norfentanyl to meet the program requirement for grouped analytes (*i.e.*, at least 80% cross-reactivity to the non-target analyte). One commenter suggested that the Department lower the cross-reactivity requirement to 5%, noting that norfentanyl is often at higher concentrations than fentanyl. One suggested including fentanyl as the initial test analyte and norfentanyl only as a confirmatory test analyte, noting it is a Schedule II drug because it is used in the synthesis of fentanyl, and is not a pharmacologically active metabolite or a separate drug of misuse.

Nine commenters addressed the proposed 1 ng/mL fentanyl initial test cutoff for urine. Of these, one agreed with the fentanyl cutoff, noting that current FDA-cleared immunoassays used for initial testing can meet this cutoff. Eight commenters disagreed, stating that a 1 ng/mL cutoff is beyond the limits of traditional immunoassay technologies, and that laboratories would not be able to meet the UrMG requirement for initial test controls targeted at 25% above and below the cutoff. One commenter suggested a lower cutoff (0.75 ng/mL) but did not provide supporting information. The Department notes that there is a commercial immunoassay at this cutoff.

Regarding the proposed confirmatory test analytes and cutoffs, one commenter agreed with testing both fentanyl and norfentanyl using the proposed 0.5 ng/mL cutoff. Two other commenters agreed with norfentanyl as a confirmatory test analyte but disagreed with the proposed cutoff. One of these

commenters provided 2022–2023 data from non-regulated drug testing showing that only 1.6% of specimens had results below 1.0 ng/mL, while more than 50% had results above 100 ng/mL for fentanyl and above 1000 ng/mL for norfentanyl. The commenter did not indicate the initial test cutoff(s) used for these specimens. An initial test cutoff of 1 or 2 ng/mL could explain the low percentage of confirmatory test results below 1 ng/mL.

One commenter disagreed with the proposed fentanyl cutoffs for both initial and confirmatory testing, stating the cutoffs were too low and would present legal challenges due to long elimination times in urine following fentanyl use. The commenter noted that there are no controlled studies in the literature on this topic. Concerns were based on a laboratory's reports of six cases involving norfentanyl >0.5 ng/mL for at least one month after self-reported cessation of fentanyl use, and two other studies indicating possible long elimination time based on positive results after self-reported cessation of fentanyl use by individuals with opioid use disorder.¹⁷

The Department considered all comments. Regarding initial test analyte selection, the Department agrees with commenters that, at the time of this writing, most commercial immunoassays for fentanyl in urine are calibrated to fentanyl and exhibit little cross-reactivity to norfentanyl. The Department is aware of one immunoassay for fentanyl that has 5–7% cross-reactivity to norfentanyl and another immunoassay for norfentanyl in urine with a 5 ng/mL cutoff (*i.e.*, above the cutoff specified in the drug testing panel). As detailed above, HHS-certified laboratory test information, the pulse testing study, and review of fentanyl and norfentanyl concentrations from other tested populations demonstrate the importance of testing for norfentanyl.

To facilitate implementation of fentanyl testing into Federal workplace drug testing programs, the Department has decided to include only fentanyl (not norfentanyl) as the sole initial test analyte for urine at a cutoff of 1 ng/mL and require a fentanyl immunoassay initial test to exhibit at least 5% cross-reactivity for norfentanyl. The Department also increased the proposed 0.5 ng/mL confirmatory test cutoffs to 1 ng/mL for both fentanyl and norfentanyl. These changes are consistent with the current initial and confirmatory test technologies already available in HHS-certified laboratories and detailed in the current scientific literature.

Fentanyl Analyte Selection and Cutoff Determination—Oral Fluid

Information provided by HHS-certified urine laboratories in 2023 indicated that 43% offered oral fluid testing to non-regulated workplace clients and that 71% of these laboratories offered testing for fentanyl. These laboratories indicated they had the ability to analyze oral fluid specimens for fentanyl with sufficiently sensitive detection limits using commercially available immunoassay kits and confirmatory test instrumentation commonly used in HHS-certified laboratories. The laboratories' initial test cutoffs ranged from 1 to 4 ng/mL for fentanyl and confirmatory test cutoffs for fentanyl ranged from 0.5 to 1 ng/mL for fentanyl.

Fentanyl has been detected in oral fluid in non-regulated workplace drug testing, patients receiving pain management, overdose cases, and driving under the influence of drugs (DUID) cases. Laboratory data from non-regulated workplace drug testing show around 4% fentanyl positivity in oral fluid. The median, mean and max fentanyl concentrations were 8.6 ng/mL, 55.7 ng/mL and 17,409 ng/mL, respectively.¹¹ The median norfentanyl concentration was 4.5 ng/mL. For DUID testing, cutoffs of 1 ng/mL for the initial test and 0.5 ng/mL for the confirmatory test have been recommended for fentanyl in oral fluid.¹⁸ In a study of people arrested for DUID, 59% of oral fluid specimens had concentrations above 20 ng/mL.¹⁹ In a large study, oral fluid specimens were collected from 6,441 patients receiving pain care and screened by immunoassay (1 ng/mL fentanyl cutoff) and confirmed by LC-MS/MS.²⁰ Of the collected specimens, 6.9% screened positive (443 specimens) and 98.4% of those (436 specimens) were confirmed positive. The fentanyl, median, mean, and range concentrations were, 6.6, 49.8, and 0.2 to 5,341.3 ng/mL, respectively. For the 148 confirmed positive norfentanyl specimens, the norfentanyl median, mean, and range concentrations were 1.6, 4.7, and 0.5 to 125 ng/mL, respectively. In a study of patients treated with buprenorphine, the prevalence of fentanyl in oral fluid was 2.9% (n=146) with a median concentration of 1.3 ng/mL (Q1–Q3, 0.4–10.4).²¹ In a study of patients wearing fentanyl patches (n=162), the median fentanyl concentration was around 5 ng/mL, range 0.012–38.4 ng/mL.²²

Based on this information and review of the scientific literature, the Department originally proposed fentanyl as the only analyte for oral

fluid, with a 1 ng/mL initial test cutoff and a 0.5 ng/mL confirmatory test cutoff.

Three commenters disagreed with testing fentanyl in oral fluid noting that, because there are no FDA-cleared immunoassays meeting program requirements, inclusion of fentanyl would delay implementation of oral fluid into Federal workplace drug testing programs. One of these commenters raised concern that the added burden and cost to develop and implement an alternate technology initial test (e.g., LC-MS/MS) would deter some laboratories from applying for oral fluid certification. Another commenter noted that, unless the regulatory process is streamlined, HHS will not be able to respond quickly to changes in drug use.

One commenter agreed with the proposed 1 ng/mL fentanyl initial test cutoff for oral fluid, while 10 commenters disagreed. Most commenters were concerned that the cutoff was too low, stating that oral fluid collection devices containing a buffer (i.e., diluting the oral fluid) would not be able to meet program analytical requirements (e.g., controls at 25% above and below the initial test cutoff). Many of the commenters indicated that a higher cutoff is supported by drug test results. One commenter suggested raising the cutoff: suggesting that the Department select a cutoff between 2 and 4 ng/mL. Two commenters requested research supporting the proposed 1 ng/mL initial test cutoff and 0.5 confirmatory test cutoff. This information is provided above. One commenter recommended a lower initial test cutoff (0.75 ng/mL) and a higher confirmatory cutoff (5 ng/mL), with no scientific support.

The Department has considered all comments and has decided to increase the initial test cutoff to 4 ng/mL and the confirmatory test cutoff for fentanyl to 1 ng/mL. Based on information provided by the public, review of the scientific literature, and current methods and technologies used for oral fluid drug testing, the Department has determined that these fentanyl cutoffs are appropriate for initial and confirmatory tests.

Revised Criteria for Grouped Analytes Using an Alternate Technology Initial Drug Test

The Department defines grouped initial test analytes as two or more analytes that are in the same drug class and have the same initial drug test cutoff. Footnote 1 of the drug testing panel specifies requirements for initial tests using immunoassay and those

using an alternate technology (e.g., liquid chromatography-tandem mass spectrometry, LC-MS/MS). The Department has revised Footnote 1 of the Section 3.4 tables in the UrMG and OFMG to include more specific and updated criteria for alternate technology initial drug tests, based on current technology and program experience.

For a technology other than immunoassay that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

Biomarker Testing Panel

Section 3.4 of the UrMG and OFMG call upon the Secretary to add biomarkers to the biomarker testing panel; however, at the time of this writing, no biomarkers have been approved for Federal workplace drug testing. The Department will review and approve biomarkers based on laboratory data and support from the scientific and medical literature and add them to the biomarker testing panel in a subsequent FRN.

A biomarker is defined in Section 1.5 of the UrMG and OFMG as "an endogenous substance used to validate a biological specimen". While creatinine in urine meets this definition, it is not sufficient as a sole analyte. The UrMG include requirements for testing both creatinine and specific gravity to report a specimen as dilute, invalid, or substituted.

Costs and Benefits

HHS-certified test facilities and MROs will incur initial costs for administrative and programming changes for the addition of fentanyl and/or norfentanyl.

Laboratories that already offer fentanyl and norfentanyl testing and use the same cutoff(s) for their non-regulated clients may experience some savings compared to laboratories that do not test for these analytes. Estimated costs for testing for fentanyl range from \$0.23 to \$5.00 (for initial testing) and \$8.00 to \$25.00 (for confirmatory testing) per specimen tested. Total laboratory costs for fentanyl confirmatory testing of Federal employee specimens are estimated to range from \$577–\$4,750. Based on the

number of tests performed on Federal employees, the added cost for fentanyl confirmatory testing will be \$0.0152 to \$0.125 per submitted specimen, and the total cost for adding fentanyl will range from \$9,317 to \$194,750, based on these estimates.

MROs may experience increased costs when an agency chooses to test their federal job applicants and employees for the added analytes, as fentanyl analytes are expected to have high positivity rates and, in addition, fentanyl is a Schedule II drug with approved therapeutic uses requiring the MRO to review potential medical explanations. Additional costs for testing and MRO review will be incorporated into the overall costs for the Federal agency submitting the specimen to the laboratory. Added costs to MROs would be expected to shift to Federal agencies over time, as existing contracts expire, and new contract terms are negotiated.

Currently, the Department does not require HHS-certified test facilities to implement authorized biomarker tests. Each laboratory and IITF should conduct their own cost analysis when deciding whether to offer biomarker testing to federally regulated clients. The Department will consider costs when deciding whether to require all certified test facilities to test for a specific biomarker.

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REPORT NOMENCLATURE—URINE

Urine	
Abbreviation	Analyte
Δ9THCC	Δ-9-tetrahydrocannabinol-9-carboxylic acid.
BZE	Benzoylecgonine.
COD	Codeine.
MOR	Morphine.
HYC	Hydrocodone.
HYM	Hydromorphone.
OXYC	Oxycodone.
OXYM	Oxymorphone.
6-AM	6-Acetylmorphine.
PCP	Phencyclidine.
FENT	Fentanyl.
NFENT	Norfentanyl.
AMP	Amphetamine.
MAMP	Methamphetamine.
MDMA	Methylenedioxymethamphetamine.
MDA	Methylenedioxyamphetamine.

HHS DRUG TESTING PANEL—URINE

Initial test analyte	Initial test cutoff ¹	Confirmatory test analyte	Confirmatory test cutoff
Marijuana metabolite (Δ9THCC)	50 ng/mL.	Δ9THCC	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL. ²	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2,000 ng/mL.	Codeine	2,000 ng/mL.
		Morphine	4,000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL.	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL.	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL.	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL.	Phencyclidine	25 ng/mL.
Fentanyl ³	1 ng/mL.	Fentanyl	1 ng/mL.
		Norfentanyl	1 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL.	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA/MDA	500 ng/mL.	Methylenedioxymethamphetamine	250 ng/mL.
		Methylenedioxyamphetamine	250 ng/mL.

¹ For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. For a technology that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

² *Alternate technology (BZE):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 100 ng/mL for benzoylecgonine).

³ A fentanyl immunoassay must have at least 5% cross-reactivity to norfentanyl.

HHS Biomarker Testing Panel—Urine

SAMHSA has not yet authorized routine testing for any biomarker in urine. HHS-certified laboratories and instrumented initial test facilities (ITFs) may request authorization to test Federal agency specimens for a biomarker upon Medical Review Officer (MRO) request by submitting supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval.

REPORT NOMENCLATURE—ORAL FLUID

Oral fluid	
Abbreviation	Analyte
Δ9THC	Δ-9-tetrahydrocannabinol.
COC	Cocaine.
BZE	Benzoylecgonine.
COD	Codeine.
MOR	Morphine.
HYC	Hydrocodone.
HYM	Hydromorphone.
OXYC	Oxycodone.
OXYM	Oxymorphone.
6-AM	6-Acetylmorphine.

REPORT NOMENCLATURE—ORAL FLUID—Continued

Oral fluid	
Abbreviation	Analyte
PCP	Phencyclidine.
FENT	Fentanyl.
AMP	Amphetamine.
MAMP	Methamphetamine.
MDMA	Methylenedioxymethamphetamine.
MDA	Methylenedioxyamphetamine.

HHS DRUG TESTING PANEL—ORAL FLUID

HHS drug testing panel—undiluted (neat) oral fluid			
Initial test analyte	Initial test cutoff ¹	Confirmatory test analyte	Confirmatory test cutoff
Marijuana (Δ9THC)	4 ng/mL.	Δ9THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL.	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL.	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL.	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL.	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL. ²	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL.	Phencyclidine	10 ng/mL.
Fentanyl	4 ng/mL.	Fentanyl	1 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL.	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA/MDA	50 ng/mL.	Methylenedioxymethamphetamine	25 ng/mL.
		Methylenedioxyamphetamine	25 ng/mL.

¹ For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. For a technology that measures a response from the entire group without differentiating between analytes (e.g., an activity-based assay, a mass spectrometric assay that does not differentiate isobaric compounds), the laboratory must compare the result to the initial test cutoff. In the case of an alternate technology that differentiates and quantifies each analyte in the group, the laboratory must compare each analyte's result to the confirmatory test cutoff and reflex specimens with a positive initial test result to confirmatory testing.

² *Alternate technology (6-AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for 6-AM).

HHS Biomarker Testing Panel—Oral Fluid

SAMHSA has not yet authorized routine testing for any biomarker in oral fluid. HHS-certified laboratories may request authorization to test Federal

agency specimens for a biomarker by submitting supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval. Authorized biomarker test

cutoffs for oral fluid will be based on undiluted (neat) oral fluid.

Xavier Becerra,
Secretary, Department of Health and Human Services.

[FR Doc. 2025–00425 Filed 1–15–25; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR**Office of the Secretary****43 CFR Part 8**

[Docket No. DOI-2024-0017; 256D0102DM, DS6CS00000, DLSN00000.000000, DX6CS25]

RIN 1093-AA29

Joint Policies of the Departments of the Interior and of the Army Relative to Reservoir Project Lands

AGENCY: Office of the Secretary, Interior.

ACTION: Direct final rule.

SUMMARY: We, the Department of the Interior (DOI), are revising regulations that govern DOI's internal real property acquisition policies for reservoir lands. This direct final rule adds a section to allow deviations for the acquisition of less than fee title realty interests in and around reservoirs owned by DOI and typically only those constructed before 1962, a relatively infrequent occurrence.

DATES: This direct final rule is effective April 16, 2025 without further action, unless significant adverse comment is received by March 17, 2025. If significant adverse comment is received, we will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number DOI-2024-0017. Follow the instructions for submitting comments.

- *By hard copy:* Submit by U.S. mail to U.S. Department of the Interior, Office of the Solicitor, 960 South Broadway, Suite 400, Boise, ID 83706, Attention: Jeremiah Williamson.

See Public Comments under **SUPPLEMENTARY INFORMATION** for more information about submitting comments.

FOR FURTHER INFORMATION CONTACT:

Jeremiah Williamson, Senior Attorney, jeremiah.williamson@sol.doi.gov, (208) 334-1915. 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:**Purpose of Direct Final Rule and Next Steps**

The purpose of this direct final rule is to revise 43 CFR part 8 by adding section 8.7, Interior Deviations, which solely establishes internal DOI policy for acquisition of certain reservoir realty interests. This revision is only a change in internal policy for a particular and relatively infrequent circumstance; namely, the acquisition of interests in realty in and around reservoirs owned by Interior and typically only those constructed before February 21, 1962, when the policies in 43 CFR part 8 first took effect. It allows future DOI acquisitions to be consistent with historical acquisition practices on existing reservoirs that differed from the policies in 43 CFR part 8.

We are publishing this rule without a prior proposal because this is a noncontroversial action relating to agency management that, in the best interest of the public, should be undertaken as quickly as possible. This rule will be effective, as published in this document, on the effective date specified above in the **DATES** section of this document, unless we receive significant adverse comments on or before the comment due date specified above in **DATES**. Significant adverse comments are comments that provide strong justification as to why our rule should not be adopted or why it should be changed.

If we receive significant adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date, and we will determine whether to engage in the normal rulemaking process to promulgate changes to 43 CFR part 8.

Public Comments

You may submit your comments regarding this direct final rule by one of the methods listed in **ADDRESSES**. Please include sufficient information with your comments that allows us to verify information you include. We will not consider comments sent by email or fax, or to an address not listed in **ADDRESSES**. We will not consider hand-delivered comments, or mailed comments that are not postmarked by the date specified in **DATES**.

We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us. Before including your address, phone number, email address, or other personal 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.

Comments we receive will be available for public inspection on the internet at <http://www.regulations.gov>. Please note that comments posted to <https://www.regulations.gov> are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publicly viewable until we post it, which might not occur until several days after submission.

Background

In 1962, DOI and the Department of the Army (Army) published in the **Federal Register** a joint policy requiring each Department to obtain fee simple title to lands acquired for reservoir inundation, specifically those lands “below the maximum flowage line of the reservoir.” The policy did not permit exceptions for lands lying within the “storage pool” of the reservoir. Four years later, DOI and Army promulgated a direct final rule (31 FR 9108, July 2, 1966) to codify this policy at 43 CFR part 8, *Joint Policies of the Departments of the Interior and of the Army Relative to Reservoir Project Lands*. Not long thereafter, in 1969, the Government Accounting Office, now known as the Government Accountability Office, published a report criticizing the policy, finding it had resulted in excessive Federal expenditures on unnecessary realty acquisitions; specifically acquisitions of fee simple title when “less costly flowage easements would have sufficed.” Elmer B. Staats, *Report to the Congress: Review of Policies and Practices for Acquiring Land for Reservoir Projects*, Government Accounting Office (Feb. 3, 1969), <https://www.gao.gov/assets/b-118634-087811.pdf>.

On January 15, 1979, the U.S. Army Corps of Engineers (Army Corps) promulgated a direct final rule at 32 CFR 644.4(b) (44 FR 3168) to revise Army's policy and treat the 43 CFR part 8 rule only as “guidelines.” In 2018, Congress directed the Army Corps to “first consider the minimum interest in real property necessary to support the water resources development project for which such interest is acquired,” including “a temporary easement or other interest designed to reduce the overall cost of the water resources development project for which such interest is acquired, reduce the time to complete such project, and minimize conflict with property owners related to

such project.” 33 U.S.C. 598a. The Army Corps’ Real Estate Handbook also treats the 43 CFR part 8 rule as guidelines and not mandatory. U.S. Army Corps of Engineers, Real Estate Handbook Ch. 12, sections 12–5, 12–9, and 12–12.

This direct final rule formalizes similar policy for DOI. This rule will allow DOI greater flexibility in its acquisition of realty interests for reservoir lands to account for site-specific circumstances that can warrant utilization of flowage easements, rather than fee simple title, where DOI determines it is in the best interests of the United States. Such site-specific circumstances can include, for example, new acquisition of realty interests in parcels on which DOI had previously acquired a less than fee title interest, such as a flowage easement. It will also allow for more consistency in Federal acquisition of reservoir lands. This flexibility is expected to accomplish similar goals that Congress sought for the Army Corps: namely, reductions in the cost and time to complete water resources development projects and minimization of conflicts with property owners.

Compliance With Other Laws, Executive Orders, and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the Nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 also directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

This rule will not have a significant regulatory effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it only governs internal DOI policy for acquisition of reservoir lands.

Congressional Review Act

The Congressional Review Act (CRA) defines a rule as major if it meets any of three criteria. The three criteria are:

(a) Does the rule have an annual effect on the economy of \$100 million or more?

(b) Will the rule cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions?

(c) Does the rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises?

This rule will not cause any of the aforementioned effects and thus is not a major rule under the CRA.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than \$200 million per year. This rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. This rule is not a government action capable of interfering with constitutionally protected property rights. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in Section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. It does not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation, and

(b) meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175)

The DOI strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under DOI’s consultation policy and under the criteria in Executive Order 13175 and have concluded it will have no substantial direct effects on any federally recognized 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, and that consultation is not required. Because, however, the rule will have the indirect effect of allowing the Cle Elum pool raise project in central Washington to proceed as planned, the Department has consulted informally with the Yakama Nation, whose views DOI has fully considered in this rule. No other potential indirect effects to any federally recognized Indian Tribes have been identified.

Paperwork Reduction Act of 1995

This rule does not contain information collection requirements and does not require a submission to the Office of Management and Budget under the Paperwork Reduction Act.

National Environmental Policy Act

This rule is categorically excluded from National Environmental Policy Act of 1969 (NEPA) under the DOI categorical exclusion codified at 43 CFR 46.210(i), which applies to “Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively, or case-by-case.” This rule establishes internal policy on DOI’s reservoir realty

acquisitions. The policy is administrative (how DOI chooses to own real property), financial (how much DOI expends for real property), and legal (how different property interests serve legal needs on individual reservoir projects). The type of realty interest DOI owns for reservoir inundation will not alter the effects resulting from inundation, which are subject to project specific NEPA analysis. While this rule could theoretically have negligible causally removed socioeconomic effects related to different opportunities available to owners of inundated parcels subject to flowage easements versus landowners who have relinquished title in a fee simple acquisition, any such potential effects are so intertwined with site specific conditions as to be too broad, speculative, and conjectural to support meaningful analysis. Those effects, if any, would be considered in project specific NEPA analysis in situations where this rule could apply.

Effects on the Energy Supply (Executive Order 13211)

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

List of Subjects in 43 CFR Part 8

Reservoir project lands, Acquisition of easements.

Promulgation of Direct Final Rule

For the reasons stated in the preamble, DOI is amending part 8 of title 43 of the CFR as set forth below:

PART 8—JOINT POLICIES OF THE DEPARTMENTS OF THE INTERIOR AND OF THE ARMY RELATIVE TO RESERVOIR PROJECT LANDS

- 1. The authority citation for part 8 continues to read as follows:

Authority: Sec. 7, 32 Stat. 389; sec. 14, 53 Stat. 1197; 43 U.S.C. 421, 389.

- 2. Add § 8.7 to read as follows:

§ 8.7 Interior deviations.

On Department of the Interior projects, a bureau director or secretarial officer may authorize acquisition of easements in lieu of fee title to property to allow reservoir inundation of lands if the acquisition meets a combined total of at least five conditions listed in § 8.3 and in this section:

- (a) The reservoir was originally constructed before February 21, 1962.
- (b) The current reservoir has utilized more than de minimis acquisition of easements for inundation.

- (c) The acquisition of less than fee title is in the best interests of the United States.

Joan M. Mooney,
*Principal Deputy Assistant Secretary
Exercising the Delegated Authority of the
Assistant Secretary—Policy, Management,
and Budget.*

[FR Doc. 2025–00510 Filed 1–15–25; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary of the Interior

43 CFR Part 10

**[NPS–WASO–NAGPRA–NPS0039273;
PPWOVPADUO/PPMPRL1Y.Y00000]**

RIN 1024–AE94

Civil Penalties Inflation Adjustments

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: This rule revises U.S. Department of the Interior (DOI) regulations implementing the Native American Graves Protection and Repatriation Act (NAGPRA) to provide for annual adjustments of civil penalties to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget guidance. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statute. This rule also updates the mailing address for the NAGPRA Program.

DATES: This rule is effective on January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Melanie O'Brien, Manager, National NAGPRA Program, (202) 354–2204, National Park Service, 1849 C Street NW, Washington, DC 20240. 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:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of

Pub. L. 114–74) (“the Act”). The Act requires Federal agencies to adjust the level of civil monetary penalties annually for inflation no later than January 15 of each year.

II. Calculation of Annual Adjustments

The Office of Management and Budget (OMB) recently issued guidance to assist Federal agencies in implementing the annual adjustments required by the Act which agencies must complete by January 15, 2025. *See* December 17, 2024, Memorandum for the Heads of Executive Departments and Agencies, from Shalanda D. Young, Director, Office of Management and Budget, re: *Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–25–02). The guidance states that the cost-of-living adjustment multiplier for 2025, based on the Consumer Price Index (CPI–U) for the month of October 2024, not seasonally adjusted, is 1.02598.

Annual inflation adjustments are based on the percent change between each published October’s CPI–U. In this case, October 2024 CPI–U (315.664)/October 2023 CPI–U (307.671) = 1.02598. The guidance instructs agencies to complete the 2025 annual adjustment by multiplying each applicable penalty by the amount, 1.02598, and rounding to the nearest dollar.

The annual adjustment applies to all civil monetary penalties with a dollar amount that are subject to the Act. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. This final rule adjusts the following civil monetary penalties contained in the DOI regulations implementing NAGPRA for 2025 by multiplying 1.02598 by each penalty amount as updated by the adjustment made in 2024:

¹ When DOI last updated the NAGPRA regulations to adjust the civil penalties on February 15, 2024 (89 FR 11740), it adjusted the daily civil penalty amounts in one of the two locations where they appear in 43 CFR 10.11. In order to accurately adjust the daily civil penalty amount in 43 CFR 10.11(m)(1) that was not updated in 2024, DOI is multiplying 1.02598 by the penalty amount that should be in the CFR had it been updated in 2024. The calculation therefore is \$1,664 multiplied by 1.02598 = \$1,707.

CFR citation	Description of the penalty	2024 Penalty	Annual adjustment (multiplier)	2025 Adjusted penalty
43 CFR 10.11(c)(1)	Failure of Museum to Comply	\$8,315	1.02598	\$8,531
43 CFR 10.11(g)(4)	Continued Failure to Comply Per Day	1,664	1.02598	1,707
43 CFR 10.11(m)(1)	Continued Failure to Comply Per Day	1,496	1.02598	¹ 1,707

Consistent with the Act, the adjusted penalty levels for 2025 will take effect immediately upon the effective date of the adjustment. The adjusted penalty levels for 2025 will apply to penalties assessed after that date including, if consistent with agency policy, assessments associated with violations that occurred on or after November 2, 2015. The Act does not, however, change previously assessed penalties that the Department is collecting or has collected. Nor does the Act change an agency's existing statutory authorities to adjust penalties.

In addition to adjusting the amount of civil penalties, this rule updates the NAGPRA regulations at 43 CFR 10.1(e)(2) to reflect the new address of the NAGPRA Program. This change is needed to provide the public with accurate information about where communications to the NAGPRA Program Manager may be sent if electronic submission is not possible.

III. Procedural Requirements

A. Compliance With Other Laws, Executive Orders, and Department Policy. Regulatory Planning and Review (Executive Orders 12866 and 13563 and 14094)

Executive Order (E.O.) 14094 amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866 and E.O. 13563. Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We developed this rule in a manner consistent with these requirements.

E.O. 12866, as reaffirmed by E.O. 13563 and amended and reaffirmed by E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA determined that this final rule is not significant.

B. Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The RFA does not apply to this final rule because the Office of the Secretary is not required to publish a proposed rule for the reasons explained below in section III.L.

C. Congressional Review Act

This rule is not a major rule under 5 U.S.C. 804(2), the Congressional Review Act. This rule:

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

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

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

D. Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*)

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

E. Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have taking implications under E.O. 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary

impact statement. A federalism summary impact statement is not required.

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

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department has evaluated this rule under its consultation policy and under the criteria in E.O. 13175 and has determined that the rule has no substantial direct effects on federally recognized Indian Tribes and that consultation under the Department's Tribal consultation policy is not required.

I. Paperwork Reduction Act

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

J. National Environmental Policy Act (NEPA)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative

nature. (For further information see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

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

This rule is not a significant energy action under the definition in E.O. 13211; the rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the rule has not otherwise been designated by the OIRA Administrator as a significant energy action. A statement of energy effects is not required.

L. Administrative Procedure Act

The Act requires agencies to publish annual inflation adjustments by no later than January 15 of each year, notwithstanding section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). OMB has interpreted this direction to mean that the usual procedure for rulemaking under the APA—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to civil penalties that the Act requires. Accordingly, we are issuing the 2025 annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**. Providing an opportunity for public comment and a delay in the effective date for changing the regulations to reflect the current mailing address of the NAGPRA Program Manager would be unnecessary and contrary to the public interest.

List of Subjects in 43 CFR Part 10

Administrative practice and procedure, Alaska, Cemeteries, Citizenship and naturalization, Colleges and universities, Hawaiian Natives, Historic preservation, Human remains, Indians, Indians—claims, Indians—law, Indians—lands, Museums, Penalties, Public lands, Reporting and recordkeeping requirements, Treaties.

For the reasons given in the preamble, the Office of the Secretary amends 43 CFR part 10 as follows:

PART 10—NATIVE AMERICAN GRAVES PROTECTION AND REPATRIATION REGULATIONS

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 25 U.S.C. 3001 *et seq.* and 25 U.S.C. 9.

§ 10.1 [Amended]

■ 2. In § 10.1, remove “7360” and add in its place “2343” in paragraph (e)(2).

§ 10.11 [Amended]

■ 3. In § 10.11:

- a. Remove “\$8,315” and add in its place “\$8,531” in paragraph (c)(1);
- b. Remove “\$1,664” and add in its place “\$1,707” in paragraph (g)(4); and
- c. Remove “\$1,496” and add in its place “\$1,707” in paragraph (m)(1).

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2025–00976 Filed 1–15–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH–2022–0002]

RIN 0925–AA69

Privacy Act; Implementation

AGENCY: National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or Department) is issuing this final rule to make effective the exemptions that were previously proposed for a new Privacy Act system of records, “NIH Police Records,” maintained by the National Institutes of Health (NIH), from certain requirements of the Act. The new system of records covers criminal and non-criminal law enforcement investigatory material maintained by the NIH Division of Police, a component of NIH which performs criminal law enforcement as its principal function. The exemptions are necessary and appropriate to protect the integrity of law enforcement proceedings and records compiled during the course of NIH Division of Police activities, prevent disclosure of investigative techniques, and protect the identity of confidential sources involved in those activities.

DATES: This final rule is effective February 18, 2025.

FOR FURTHER INFORMATION CONTACT: Dustin Close, Office of Management Assessment, National Institutes of Health, 6705 Rockledge Drive, Suite 601, Bethesda, Maryland 20892, telephone 301–402–6469, email privacy@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

HHS/NIH published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on June 7, 2024 (89 FR 48536), seeking notice and comment concerning proposed exemptions for a new system of records with respect to certain materials maintained by the NIH Division of Police. These proposals were made in accordance with the Privacy Act of 1974 (Privacy Act) and the Office of Management and Budget (OMB) Circular A–108, Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act. This new system of records was described in a System of Records Notice (SORN) that was published in the **Federal Register** (89 FR 48654) on the same day for notice and comment. A 60-day comment period was provided for both the NPRM and the SORN. The public comment period for both the NPRM and the SORN expired on August 6, 2024. One comment was received in response to the NPRM, and no comments were received in response to the SORN. The comment received in response to the NPRM supported the rulemaking action. HHS/NIH made no changes to the exemptions that were proposed in the NPRM or to the SORN in response to the public comment received. The NPRM, as published on June 7, 2024 (89 FR 48654), provided for the SORN to be effective upon publication of this final rule. Therefore, the SORN, as published on June 7, 2024 (89 FR 48654), is now effective.

II. Background on the NIH Police Division and New System of Records 09–25–0224

The NIH Division of Police, organizationally located within the Office of Research Services (ORS), Office of the Director, NIH, was established in 1968 to provide an immediate and primary law enforcement program for the NIH and derives its authority from Memorandum from the Assistant Secretary for Administration, Office of the Secretary (OS), to the Director, NIH, June 13, 1968, entitled: Delegation of Authority to Assist in Controlling Violations of Law at Certain HEW [Department of Health, Education, and Welfare] Facilities Located in Montgomery County, Maryland; 40 U.S.C. 1315 (Law enforcement authority of Secretary of Homeland Security for protection of public property; a Department of Homeland Security (DHS) delegation of authority to HHS/NIH; and an NIH delegation of authority to the NIH Division of Police); General

Administrative Delegation of Authority Number 08, Control of Violations of Law at Certain NIH Facilities (Sept. 1, 2020). Based on that establishing authority, the Division of Police performs criminal law enforcement as its principal function. However, the Division of Police conducts criminal, civil, administrative, and regulatory law enforcement investigations.

The NIH Division of Police is directly responsible for the provision of daily law enforcement and criminal and civil investigative activities required to protect the life, safety, and property of NIH employees, contractors, patients, and visitors at NIH. To perform these responsibilities, the NIH Division of Police compiles and maintains records of complaints of incidents, inquiries, investigative findings, arrest records, and court dispositions which are retrieved by personal identifiers and therefore constitute a “system of records” as defined by the Privacy Act at 5 U.S.C. 552a(a)(5). The primary purposes for which the records are used are to: (1) record incidents of crime, civil disturbance, and traffic accidents on the NIH enclave, and the investigation of such incidents; (2) maintain information essential to the protection of life, safety, and property at NIH; (3) provide official records of law enforcement investigative efforts for use in administrative, criminal and/or civil proceedings; and (4) document criminal and civil law enforcement investigations.

III. Eligible Records and Exemptions

The new system of records includes both criminal and non-criminal (*e.g.*, civil, administrative, regulatory) law enforcement investigatory records which will be retrieved by subject individuals’ personal identifiers. Such records are eligible to be exempted from certain Privacy Act requirements, as follows:

- Subsection (j)(2) of the Privacy Act (5 U.S.C. 552a(j)(2)) allows an agency head to exempt from certain Privacy Act provisions a system of records maintained by the agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws.
- Subsection (k)(2) of the Act (5 U.S.C. 552a(k)(2)) allows an agency head to exempt from certain Privacy Act provisions a system of records containing investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) (for example, material compiled for a civil, administrative, or regulatory law enforcement purpose, or material compiled for a criminal law

enforcement purpose by an agency component that does not perform criminal law enforcement as its principal function). This exemption’s effect on the subject individual’s access rights is qualified in that if any individual is denied any right, privilege, or benefit to or for which the individual otherwise would be entitled by Federal law, or for which the individual would otherwise be eligible, as a result of the maintenance of the system of records, the individual must be provided the requested materials except to the extent that disclosure would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

HHS/NIH is establishing the following exemptions for the records:

- Based on 5 U.S.C. 552a(k)(2), HHS/NIH is exempting non-criminal (*e.g.*, civil, administrative, regulatory) law enforcement investigatory material in System No. 09–25–0224 from the requirements in subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Privacy Act, which require the agency to provide an accounting of disclosures; provide notification, access, and amendment rights; maintain only relevant and necessary information authorized by a statute or Executive order; establish and describe procedures whereby an individual can be notified if a system of records contains information pertaining to that individual and how to gain access to pertinent records; identify categories of record sources; and promulgate rules regarding these procedures. The effect of this exemption on a subject individual’s access rights will be to permit withholding the records during an ongoing investigation, but limited as required by subsection (k)(2) to information that would reveal the identity of a source who was expressly promised confidentiality in cases in which maintenance of the records results in denial of a Federal right, privilege, or benefit to or for which the individual would otherwise be entitled or eligible.

- Based on subsection 5 U.S.C. 552a(j)(2), HHS/NIH is exempting criminal law enforcement investigatory material in System No. 09–25–0224 from the same requirements identified above, and from these additional subsections:

- (c)(4), requiring the agency to inform disclosure recipients of corrections and notations of dispute affecting disclosed records;
- (e)(2) and (3), requiring the agency to collect information directly from the subject individual to the greatest extent practicable and to provide a Privacy Act

notice to the individual at the time of collection;

- (e)(5), requiring the agency to maintain records used in agency determinations with sufficient accuracy, relevance, timeliness, and completeness to ensure fairness to individuals;
- (e)(8), requiring the agency to attempt to notify an individual when a record about the individual is disclosed under compulsory legal process; and
- (g), subjecting the agency to civil action and civil remedies for noncompliance with access, amendment, and accuracy, relevance, timeliness, and completeness requirements, and for noncompliance that adversely affects an individual.

Notwithstanding the establishment of these exemptions, individual record subjects may submit accounting, access, notification, and amendment requests, and HHS/NIH will consider such requests on a case-by-case basis. Only information that is not factually accurate, or is not relevant, timely, or complete may be contested.

In addition to the exemptions that HHS/NIH is establishing for system of records 09–25–0224 in this final rule, if any law enforcement investigatory material compiled in that system of records is from another system of records in which such material was exempted from access and other requirements of the Privacy Act based on 5 U.S.C. 552a(j)(2), NIH may claim the same exemptions in system of records 09–25–0224 on the same basis (*i.e.*, 5 U.S.C. 552a(j)(2)) and from the same requirements as in the source system from which they originated.

IV. Exemption Rationales

The following specific rationales explain why each exemption is necessary and appropriate for law enforcement investigation records maintained by the NIH Division of Police, in order to prevent interference with and protect the integrity of pending, closed, and future investigations, including related investigations. All subsections referenced are subsections of 5 U.S.C. 552a.

- Subsection (c)(3) (Provide Accountings of Disclosures). This exemption will apply to both criminal and non-criminal law enforcement investigatory material. Providing an accounting of disclosures to an individual record subject could reveal the existence of a pending or prior investigation or present or past investigative interest on the part of NIH or another agency. This would pose a serious impediment to law enforcement efforts and undermine the investigative

process by enabling a subject individual or others in concert with that individual to harass, intimidate, or collude with witnesses, destroy, conceal, or tamper with evidence, threaten or endanger law enforcement personnel, alter patterns of behavior, and avoid detection or apprehension by law enforcement authorities.

- Subsection (c)(4) (Inform Disclosure Recipients of Corrections and Notations of Dispute). This exemption applies to only criminal law enforcement investigatory material. Because system of records 09–25–0224 will be exempt from amendment requirements in subsection (d) and HHS/NIH's compliance with amendment requirements therefore will be voluntary, it is necessary and appropriate that HHS/NIH's compliance with the requirement in subsection (c)(4) be voluntary also. This will give HHS/NIH the flexibility to decide which cases warrant expending resources to meet those administratively burdensome requirements.

- Subsection (d)(1) through (4) (Provide Notification, Access, and Amendment Rights). These exemptions apply to both criminal and non-criminal law enforcement investigatory material. Providing subject individuals with the right to be notified of whether the system of records contains a record about them and to access and amend such records could reveal the existence of a pending or prior investigation or present or past investigative interest by NIH or another agency and details about the investigation, including identities of sources of information, personal information about third parties, and sensitive investigative techniques. This could impair pending and future investigations by chilling or deterring sources of information from providing information to investigators (particularly if they are not certain of its accuracy or fear retribution), by providing an opportunity for subject individuals and others acting in concert with subject individuals to tamper with witnesses or evidence, and by allowing individuals to alter their behavior to defeat investigative techniques and avoid detection or apprehension. Complying with amendment requirements could significantly delay investigations while attempts are made to resolve questions of accuracy, relevance, timeliness, and completeness and would impose an impossible administrative burden by requiring investigations to be continuously reinvestigated. In the case of criminal investigations, since the system of records will be exempt from having to maintain records that are accurate,

relevant, timely, and complete, the exemption from amendments seeking to correct to those standards is also appropriate.

- Subsection (e)(1) (Maintain Only Relevant and Necessary Information Authorized by Statute or Executive order). This exemption applies to both criminal and non-criminal law enforcement investigatory material. In the course of a law enforcement investigation, and especially in the early stages of an investigation, the relevance and necessity of information obtained or introduced may be unclear or the information may not be strictly relevant or necessary to a specific investigation but may lead to discovery of relevant information. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

- Subsections (e)(2) and (3) (Collect Information Directly From the Subject Individual to the Greatest Extent Practicable, and Provide a Privacy Act Notice). These exemptions apply to only criminal law enforcement investigatory material. It is not always practicable to collect information sought in a criminal law enforcement investigation directly from subject individuals. Individuals who could be adversely affected by an investigation may intentionally provide unreliable information to avoid being implicated in criminal activity. Questioning subject individuals and providing a Privacy Act notice to them (*i.e.*, informing them of the purposes for which information collected from them will be used and disclosed and how providing or not providing it could affect them), could inappropriately reveal the existence, nature, scope, and details of the investigation. This would provide an opportunity for the subject individual or others acting in concert with that individual to conceal evidence, alter patterns of behavior, or take other actions that could thwart investigative efforts; reveal the identity of witnesses in investigations, thereby providing an opportunity for the subjects of the investigations or others to harass, intimidate, or otherwise interfere with the collection of evidence or other information from such witnesses; or reveal the identity of confidential or other informants who provide information to investigators, which would negatively affect an informant's usefulness in any ongoing or future investigations and discourage members of the public from cooperating with future investigations.

- Subsections (e)(4)(G) and (H) (Describe Procedures for Notification, Access, and Amendment). These

exemptions apply to both criminal and non-criminal law enforcement investigatory material. Because system of records 09–25–0224 will be exempt from request requirements in subsection (d)(1) through (4) (Provide Notification, Access, and Amendment Rights) and HHS/NIH's compliance with those request requirements will therefore be voluntary, it is appropriate that HHS/NIH's compliance with the requirements in subsection (e)(4)(G) and (H) to provide request procedures be voluntary also. HHS/NIH has included request procedures in the SORN for system of records 09–25–0224 because, notwithstanding the exemptions, individual record subjects may submit access and amendment requests, and HHS/NIH will consider such requests on a case-by-case basis.

- Subsection (e)(4)(I) (Identify Categories of Record Sources in the SORN). This exemption applies to both criminal and non-criminal law enforcement investigatory material. Because the information in these records may come from any source, it is not possible to know every category in advance in order to include them all in the SORN. Further, some record source categories would not be appropriate to publish in the SORN if, for example, revealing them could thwart or impede pending and future law enforcement investigations by enabling record subjects or other individuals to discover sensitive investigative techniques and devise ways to bypass or defeat them to evade detection and apprehension.

- Subsection (e)(5) (Maintain Records Used in Agency Determinations with Sufficient Accuracy, Relevance, Timeliness, and Completeness to Ensure Fairness). This exemption applies to only criminal law enforcement investigatory material. It is not always possible to know whether criminal law enforcement investigation information is accurate, relevant, timely, and complete. With regard to relevance, in the course of a law enforcement investigation, and especially in the early stages of an investigation, the relevance of information obtained or introduced may be unclear or the information may not be strictly relevant to a specific investigation. Compliance with (e)(5) would preclude NIH agents from using their investigative training and exercise of good judgment to both conduct and report on investigations.

- Subsection (e)(8) (Make Reasonable Efforts to Provide Notice of Disclosures Made Under Compulsory Legal Process When Such Process Becomes A Matter of Public Record). This exemption applies to only criminal law enforcement investigatory material.

Compliance with this requirement would risk revealing an ongoing criminal investigation to the target of an investigation who otherwise might not be aware of it, defeating a law enforcement advantage in those cases. Compliance with this requirement would also risk revealing a criminal investigation by mistake or inappropriately in cases in which an investigation was not in fact a matter of public record or was not intended to be made public.

- Subsection (g) (Civil Liability for Noncompliance with Notification, Access, Amendment, and Accuracy, Relevance, Timeliness, and Completeness Requirements, or for Noncompliance That Causes an Adverse Effect). This exemption applies to only criminal law enforcement investigatory material. The exemption would prevent a subject individual from bringing a civil action against the agency for violations of Privacy Act requirements as to those records; this would include violations of the preceding requirements, from which the agency would be exempt anyway (which violations therefore would be unlikely to support a successful civil action), and any other violations causing an adverse effect on the individual. Any civil action (even an untenable one) could interfere with, delay, and undermine pending and prospective investigations, reveal sensitive investigative techniques and evidence, cause unwarranted invasions of personal privacy, and reveal identities of witnesses, potential witnesses, and confidential sources.

Subsection (f) (Promulgate Rules Regarding These Procedures). This exemption applies to both criminal and non-criminal law enforcement investigatory material provided however, that for investigative material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2), if any individual is denied any right, privilege, or benefit for which he or she would otherwise be eligible, as a result of the maintenance of these records, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence. Compliance with this requirement may help protect the agency from a claim regarding adequacy of or procedural objections to any relevant rules.

For the reasons stated, HHS/NIH believes that the exemptions authorized in 5 U.S.C. 552a(j)(2) and (k)(2) are essential to system of records 09–25–

0224 to prevent interference with and protect the integrity of all investigations concerning the NIH Division of Police. In NIH's past experience, not having these protections has led to the overall hinderance of law enforcement operations. These exemptions will help prevent such problems from recurring in the future.

Accordingly, HHS exempts both criminal and non-criminal law enforcement investigatory material in system of records 09–25–0224 NIH Police Records from the requirements in subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Privacy Act, based on 5 U.S.C. 552a(j)(2) and (k)(2), and exempts criminal law enforcement investigatory material in the same system of records from the additional requirements in subsections (c)(4), (e)(2) and (3), (e)(5), (e)(8), and (g) of the Privacy Act, based on 5 U.S.C. 552a(j)(2).

Regulatory Impact Analysis

I. Introduction

We examined the impacts of this rule under Executive Order 12866, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review; Executive Order 14094, Modernizing Regulatory Review; the Regulatory Flexibility Act (5 U.S.C. 601–612); the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the Paperwork Reduction Act of 1995 (44 U.S.C. 35–1 *et seq.*, and Executive Order 13132, Federalism.

II. Review Under Executive Orders 12866, 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled “Modernizing Regulatory Review” amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment,

public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is “not significant” under section 3(f) and does not meet the criteria set forth in 5 U.S.C. 804(2) under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Thus, an RIA is unnecessary.

This rule renders certain Privacy Act requirements inapplicable to certain records (in this case, law enforcement investigatory records) in accordance with criteria established in the Privacy Act based on a showing that agency compliance with those requirements with respect to those records would harm the effectiveness or integrity of the agency function or process for which the records are maintained (in this case, law enforcement investigations). However, OMB has reviewed this regulation under its Privacy Act oversight authority.

III. Review Under the Regulatory Flexibility Act (5 U.S.C. 601–612)

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule concerns records about individuals, it imposes no duties or obligations on small entities; the agency therefore certifies that the rule will not have a significant economic impact on a substantial number of small entities.

IV. Review Under the Unfunded Mandates Reform Act of 1995 (Section 202, Pub. L. 104–4)

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and

benefits, before 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 inflation-adjusted statutory threshold is approximately \$156 million based on the Bureau of Labor Statistics inflation calculator. The agency does not expect this rule will result in any one-year expenditure that would meet or exceed this amount.

V. Review Under the Paperwork Reduction Act of 1995 (44 U.S.C. 35–1 et seq.)

This rule does not contain any information collection requirements subject to the Paperwork Reduction Act.

VI. Review Under Executive Order 13132, Federalism

This rule will not have any direct effects on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, no federalism assessment is required.

List of Subjects in 45 CFR Part 5b

Privacy.

For the reasons set out in the preamble, the Department of Health and Human Services amends 45 CFR part 5b as follows:

PART 5B—PRIVACY ACT REGULATIONS

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

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

■ 2. Amend § 5b.11 by adding paragraph (b)(2)(ix) to read as follows:

§ 5b.11 Exempt systems.

* * * * *

(b) * * *

(2) * * *

(ix) Pursuant to subsections (j)(2) and (k)(2) of the Act:

(A) *NIH Police Records, 09–25–0224*. (All law enforcement investigatory records are exempt from subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Act; criminal law enforcement investigatory records are exempt from additional subsections (c)(4), (e)(2) and (3), (e)(5), (e)(8), and (g); the access exemption for non-criminal law enforcement investigatory records is limited as provided in subsection (k)(2).)

(B) [Reserved]

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–00670 Filed 1–15–25; 8:45 am]

BILLING CODE 4150–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 831

[Docket No.: NTSB–2025–0001]

RIN 3147–AA33

Civil Monetary Penalty Annual Inflation Adjustment

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, this final rule provides the 2025 adjustment to the civil penalties that the agency may assess for violations of certain NTSB statutes and regulations.

DATES: This final rule is effective January 16, 2025.

ADDRESSES: A copy of this final rule, published in the **Federal Register** (FR), is available at <https://www.regulations.gov> (Docket ID Number NTSB–2025–0001).

FOR FURTHER INFORMATION CONTACT: William Thomas (Tom) McMurry, Jr., General Counsel, (202) 314–6080 or rulemaking@ntsb.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) requires, in pertinent part, agencies to make an annual adjustment for inflation by January 15th every year. OMB, M–16–06, *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (Feb. 24, 2016). The Office of Management and Budget (OMB) annually publishes guidance on the adjustment multiplier to assist agencies in calculating the mandatory annual adjustments for inflation.

The NTSB’s most recent adjustment was for fiscal year (FY) 2024, allowing the agency to impose a civil penalty up to \$2,058, effective January 9, 2024 for violations involving 49 U.S.C. 1132 (Civil aircraft accident investigations), 1134(b) (Inspection, testing, preservation, and moving of aircraft and

parts), 1134(f)(1) (Autopsies), or 1136(g) (Prohibited actions when providing assistance to families of passengers involved in aircraft accidents). Civil Monetary Penalty Annual Inflation Adjustment, 89 FR 1035 (Jan. 9, 2024).

OMB has since published updated guidance for FY 2024. OMB, M–25–02, *Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (Dec. 17, 2024). Accordingly, this final rule reflects the NTSB’s 2025 annual inflation adjustment and updates the maximum civil penalty from \$2,058 to \$2,111.

II. The 2025 Annual Adjustment

The 2025 annual adjustment is calculated by multiplying the applicable maximum civil penalty amount by the cost-of-living adjustment multiplier, which is based on the Consumer Price Index and rounding to the nearest dollar. OMB, M–25–02, *Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (Dec. 17, 2024). For FY 2025, OMB’s guidance states that the cost-of-living adjustment multiplier is 1.02598.

Accordingly, multiplying the current penalty of \$2,058 by 1.02598 equals \$2,111.46684 which rounded to the nearest dollar equals \$2,111. This updated maximum penalty for the upcoming fiscal year applies only to civil penalties assessed after the effective date of this final rule. The next civil penalty adjustment for inflation will be calculated by January 15, 2026.

III. Regulatory Analysis

The Office of Information and Regulatory Affairs has determined that agency regulations that exclusively implement the annual adjustment are consistent with OMB’s annual guidance, and have an annual impact of less than \$200 million are generally not significant regulatory actions under Executive Order (E.O.) 12866. OMB, M–23–05, *Implementation of Penalty Inflation Adjustments for 2024, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (Dec. 19, 2023). Thus, an assessment of its potential costs and benefits under E.O. 12866, *Regulatory Planning and Review* and E.O. 13563, *Improving Regulation and Regulatory Review* is not required because this final rule is not a “significant regulatory action.” Likewise, this rule does not require analysis under the Unfunded Mandates Reform Act of 1995 because this final rule is not significant.

The Regulatory Flexibility Act (5 U.S.C. 801 *et seq.*) requires each agency to review its rulemaking to assess the potential impact on small entities, unless the agency determines a rule is not expected to have a significant economic impact on a substantial number of small entities. In accordance with 5 U.S.C. 605(b), the NTSB certifies that the final rule will not have a significant economic impact on a substantial number of small entities; only those entities that are determined to have violated Federal law and regulations would be affected by the increase in penalties made by this rule.

This final rule complies with all applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988 “Civil Justice Reform,” to minimize litigation, eliminate ambiguity, and reduce burden. In addition, the NTSB has evaluated this rule under E.O. 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights”; and E.O. 13045, “Protection of Children from Environmental Health Risks and Safety Risks.”

The NTSB does not anticipate this rule will have a substantial direct effect

on state government or will preempt state law. Accordingly, this rule does not have implications for federalism under E.O. 13132, *Federalism*.

The NTSB also evaluated this rule under E.O. 13175, *Consultation and Coordination with Indian Tribal Governments*. The agency has concluded that this final rule will 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.

The Paperwork Reduction Act of 1995 is inapplicable because the final rule imposes no new information reporting or recordkeeping necessitating clearance by OMB.

The NTSB has concluded that this final rule neither violates nor requires further consideration under the aforementioned Executive Orders and acts.

List of Subjects in 49 CFR Part 831

Aircraft accidents, Aircraft incidents, Aviation safety, Hazardous materials transportation, Highway safety,

Investigations, Marine safety, Pipeline safety, Railroad safety.

Accordingly, for the reasons stated in the preamble, the NTSB amends 49 CFR part 831 as follows:

PART 831—INVESTIGATION PROCEDURES

- 1. The authority citation for part 831 continues to read as follows:

Authority: 49 U.S.C. 1113(f).

Section 831.15 also issued under Pub. L. 101–410, 104 Stat. 890, amended by Pub. L. 114–74, sec. 701, 129 Stat. 584 (28 U.S.C. 2461 note).

§ 831.15 [Amended]

- 2. Amend § 831.15 by removing the dollar amount “\$2,058” and adding in its place “\$2,111”.

William T. McMurtry, Jr.,

General Counsel.

[FR Doc. 2025–00835 Filed 1–15–25; 8:45 am]

BILLING CODE 7533–01–P

Proposed Rules

Federal Register

Vol. 90, No. 10

Thursday, January 16, 2025

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

9 CFR Part 201

[Doc. No. AMS–FTPP–21–0046]

RIN 0581–AE04

Fair and Competitive Livestock and Poultry Markets

AGENCY: Agricultural Marketing Service, Department of Agriculture.

ACTION: Withdrawal of proposed rulemaking and termination of rulemaking proceeding.

SUMMARY: The United States Department of Agriculture’s (“USDA” or “the Department”) Agricultural Marketing Service (“AMS” or “the Agency”) is withdrawing a notice of proposed rulemaking, the “Fair and Competitive Livestock and Poultry Markets” proposed rule.

ADDRESSES: Packers and Stockyards Division, USDA, AMS, FTPP; Room 2097–S, Mail Stop 3601, 1400 Independence Ave. SW, Washington, DC 20250–3601.

DATES: The proposed rule published on June 28, 2024, 89 FR 53886, is withdrawn on January 16, 2025.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, USDA AMS Fair Trade Practices Program, 1400 Independence Ave. SW, Washington, DC 20250; Phone: (202) 690–4355; or email: s.brett.offutt@usda.gov.

SUPPLEMENTARY INFORMATION: On June 28, 2024, AMS published the proposed rule entitled, “Fair and Competitive Livestock and Poultry Markets,” which sought to amend 9 CFR part 201 by adding § 201.308, “Unfair practices and devices,” to specify general practices that are unfair and in violation of section 202(a) of the Packers and Stockyards Act, 1921 (“P&S Act”). The proposed rule defined unfair conduct to include harms to market participants

and harms to the market. Regarding harm to market participants, proposed § 201.308(a) defined unfair practices with respect to market participants and proposed § 201.308(b) set forth standards for assessing whether an allegedly unfair practice under proposed § 201.308(a) causes or was likely to cause substantial injury with respect to market participants. Regarding harm to markets, proposed § 201.308(c) set standards for the unfair practices with respect to markets and competition and proposed § 201.308(d) set forth standards for assessing whether a practice poses or was likely to pose a threat to competition under proposed paragraph (c).

AMS received 13,241 public comments (some single comments including hundreds of signatories) on the proposed rule during the 75-day comment period, which closed on September 11, 2024. Of the comments received, 352 submissions were unique and 12,889 were part of several form letter campaigns. These comments were submitted or signed by producers, processors, industry trade organizations, farmers’ coalitions, advocacy organizations, government entities, and a variety of other interested parties. Topics that garnered considerable attention in the comments—positive and negative—included questions of legality and authority surrounding the proposed rule, potential impacts to the market and market participants, potential economic impacts of the proposed rule, potential changes to and ramifications of legitimate business justifications, and countervailing benefits.

Withdrawal of the Notice of Proposed Rulemaking and Termination of the Rulemaking Proceeding

While AMS continues to support the intent and purpose of the proposed rule to increase competition and clarify the unfair practices prohibited under the P&S Act, based on the considerable feedback we received through the public comment process, we have determined it appropriate to withdraw the proposed rule. AMS believes that withdrawing the rule both preserves its ability to re-examine these important issues in the future and enables the Agency to explore with stakeholders regarding how best to implement the requirements of the P&S Act.

Although this proposal is being withdrawn, AMS continues to support the intent and purpose of the proposed rule. Notably, the Department is not withdrawing this proposed rule and terminating this rulemaking proceeding based upon a change in agency interpretation of its authority under section 202(a) or 407 of the P&S Act. Nor should the withdrawal of this proposed rule be read to affect any other existing legal requirements or policies of the Department. This withdrawal action does not affect AMS’ ongoing application of existing statutory and regulatory requirements or its responsibility to faithfully administer the P&S Act on a case-by-case basis.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2025–00534 Filed 1–15–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2453; Airspace Docket No. 24–ANE–8]

RIN 2120–AA66

Establishment of Class E Airspace; North Conway, NH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Memorial Hospital Heliport, North Conway, NH. This action would accommodate a new instrument approach procedure for Memorial Hospital Heliport, North Conway, NH. **DATES:** Comments must be received on or before March 3, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2453 and Airspace Docket No. 24–ANE–8 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Docket Operations, M–30; U.S. Department of Transportation, 1200

New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

FAA Order JO 7400.11J Airspace Designations and Reporting Points and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Rachel Cruz, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305-5571.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory,

aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edits, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the

current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. These updates will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 6-mile radius of Memorial Hospital Heliport, North Conway, NH. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11], Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ANE NH E5 North Conway, NH [New]

Memorial Hospital Heliport, North Conway, NH

(Lat. 44°03'45" N, long. 71°08'14" W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Memorial Hospital Heliport, North Conway, NH.

* * * * *

Issued in College Park, Georgia, on January 8, 2025.

Patrick Young,

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

[FR Doc. 2025–00629 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2025–0062; Airspace Docket No. 25–AEA–1]

RIN 2120–AA66

Amendment of Class E Airspace; Beckley, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Beckley, WV. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Beckley very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operational Network (MON) Program. This action will bring the airspace into compliance

with FAA orders and support instrument flight rule (IFR) procedures and operations.

DATES: Comments must be received on or before March 3, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2025–0062 and Airspace Docket No. 25–AEA–1 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instruction for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11], Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that

section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E surface airspace and Class E airspace extending upward from 700 feet above the surface at Raleigh County Memorial Airport, Beckley, WV, to support IFR operations at this airport.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post these comments, without edit, including any personal information the commenter provides, to www.regulations.gov as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in

person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraphs 6002 and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Modifying the Class E surface airspace at Raleigh County Memorial Airport, Beckley, WV, by removing the Beckley VORTAC and all associated extensions from the airspace legal description; adding an extension within 1 mile each side of the 007° bearing from the Raleigh County MEML: RWY 19–LOC extending from the 4.3-mile radius to 5.2 miles north of the Raleigh County MEML: RWY 19–LOC; adding an extension within 1 mile each side of the 008° bearing from the airport extending from the 4.3-mile radius to 4.9 miles north of the airport; adding an extension 1 mile each side of the 048° bearing from the airport extending from the 4.3-mile radius to 5 miles northeast of the airport; and adding an extension 1 mile each side of the 187° bearing from the airport extending from the 4.3-mile radius to 5.1 miles south of the airport;

And modify the Class E airspace extending upward from 700 feet above the surface to within a 6.8-mile (reduced from a 7-mile) radius of Raleigh County Memorial Airport; removing the Beckley VORTAC and associated extensions from the airspace legal description; adding an extension 2 miles each side of the 048° bearing from the airport extending from the 6.8-mile radius to 8.9 miles northeast of the airport; and adding an extension 2 miles each side of the 187° bearing from the airport

extending from the 6.8-mile radius to 8.8 miles south of the airport.

This action is the result of an airspace review conducted as part of the decommissioning of the Beckley VOR as part of the VOR MON Program and to support IFR operations at this airport.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AEA WV E2 Beckley, WV [Amended]

Raleigh County Memorial Airport, WV

(Lat 37°47′14″ N, long 81°07′27″ W)

Raleigh County MEML: RWY 19–LOC

(Lat 37°46′42″ N, long 81°07′36″ W)

Within a 4.3-mile radius of Raleigh County Memorial Airport; and within 1 mile each side of the 007° bearing from the Raleigh County MEML: RWY 19–LOC extending from the 4.3-mile radius to 5.2 miles north of the Raleigh County MEML: RWY 19–LOC; and within 1 mile each side of the 008° bearing from the airport extending from the 4.3-mile radius to 4.9 miles north of the airport; and within 1 mile each side of the 048° bearing from the airport extending from the 4.3-mile radius to 5 miles northeast of the airport; and within 1 mile each side of the 187° bearing from the airport extending from the 4.3-mile radius to 5.1 miles south of the airport.

* * * * *

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

* * * * *

AEA WV E5 Beckley, WV [Amended]

Raleigh County Memorial Airport, WV

(Lat 37°47′14″ N, long 81°07′27″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Raleigh County Memorial Airport; and within 2 miles each side of the 048° bearing from the airport extending from the 6.8-mile radius to 8.9 miles northeast of the airport; and within 2 miles each side of the 187° bearing from the airport extending from the 6.8-mile radius to 8.8 miles south of the airport.

* * * * *

Issued in Fort Worth, Texas, on January 13, 2025.

Martin A. Skinner,

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

[FR Doc. 2025–00972 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2710; Airspace
Docket No. 24–ASO–36]

RIN 2120–AA66

Establishment of Class E Airspace; Sunbury, NC

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Sunbury, NC, by adding airspace for Sunbury Fire Department Heliport, Sunbury, NC. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this heliport.

DATES: Comments must be received on or before March 3, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2710 and Airspace Docket No. 24–ASO–36 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

FAA Order JO 7400.11J Airspace Designations and Reporting Points and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Marc Ellerbee, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–5589.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator.

Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend Class E airspace in Sunbury, NC.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edits, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to establish Class E airspace by adding airspace extending upward from 700 feet above the surface within a 6-mile radius of the Sunbury Fire Department Heliport, Sunbury, NC. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ASO NC E5 Sunbury, NC [New]

Sunbury Fire Department Heliport
(Lat. 36°26′16″ N, long. 76°36′29″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Sunbury Fire Department Heliport.

* * * * *

Issued in College Park, Georgia, on January 7, 2025.

Patrick Young,

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

[FR Doc. 2025–00503 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2455; Airspace Docket No. 24–ANM–98]

RIN 2120–AA66

Modification & Establishment of Class E Airspace; Cortez Municipal Airport, Cortez, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace designated as a surface area, modify the Class E airspace extending upward from 700 feet above the surface, and establish Class E airspace designated as an extension to a Class E surface area at Cortez Municipal Airport, Cortez, CO. Additionally, this action proposes administrative amendments to update the airport’s legal descriptions. These actions would support the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before March 3, 2025.

ADDRESSES: Send comments identified by FAA Docket No. [FAA–2024–2455] and Airspace Docket No. [24–ANM–98] using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and

subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT:

Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is

possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

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

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

Incorporation by Reference

Class E2, E4, and E5 airspace designations are published in paragraphs 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024 and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would modify the Class E airspace designated as a surface area, modify the Class E airspace extending upward from 700 feet above the surface, and establish Class E airspace designated as an extension to a

Class E surface area at Cortez Municipal Airport, Cortez, CO.

The radius of the Class E airspace designated as a surface area should be widened by a half mile to better contain arriving IFR aircraft when less than 1,000 feet above the surface when conducting circling maneuvers or when executing the area navigation (RNAV) (Global Positioning System [GPS]) Runway (RWY) 3 approach, and aircraft conducting the missed approach portions of the Very High Frequency Omnidirectional Range (VOR) RWY 3, RNAV (GPS) Y RWY 21, and RNAV (GPS) Z RWY 21 approaches until reaching the next adjacent airspace. Furthermore, the Class E surface area should be extended .8 miles to the northeast to laterally contain IFR departure operations while between the surface and the base of adjacent controlled airspace when executing the LEDVE RWY 3 or CORTEZ TWO RWY 3 departure procedures. Moreover, the Class E surface area should be extended 2.4 miles to the southwest to laterally contain IFR departure operations while between the surface and the base of adjacent controlled airspace when executing the LEDVE RWY 21 or CORTEZ TWO RWY 21 departure procedures. Finally, the northern leg of the Class E surface area no longer serves the purpose of containment and should be removed.

An extension to the Class E surface area measuring approximately 8 x 8 miles should be established to the northeast, as the Class E surface area does not fully contain arriving IFR aircraft when less than 1,000 feet above the surface when executing the RNAV (GPS) Y RWY 21 or RNAV (GPS) Z RWY 21 approaches. An extension to the Class E surface area would contain these operations more appropriately without imposing a 2-way radio communication requirement.

The central radius of the Class E airspace extending upward from 700 feet above the surface should be reduced from 7 miles to 6.1 miles, as there are portions of the airspace to the southeast and west that do not provide procedural containment. Secondly, the northern extension of the Class E airspace extending upward from 700 feet above the surface should be widened by 6 miles and re-aligned to the northeast, which would better contain arriving IFR operations below 1,500 feet above the surface when executing the RNAV (GPS) Y RWY 21 or RNAV (GPS) Z RWY 21 approaches. The Class E airspace extending upward from 700 feet above the surface should be extended to the southwest to contain aircraft more appropriately until reaching 1,200 feet

above the surface when executing the CORTEZ TWO RWY 21 or LEDVE ONE RWY 21 departure procedures, or the missed approach portion of the RNAV (GPS) Z RWY 21 approach until reaching 1,200 feet above the surface. Lastly, the Class E airspace extending upward from 700 feet above the surface should be extended 1.8 miles to the north-northwest of the airport to better contain aircraft executing the missed approach portion of the RNAV (GPS) Y RWY 21 approach until reaching 1,200 feet above the surface.

Finally, the FAA proposes administrative modifications to the airport's legal descriptions. The airport's name on line two of the legal description text headers should be amended to read "Cortez Municipal Airport" to match the FAA's database. Reference to the Cortez VOR/distance measuring equipment (DME) on line three of the airport's legal descriptions is no longer needed and should be removed. The airspace should be described using the airport reference point. The Class E surface area legal description should be updated to replace the outdated use of the phrases "Notice to Airmen" and "Airport/Facility Directory." These phrases should read "Notice to Air Missions" and "Chart Supplement," respectively, to align with the FAA's current nomenclature.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

- 1. The authority citation for 14 CFR part 71 continues to read as follows:
Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11], Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

ANM CO E2 Cortez, CO [Amended]

Cortez Municipal Airport, CO
(Lat. 37°18'11" N, long. 108°37'41" W)
That airspace extending upward from the surface within a 4.8-mile radius of the airport, within 1.9 miles either side of the airport's 032° bearing extending from its 4.8-mile radius to 5.6 miles northeast, and within 1.9 miles either side of the airport's 217° bearing extending from its 4.8-mile radius to 7.2 miles southwest. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.
* * * * *

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

ANM CO E4 Cortez, CO [New]

Cortez Municipal Airport, CO
(Lat. 37°18'11" N, long. 108°37'41" W)
That airspace extending upward from the surface within 4.1 miles either side of the airport's 042° bearing extending from its 4.8-mile radius to 13 miles northeast of the airport, excluding that airspace within the airport's Class E airspace designated as a surface area.
* * * * *
Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.
* * * * *

ANM CO E5 Cortez, CO [Amended]
Cortez Municipal Airport, CO
(Lat. 37°18'11" N, long. 108°37'41" W)
That airspace extending upward from 700 feet above the surface within a 6.1-mile radius of the airport, within 6.1 miles either side of the airport's 048° bearing extending from the 6.1-mile radius to 18.8 miles northeast, within 1.9 miles either side of the airport's 217° bearing extending from the 6.1-mile radius to 9.4 miles southwest, and within 4.2 miles west of the airport's 350° bearing extending from the 6.1-mile radius to 7.9 miles north.
* * * * *

Issued in Des Moines, Washington, on December 20, 2024.
B.G. Chew,
Group Manager, Operations Support Group,
Western Service Center.
[FR Doc. 2025–00113 Filed 1–15–25; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
24 CFR Parts 5, 245, 882, 960, 966, and 982
[Docket No. FR–6362–N–02]
RIN 2501–AE08

Reducing Barriers to HUD-Assisted Housing; Withdrawal
AGENCY: U.S. Department of Housing and Urban Development (HUD).
ACTION: Proposed rule; withdrawal.

SUMMARY: This document informs the public that HUD has determined not to pursue the proposed rule previously published in the **Federal Register** on April 10, 2024, entitled “Reducing Barriers to HUD-Assisted Housing”. HUD will proceed to formally withdraw the rule from HUD’s Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions.
DATES: The proposed rule published at 89 FR 25332, April 10, 2024, is withdrawn as of January 16, 2025.

ADDRESSES: Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington, DC 20410.
FOR FURTHER INFORMATION CONTACT: Aaron Santa Anna, Associate General Counsel for Legislation and Regulations, Office of Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington, DC 20410; telephone number (202) 402–5300 (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>.
SUPPLEMENTARY INFORMATION: On April 10, 2024 (89 FR 25332), HUD published a proposed rule in the **Federal Register** entitled “Reducing Barriers to HUD-Assisted Housing” that proposed to amend the regulations for certain HUD Public and Indian Housing and Housing programs that govern admission for applicants with criminal records or a history of involvement with the criminal justice system and eviction or termination of assistance of persons on the basis of illegal drug use, drug-related criminal activity, or other criminal activity.
The Department has determined to withdraw the proposed rule at this time and to terminate this rulemaking proceeding. HUD does not intend for a final rule to be issued on this NPRM. If, in the future, HUD decides it is appropriate to issue regulations on this topic, HUD will do so via a new notice of proposed rulemaking, subject to the requirements of the Administrative Procedure Act, 5 U.S.C. 551, *et seq.* and 24 CFR part 10.
HUD’s Withdrawal of Proposed Rule
Accordingly, HUD will proceed to formally withdraw the following proposed rule from its Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions: Reducing Barriers to HUD-Assisted Housing (89 FR 25332, April 10, 2024) (RIN 2501–AE08). HUD’s Unified Agenda of Regulatory and Deregulatory Actions is available on [Reginfo.gov](https://www.reginfo.gov/public/do/eAgendaMain) and can be accessed at <https://www.reginfo.gov/public/do/eAgendaMain>.
Benjamin Klubes,
Acting General Counsel.
[FR Doc. 2025–00996 Filed 1–15–25; 8:45 am]
BILLING CODE 4210–67–P
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
24 CFR Parts 5, 91, 92, 93, 570, 574, 576, 903, and 983
[Docket No. FR–6250–N–03]
RIN 2529–AB05
Affirmatively Furthering Fair Housing; Withdrawal
AGENCY: U.S. Department of Housing and Urban Development (HUD).
ACTION: Proposed rule; withdrawal.

SUMMARY: This document informs the public that HUD has determined not to pursue the proposed rule published in the **Federal Register** on February 9, 2023, entitled “Affirmatively Furthering Fair Housing”. HUD will proceed to formally withdraw the rule from HUD’s upcoming Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions.

ADDRESSES: Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington, DC 20410.

DATES: The proposed rule published at 88 FR 8516, February 9, 2023, is withdrawn as of January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Aaron Santa Anna, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington, DC 20410; telephone number 202–402–5138 (this is not a tollfree 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>.

SUPPLEMENTARY INFORMATION: On February 9, 2023 (88 FR 8516), HUD published a proposed rule in the **Federal Register** entitled “Affirmatively Furthering Fair Housing” that included, among others, provisions reestablishing a formal AFFH planning process and creating an enforcement mechanism to ensure program participants comply with the duty to affirmatively further fair housing.

The Department has determined to withdraw the proposed rule at this time and to terminate this rulemaking proceeding. HUD does not intend for a final rule to be issued on this NPRM. If, in the future, HUD decides it is appropriate to issue regulations on this topic, HUD will do so through a new notice of proposed rulemaking, subject to the requirements of the Administrative Procedure Act, 5 U.S.C. 551, *et seq.* and 24 CFR part 10.

HUD’s Withdrawal of Proposed Rule

Accordingly, HUD will proceed to formally withdraw the following proposed rule from its Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions: Affirmatively Furthering Fair Housing (88 FR 8516, February 9, 2023) (RIN 2529–AB05). HUD’s Unified Agenda of Regulatory and Deregulatory Actions is available on [Reginfo.gov](https://www.reginfo.gov) and can be accessed at

<https://www.reginfo.gov/public/do/eAgendaMain>.

Benjamin Klubes,
Acting General Counsel.

[FR Doc. 2025–00981 Filed 1–15–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–116085–23]

RIN 1545–BR00

Multi-Year Reporting Requirements for Corporate Separations and Related Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would require multi-year tax reporting for corporate separations and related transactions. The information to be reported under these proposed regulations would establish the taxpayer’s position that the corporate separation and related transactions qualify for nonrecognition treatment under subchapter C of the Internal Revenue Code. The proposed regulations would affect corporations and their shareholders and security holders. Proposed regulations regarding certain matters relating to corporate separations, incorporations, and reorganizations qualifying for nonrecognition of gain or loss are published elsewhere in the Proposed Rules section of this issue of the **Federal Register**.

DATES: Written or electronic comments and requests for a public hearing must be received by March 17, 2025.

ADDRESSES: Commenters are strongly encouraged to submit public comments on these proposed regulations and the related form and instructions electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> (indicate IRS and REG–116085–23) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Requests for a Public Hearing” section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments to the IRS’s public docket. Send paper

submissions to CC:PA:01:PR (REG–116085–23), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Barrett D. Cappadonna at (202) 317–6975 (not a toll-free number); concerning submissions of comments and requests for a hearing, contact the Publications and Regulations branch at (202) 317–6901 (not a toll-free number) or by email to publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:

Authority

This document contains proposed regulations under section 355 of the Internal Revenue Code (Code) that would amend the Income Tax Regulations (26 CFR part 1) by substantially revising the information reporting requirements of § 1.355–5 (proposed regulations). The proposed regulations are issued under the express delegation of section 7805(a) of the Code, which authorizes the Secretary to “prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.”

Background

I. Overview of Section 355

Section 355(a)(1) provides that, if certain requirements are met, a distribution of stock, or stock and securities, of one or more controlled corporations by a distributing corporation to the distributing corporation’s shareholders, or to the distributing corporation’s shareholders and security holders, may be received by the distributees without the distributees recognizing gain or loss or including any amount in income (section 355 transaction). Section 355(c) generally provides that no gain or loss is recognized to a distributing corporation upon a distribution of qualified property that is not in pursuance of a plan of reorganization (section 355(c) distribution). Section 355(c)(2)(B) defines “qualified property” as any stock or securities in a controlled corporation. If, in addition to the distribution of qualified property, the distributing corporation distributes other property in the section 355 transaction and the fair market value of that other property exceeds the distributing corporation’s adjusted basis in that other property, gain is recognized to the distributing

corporation as if the property were sold to the distributee at its fair market value. See section 355(c)(2)(A).

Taxpayers also may carry out a section 355 transaction as part of a transaction that qualifies as a reorganization under section 368(a)(1)(D) or (G) of the Code and to which neither section 354 of the Code nor so much of section 356 of the Code as relates to section 354 applies (divisive reorganization). A transfer by a distributing corporation of part of its assets to a controlled corporation is a divisive reorganization if, immediately after the transfer, one or more of the distributing corporation's shareholders (including persons who were shareholders immediately before the transfer) have control (as defined in section 368(c)) of the controlled corporation and if, pursuant to the plan of reorganization, stock or securities of the controlled corporation are distributed in a transaction that qualifies under section 355.

Section 361(c) of the Code generally provides that no gain or loss is recognized to a distributing corporation upon a distribution of qualified property in pursuance of a plan of reorganization. Section 361(c)(2)(B) defines "qualified property" as (i) any stock, right to acquire stock, or obligation (including a security) of the distributing corporation, or (ii) any stock, right to acquire stock, or obligation (including a security) of a controlled corporation received by the distributing corporation as part of the divisive reorganization. If, in addition to the distribution of qualified property, the distributing corporation distributes other property as part of a divisive reorganization and the fair market value of that other property exceeds the distributing corporation's adjusted basis in that other property, gain is recognized to the distributing corporation as if the property were sold to the distributee at its fair market value. See section 361(c)(2)(A).

II. Current Reporting Requirements for Section 355 Transactions

Section 1.355-5(a)(1) currently requires the distributing corporation to report a section 355 transaction to the IRS by including a statement with the distributing corporation's Federal income tax return for the year of the section 355 transaction (§ 1.355-5(a) statement). The § 1.355-5(a) statement must include: (i) the name and employer identification number (if any) of the controlled corporation; (ii) the name and taxpayer identification number (if any) of every "significant distributee" (as defined in § 1.355-5(c)(1)); (iii) the date of the section 355

transaction; (iv) the aggregate fair market value and basis, determined immediately before the section 355 transaction, of the stock, securities, or other property (including money) distributed by the distributing corporation; and (v) the date and control number of any private letter ruling(s) issued by the IRS in connection with the section 355 transaction.

If the distributing corporation is a controlled foreign corporation within the meaning of section 957 of the Code (CFC), each United States shareholder (within the meaning of section 951(b) of the Code) with respect to the CFC must include a § 1.355-5(a) statement on or with its return. See § 1.355-5(a)(1). If the distributing corporation transfers assets to a controlled corporation in a transaction described in a divisive reorganization, then the distributing corporation (or, if the distributing corporation is a CFC, each United States shareholder) also must include the statement required by § 1.368-3(a) on or with its return for the year of the section 355 transaction. See § 1.355-5(a)(2).

Section 1.355-5(b) currently imposes requirements similar to those in § 1.355-5(a) upon significant distributees. More specifically, § 1.355-5(b)(1) requires every significant distributee to include a statement on or with the significant distributee's return for the year in which the section 355 transaction is received (§ 1.355-5(b) statement). The § 1.355-5(b) statement must include: (i) the names and employer identification numbers (if any) of the distributing and controlled corporations; (ii) the date of the section 355 transaction; (iii) the aggregate basis, determined immediately before the section 355 transaction, of any stock or securities transferred by the significant distributee in the transaction; and (iv) the aggregate fair market value, determined immediately before the section 355 transaction, of the stock, securities, or other property (including money) received by the significant distributee in the section 355 transaction. If a significant distributee is a CFC, each United States shareholder with respect to the CFC must include this statement on or with the United States shareholder's return.

Section 1.355-5(d) currently imposes substantiation requirements. More specifically, § 1.355-5(d) requires taxpayers to retain their permanent records (specifically including information regarding the amount, basis, and fair market value of all property distributed or exchanged in the section 355 transaction, and relevant facts regarding any liabilities assumed or extinguished as part of the section 355

transaction) and make those records available to any authorized IRS officers and employees. See § 1.6001-1(e).

Explanation of Provisions

The Treasury Department and the IRS are of the view that enhancing the reporting requirements for section 355 transactions would improve the IRS's ability to administer section 355 (and related provisions of the Code) to ensure that transactions intended to qualify under section 355 (and such related provisions) satisfy the requirements for nonrecognition treatment. Accordingly, these proposed regulations would revise § 1.355-5 to require all covered filers, as defined in proposed § 1.355-5(b)(1), to file with the IRS an annual report with regard to each section 355 transaction (Form 7216, *Multi-Year Reporting Related to Section 355 Transactions*) that would be attached to the covered filer's Federal income tax return.

For purposes of the proposed regulations, the term "section 355 transaction" includes both divisive reorganizations and section 355(c) distributions. The term "covered filer" would include, with regard to any section 355 transaction: (i) a distributing corporation or a person that, immediately before the first distribution, was a United States shareholder (within the meaning of section 951(b)) with respect to a controlled foreign corporation (within the meaning of section 957 of the Code, but determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) of the Code) that is the distributing corporation; (ii) a controlled corporation or a person that, immediately before the first distribution, was a United States shareholder with respect to a controlled foreign corporation that is the controlled corporation; (iii) a significant distributee or a person that, immediately before the first distribution, was a United States shareholder with respect to a controlled foreign corporation that is a significant distributee; or (iv) any other person required by the Commissioner of Internal Revenue (Commissioner) to file Form 7216 (or any successor form) in instructions, guidance, or publications published in the Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter). The term "covered filer" also would include any successor (within the meaning of section 381(a) of the Code) to an entity described in the preceding sentence. The proposed regulations also would revise the definition of a "significant distributee" in current § 1.355-5(c)(1)(i) by raising the ownership threshold for

non-publicly traded stock from one percent to five percent.

However, the term “covered filer” would be defined to encompass solely taxpayers required to file certain specified Federal income tax returns. These returns would be limited to: (i) Form 1040, *U.S. Individual Income Tax Return*; (ii) Form 1040–NR, *U.S. Nonresident Alien Income Tax Return*; (iii) Form 1065, *U.S. Return of Partnership Income*; (iv) Form 1120, *U.S. Corporation Income Tax Return*; (v) Form 1120–F, *U.S. Income Tax Return of a Foreign Corporation*; (vi) Form 1120–S, *U.S. Income Tax Return for an S Corporation*; and (vii) any other form listed in instructions, guidance, or publications published in the Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter). Accordingly, a taxpayer that is not required to file one of these specified Federal income tax returns (such as an estate, a trust, or a regulated investment company (as defined in section 851(a) of the Code)) would not be required to file Form 7216. The Treasury Department and the IRS request comments as to whether taxpayers required to file additional types of Federal income tax returns should be required to file Form 7216.

Each covered filer would be required to file Form 7216 with regard to each section 355 transaction for the required reporting period. For this purpose, the term “required reporting period” would mean the period (i) beginning in the covered filer’s taxable year in which the first distribution occurs, and (ii) ending in the fifth taxable year of the covered filer after the taxable year in which the control distribution occurs. The five-year required reporting period would apply to a covered filer (or its successor) even in cases where the covered filer (or its successor) ceases to be a United States shareholder with respect to a relevant corporation and is no longer required to file Form 5471, *Information Return of U.S. Persons With Respect To Certain Foreign Corporations*, with respect to such corporation.

Consistent with current § 1.355–5(d), the proposed regulations would require that, under § 1.6001–1(e), a covered filer must retain its permanent books and records and make those books and records available for inspection by any authorized IRS officers and employees. In addition, the proposed regulations would provide that, in connection with the section 355 transaction, the covered filer’s books and records, as relevant to the section 355 transaction, will be considered to be complete and accurate if they contain all information necessary to document and substantiate

satisfaction of the requirements under section 355.

The proposed regulations would significantly enhance the IRS’s ability to identify section 355 transactions that pose the highest risk of potential Federal income tax noncompliance and abuse. These proposed regulations also would help effectuate a broader effort by the Treasury Department and the IRS to close the portion of the Federal tax gap (that is, the difference between all Federal taxes that are owed and those that are collected) due to such potential noncompliance and abuse.

Because the enhanced reporting requirements in these proposed regulations would augment the IRS’s ability to identify section 355 transactions with the highest risk of potential noncompliance and abuse, the Treasury Department and the IRS are of the view that additional flexibility can be provided in the substantive rules applicable to section 355 transactions (for example, by affording taxpayers additional time to carry out a plan of distribution). Proposed regulations that would provide guidance regarding certain matters relating to corporate separations, incorporations, and reorganizations qualifying, in whole or in part, for nonrecognition of gain or loss are published elsewhere in the Proposed Rules section of this issue of the **Federal Register**.

The proposed reporting requirements would apply to all types of section 355 transactions with a covered filer. Specifically, the proposed regulations would apply to (i) section 355 transactions within an affiliated group (as defined in section 1504(a)(1) of the Code, without regard to the exceptions in section 1504(b)) (internal section 355 transaction), and (ii) section 355 transactions in which stock or securities of a controlled corporation are distributed to a distributing corporation shareholder or security holder that is not a member of the distributing corporation’s affiliated group (external section 355 transaction). To reflect the differences between internal section 355 transactions and external section 355 transactions (including the different statutory requirements and potential for Federal income tax noncompliance or abuse), the proposed regulations would impose, through the annual Form 7216, different reporting requirements for each type of section 355 transaction.

These proposed regulations are consistent with the recommendations set forth in the Treasury Inspector General for Tax Administration (TIGTA) report titled “A Strategy Is Needed to Assess the Compliance of Corporate Mergers and Acquisitions With Federal

Tax Requirements,” Ref. No. 2019–30–050 (Sept. 5, 2019). In that report, TIGTA recommended that the Commissioner determine whether merger and acquisition (M&A) tax forms, and information provided on those forms, could be used as a compliance tool within a larger strategy to assess risk and ensure that corporate M&A transactions are compliant with the Code. These proposed regulations would enable the IRS to collect information on section 355 transactions from taxpayers engaging in those transactions and utilize that information to identify potential noncompliance with section 355 and other related provisions of the Code.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The collections of information in these proposed regulations contain reporting and recordkeeping requirements that are necessary to identify potential noncompliance with the requirements of section 355 and related sections of the Code. These collections of information generally would be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper reporting and compliance.

The recordkeeping requirements within this proposed regulation are considered general tax records under § 1.6001–1. These records are required for the IRS to validate that taxpayers have met the requirements under section 355 and related sections of the Code. For PRA purposes, general tax records are already approved by OMB under control numbers 1545–0123 for

business filers and 1545–0074 for individual filers.

The reporting requirements outlined in § 1.355–5 will be covered within the form and instructions for IRS Form 7216 (or any successor form). This form will be approved under 1545–0123 for business filers and 1545–0074 for individual filers. The IRS will be submitting the form to OMB for approval under these OMB control numbers in accordance with the PRA procedures in 5 CFR 1320.10.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these proposed regulations would not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these proposed regulations primarily would affect corporations that are publicly traded corporations, which tend to be larger businesses. Specifically, the Research, Applied Analytics, and Statistics Division of the IRS estimates that approximately 110 small businesses with gross receipts under \$25 million would be subject to collection of information in these regulations annually. In addition, the collection of information in these proposed regulations is an incremental, additional obligation on small entities to a currently existing collection of information. Moreover, the economic impact of these proposed regulations will not be significant.

Therefore, these proposed regulations would not create significant additional obligations for, or impose any meaningful economic impact on, a substantial number of small entities. Accordingly, the Secretary certifies that the proposed regulations would not have a significant economic impact on a substantial number of small entities and a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Code, the proposed regulations have been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. These proposed

regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All commenters are strongly encouraged to submit comments electronically. The Treasury Department and the IRS will publish for public availability any comment submitted electronically or on paper to its public docket on <https://www.regulations.gov>.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing also are encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Barrett D. Cappadonna of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.355–5 is revised to read as follows:

§ 1.355–5 Information reporting and record retention requirements.

(a) *Reporting of transaction information*—(1) *Annual reporting form*—(i) *In general.* For each taxable year of the required reporting period, a covered filer must file annually with the IRS a complete and accurate Form 7216, *Multi-Year Reporting Related to Section 355 Transactions* (or as provided in publications, forms, instructions, or other guidance), with regard to a section 355 transaction.

(ii) *Manner of filing form.* A covered filer must file Form 7216 (or any successor form)—

(A) With the specified Federal income tax return of the covered filer for the taxable year (see section 6011 of the Code and § 1.6011–1); and

(B) In the manner prescribed by the Commissioner in instructions, guidance, or publications published in the Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter).

(2) [Reserved]

(3) [Reserved]

(b) *Definitions.* The following definitions apply for purposes of this section:

(1) *Covered filer*—(i) *In general.* The term *covered filer* means a taxpayer that is required to file a specified Federal income tax return and that is—

(A) A distributing corporation or a person that, immediately before the first distribution, was a United States shareholder (within the meaning of section 951(b) of the Code) with respect to a controlled foreign corporation (within the meaning of section 957 of the Code, but determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3)) that is the distributing corporation;

(B) A controlled corporation or a person that, immediately before the first distribution, was a United States shareholder with respect to a controlled foreign corporation that is the controlled corporation;

(C) A significant distributee or a person that, immediately before the first distribution, was a United States shareholder with respect to a controlled foreign corporation that is a significant distributee; or

(D) Any other person required by the Commissioner to file Form 7216 (or any

successor form) in accordance with instructions, guidance, or publications published in the Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter).

(ii) *Successors*. The term *covered filer* includes any successor (within the meaning of section 381(a) of the Code) to an entity described in paragraph (b)(1)(i) of this section.

(2) *Required reporting period*. The term *required reporting period* means the period—

(i) Beginning in the taxable year of the covered filer during which the first distribution occurs; and

(ii) Ending in the fifth taxable year of the covered filer after the taxable year in which the control distribution occurs.

(3) *Significant distributee*. The term *significant distributee* means:

(i) A holder of stock of a distributing corporation that—

(A) Receives stock of a controlled corporation in a section 355 transaction; and

(B) Owned at least five percent (by vote or value) of the total outstanding stock of the distributing corporation immediately before the first distribution.

(ii) A holder of securities of a distributing corporation that—

(A) Receives stock or securities of a controlled corporation in a section 355 transaction; and

(B) Owned securities in the distributing corporation with a basis of at least \$1,000,000 immediately before the first distribution.

(4) *Specified Federal income tax return*. The term *specified Federal income tax return* means—

(i) Form 1040, *U.S. Individual Income Tax Return*;

(ii) Form 1040-NR, *U.S. Nonresident Alien Income Tax Return*;

(iii) Form 1065, *U.S. Return of Partnership Income*;

(iv) Form 1120, *U.S. Corporation Income Tax Return*;

(v) Form 1120-F, *U.S. Income Tax Return of a Foreign Corporation*;

(vi) Form 1120-S, *U.S. Income Tax Return for an S Corporation*; or

(vii) Any other form listed in instructions, guidance, or publications published in the Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter).

(c) *Substantiation information*. Under § 1.6001-1(e), a covered filer must retain its permanent books and records and make those books and records available for inspection by any authorized IRS officers and employees. In connection with the section 355 transaction, the covered filer's books and records, as relevant to the section 355 transaction,

will be considered to be complete and accurate if they contain all information necessary to document and substantiate satisfaction of the requirements under section 355.

(d) *Applicability date*—(1) *In general*. Except as provided in paragraph (d)(2) of this section, the rules of this section apply to taxable years ending after [date of publication of final regulations in the **Federal Register**] with respect to section 355 transactions occurring after January 16, 2025. For rules applicable to prior taxable years, see § 1.355-5 as in effect and contained in 26 CFR part 1, as revised April 1, 2024.

(2) [Reserved]

Douglas W. O'Donnell,
Deputy Commissioner.

[FR Doc. 2025-00312 Filed 1-13-25; 4:15 pm]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-118988-22]

RIN 1545-BQ87

Certain Employee Remuneration in Excess of \$1,000,000 Under Internal Revenue Code Section 162(m)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document sets forth proposed regulations under section 162(m) of the Internal Revenue Code, which limits the deduction for certain employee remuneration in excess of \$1,000,000 for Federal income tax purposes. These proposed regulations implement the amendments made to section 162(m) by the American Rescue Plan Act of 2021. These proposed regulations would affect publicly held corporations.

DATES: Written or electronic comments and requests for a public hearing must be received by March 17, 2025.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at www.regulations.gov (indicate IRS and REG-118988-22) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Requests for a Public Hearing” section of this preamble. Once submitted to the Federal eRulemaking

Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG-118988-22), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Ilya Enkishev at (202) 317-5600; concerning submissions of comments and/or requests for a public hearing, contact the Publications and Regulations Section of the Office of Associate Chief Counsel (Procedure and Administration) by email at publichearings@irs.gov (preferred) or by telephone at (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Authority

These proposed regulations are issued under the express delegation of authority under section 7805 of the Code. Section 7805(a) directs the Secretary of the Treasury or her delegate to prescribe all needful rules and regulations for the enforcement of the Code, including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.

Background

This document sets forth proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 162(m). Section 162(m)(1) disallows a deduction by any publicly held corporation for applicable employee remuneration that is otherwise deductible with respect to any covered employee to the extent that such remuneration for the taxable year exceeds \$1,000,000.¹ Section 162(m) was added to the Internal Revenue Code (Code) by section 13211(a) of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66, 107 Stat. 312, 469). Proposed regulations under section 162(m) were published in the **Federal Register** by the Treasury Department and the IRS on December 20, 1993 (58 FR 66310) (1993 proposed regulations). On December 2, 1994, the Treasury Department and the IRS published in the **Federal Register** amendments to the proposed regulations (59 FR 61884) (1994 proposed regulations). On December 20, 1995, the Treasury Department and the

¹ As a result, for example, such disallowed amounts generally may not be capitalized. See §§ 1.263(a)-1(b) and 1.263A-1(c)(2).

IRS published in the **Federal Register** final regulations under section 162(m) (TD 8650) (60 FR 65534) (1995 regulations).

In 2017, section 162(m) was amended by section 13601 of the Tax Cuts and Jobs Act (TCJA) (Pub. L. 115–97, 131 Stat. 2054, 2155 (2017)). Specifically, section 13601 of TCJA amended the definitions of covered employee, publicly held corporation, and applicable employee remuneration in section 162(m). On December 20, 2019, the Treasury Department and the IRS published in the **Federal Register** proposed regulations relating to the TCJA amendments (84 FR 70356). On December 30, 2020, the Treasury Department and the IRS published in the **Federal Register** final regulations (TD 9932) relating to the TCJA amendments (85 FR 86481) (the current regulations).

Section 162(m)(3) provides the definition of “covered employee.” Specifically, section 162(m)(3) defines the term “covered employee” as an “employee of the taxpayer” if (1) the employee is the principal executive officer (PEO) or principal financial officer (PFO) of the taxpayer at any time during the taxable year, or was an individual acting in such a capacity, (2) the total compensation of the employee for the taxable year is required to be reported to shareholders under the Securities Exchange Act of 1934 (Exchange Act) by reason of the employee being among the three highest compensated officers for the taxable year (other than the PEO and PFO), or (3) the individual was a covered employee of the taxpayer (or any predecessor) for any preceding taxable year beginning after December 31, 2016. Section 162(m)(3) also contains flush language providing that a covered employee includes any employee of the taxpayer whose total compensation for the taxable year places the individual among the three highest compensated officers for the taxable year (other than any individual who is the PEO or PFO of the taxpayer at any time during the taxable year, or was an individual acting in such a capacity) even if the compensation of the officer is not required to be reported to shareholders under the Exchange Act.

In 2021, section 162(m) was amended by section 9708 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2, 135 Stat. 4, 206) to expand the definition of covered employee for taxable years beginning after December 31, 2026. The ARP amended the definition of “covered employee” in section 162(m)(3) by adding section

162(m)(3)(C),² which includes any employee who is among the five highest compensated employees for the taxable year other than the PEO or PFO (as identified in section 162(m)(3)(A)) or the three highest compensated executive officers for the taxable year (as identified in section 162(m)(3)(B)). This amendment is effective for taxable years beginning after December 31, 2026. These proposed regulations (proposed regulations) would provide guidance on this amendment.

Explanation of Provisions

I. Definition of Employee

These proposed regulations would provide that, for purposes of determining whether an employee is one of the five highest compensated employees as defined in new section 162(m)(3)(C), the term “employee” means an “employee” as defined in section 3401(c). In general, under section 3401(c) and the corresponding regulations, the term “employee” includes a common law employee and an officer of a corporation. Accordingly, for purposes of section 162(m)(3)(C), the term “employee” would include, but not be limited to, executive officers.³

The text of section 162(m)(3)(C) does not exclude an individual who is a covered employee as defined in section 162(m)(3)(D). Accordingly, these proposed regulations would provide that a covered employee by reason of section 162(m)(3)(C) includes an individual who is both one of the five highest compensated employees for the current taxable year (regardless of whether the individual is employed on the last day of the taxable year) and also a covered employee on the basis of being a covered employee for a preceding taxable year (as provided in section 162(m)(3)(D)).

II. Determination of the Five Highest Compensated Employees

These proposed regulations would use “compensation” as defined in paragraph (c)(3) of the current regulations (that is, compensation that would (but for section 162(m)) be allowable as a deduction) to determine whether an employee is one of the five highest compensated employees as defined in new section 162(m)(3)(C). The Treasury Department and the IRS expect this approach to be easily

administrable because taxpayers currently track compensation to determine their tax liability for the taxable year.

Because section 162(m)(3)(B) determines the three highest compensated employees based on the total compensation required to be disclosed under the Exchange Act for executive officers, the Treasury Department and the IRS considered using this approach to determine the five highest compensated employees for purposes of section 162(m)(3)(C). These proposed regulations would not adopt this approach because, unlike the statutory text of section 162(m)(3)(B), section 162(m)(3)(C) does not reference compensation disclosure under the Exchange Act. Furthermore, unlike the covered employees defined in section 162(m)(3)(B), the five highest compensated employees under section 162(m)(3)(C) are not limited to executive officers.

Like the 1995 regulations, § 1.162–33(c)(1)(ii) of the current regulations defines the term “publicly held corporation” to include an affiliated group of corporations, as defined in section 1504 (without regard to section 1504(b)) (affiliated group) that includes a corporation that is a publicly held corporation.⁴ This definition was needed in the 1995 regulations because, among other things, the executive officers to whom section 162(m) applied could include officers of subsidiaries,⁵ and their remuneration could come from subsidiaries, as well, so failure to include members of the affiliated group would have thwarted Congress’s intent to deny a deduction for all compensation of a covered employee in excess of \$1 million per year.⁶ The definition also confirmed that each member of the affiliated group is potentially a “taxpayer” within the meaning of section 162(m)(3).

The Treasury Department and the IRS are now similarly concerned that a publicly held corporation may employ many of its highest compensated employees at subsidiaries, and may even attempt to alter the composition of its five highest compensated employees

⁴ These proposed regulations take the same approach as the current regulations of using “publicly held corporation” to mean the affiliated group (as defined in § 1.162–33(c)(1)(ii)) of which the corporation that is a publicly held corporation (as defined in § 1.162–33(c)(1)(i)) is a part, and distinguishing between the two only where necessary.

⁵ See 17 CFR 229.402, Instructions to Item 402(a)(3).

⁶ See H.R. Conf. Rep. No. 103–213, at 585 (1993) (“Unless specifically excluded, the deduction limitation applies to all remuneration for services.”).

² The addition of section 162(m)(3)(C) resulted in pre-ARP section 162(m)(3)(C) being redesignated as section 162(m)(3)(D).

³ This interpretation is consistent with the description of section 162(m)(3)(C) by the Joint Committee on Taxation in *General Explanation of the Tax Legislation Enacted in the 117th Congress*. JCS–1–23, 129 (Dec. 2023).

(as defined in section 162(m)(3)(C)) by transferring highly compensated employees to a subsidiary or by adopting a holding company structure, thereby thwarting Congress's intent to expand significantly the number of covered employees whose compensation is subject to section 162(m).⁷ Accordingly, these proposed regulations would provide that any employee of any corporation in the affiliated group may be one of the five highest compensated employees of the publicly held corporation regardless of whether the employee is an employee of or performs services for the publicly held corporation, as defined in § 1.162–33(c)(1)(i).

Consistent with the rule in the current regulations for affiliated groups that contain more than one publicly held corporation (as defined in § 1.162–33(c)(1)(i)), these proposed regulations would provide that in such an affiliated group, each publicly held corporation has its own set of five highest compensated employees (as defined in section 162(m)(3)(C)). Because, as explained in the preceding paragraph, those individuals may be employees of a corporation in the affiliated group that is not a publicly held corporation, the affiliated group is divided into smaller affiliated groups for this purpose, each consisting of a publicly held corporation and certain affiliated non-publicly held corporations, if any. These proposed regulations provide rules for dividing up the affiliated group for this purpose.

Similar to the current regulations, these proposed regulations would provide that, if an employee of a publicly held corporation (as defined in § 1.162–33(c)(1)(i)) is paid compensation by more than one member of an affiliated group, then compensation paid to the employee by each member of the affiliated group is aggregated in determining whether the employee is one of the five highest compensated employees. These proposed regulations would provide rules similar to the rules in the current regulations, but reflecting the rules described in the preceding paragraphs, for situations in which an individual performs services for members of an affiliated group that contains more than one publicly held corporation, and might also contain one or more corporations that are not publicly held corporations. Specifically, these proposed regulations would provide that whether the individual is one of the

five highest compensated employees of a publicly held corporation is determined separately with respect to each publicly held corporation in the group, excluding compensation taken into account with respect to another publicly held corporation of the affiliated group. Section 1.162–33(c)(2)(i)(D)(4) of the proposed regulations also explains how that determination is made.

For purposes of section 162(m), an affiliated group includes a foreign corporation. Pursuant to the 1995 regulations and the current regulations, compensation includes remuneration paid by a member of an affiliated group that is a foreign corporation to the extent it is otherwise allowable as a deduction under chapter 1 of the Code. Accordingly, such compensation would be taken into account under these proposed regulations, among other things, to determine whether an individual is one of the five highest compensated employees. Compensation and other expenses of a foreign corporation normally may be taken as a deduction by the foreign corporation in computing its U.S. income tax, and thus may be actually be disallowed by section 162(m), only if they are incurred in connection with a trade or business carried on in the United States.⁸ However, if the foreign corporation is a controlled foreign corporation as defined in section 957,⁹ a pro rata share of certain types of income less associated deductions may be taken into account by a United States shareholder of the corporation under subpart F (sections 951 through 965). To assist taxpayers with compliance, section 1.162–33(c)(3)(iii) of the proposed regulations would add an explicit rule to the definition of compensation regarding remuneration paid by a controlled foreign corporation that is a member of a publicly held corporation's affiliated group. This rule is not a substantive change to the 1995 regulations and the current regulations. Comments are requested on the application of these proposed rules to controlled foreign corporations, and whether these proposed rules should apply to controlled foreign corporations that are not members of an affiliated group.

These proposed regulations would also provide that an “employee” of a

publicly held corporation includes an individual who, under section 3401(c), is an “employee” of a person other than the publicly held corporation (such as a related but unaffiliated organization or certified professional employer organization) but nevertheless functions as an employee of the publicly held corporation in that the individual performs substantially all the individual's services during the taxable year for the publicly held corporation. Consequently, these proposed regulations would provide that, in such circumstance, to the extent allowable as a deduction to the publicly held corporation, amounts paid to the individual or to a third party to obtain the services performed by the individual are considered “compensation.” Absent such a rule, the adoption of the section 3401(c) definition by these proposed regulations could permit avoidance of section 162(m) through the use of third-party payors, which is not a concern under sections 162(m)(3)(A) and (B) due to their inclusion of all individuals acting as executive officers and the application of the executive compensation disclosure rules under the Exchange Act.

III. Amendment to the Current Regulations

These proposed regulations also include a technical correction that would amend the reference to Example 22 in the conclusion to the facts in Example 23 (section 1.162–33(c)(1)(vi)(W)(2)) in the current regulations. The correct reference is to Example 20 of the current regulations. These proposed regulations would make that correction.

Proposed Applicability Date

These regulations generally are proposed to apply to compensation that is otherwise deductible for taxable years beginning after the later of December 31, 2026, or the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. The amendment to the conclusion of Example 23 in section 1.162–33(c)(1)(vi)(W)(2) of the current regulations is proposed to apply to taxable years ending on or after January 16, 2025.

Statement of Availability of IRS Documents

For copies of recently issued revenue procedures, revenue rulings, notices and other guidance published in the Internal Revenue Bulletin, please visit the IRS website at www.irs.gov or contact the Superintendent of Documents, U.S.

⁷ See, for example, the Joint Committee on Taxation estimate that the amendment would raise \$7.8 billion through Fiscal Year 2031. JCX–14–21, 3 (March 9, 2021).

⁸ See section 882(c)(1).

⁹ In relevant part, section 957(a) defines a controlled foreign corporation as a foreign corporation of which more than 50% (vote or value) is owned by United States shareholders as defined in section 951(b). Publicly held corporations as defined in section 162(m)(2) can be treated as United States shareholders.

Government Publishing Office, Washington, DC 20402.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. chapter 6), it is hereby certified that these proposed regulations would not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that section 162(m)(1) applies only to publicly held corporations (for example, corporations that list securities on a national securities exchange and are rarely small entities) and only impacts those publicly held corporations that compensate certain employees in excess of \$1,000,000 in a taxable year.

III. Section 7805(f)

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. This proposed rule does not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled “Federalism”) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This

proposed rule does not have federalism implications, does not impose substantial direct compliance costs on State and local governments, and does not preempt State law within the meaning of the Executive order.

Comments and Requests for a Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments submitted will be made available at www.regulations.gov or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically by sending an email to publichearings@irs.gov. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Ilya Enkishev, Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.162–33 is amended by:

- a. Revising paragraphs (c)(1)(vi)(W)(2) and (c)(2)(i)(C);
- b. Adding paragraphs (c)(2)(i)(D) and (c)(2)(vii)(CC) through (EE);
- c. Redesignating paragraphs (c)(3)(iii) and (iv) as paragraphs (c)(3)(v) and (vi);
- d. Adding new paragraphs (c)(3)(iii) and (iv) and adding paragraphs (c)(3)(vi)(D) and (E);

- e. Revising paragraph (h)(2)(ii)(C); and
- f. Adding paragraphs (h)(2)(ii)(F) and G.

The revisions and additions read as follows:

§ 1.162–33 Certain employee remuneration in excess of \$1,000,000 not deductible for taxable years beginning after December 31, 2017.

* * * * *

(c) * * *

(1) * * *

(vi) * * *

(W) * * *

(2) *Conclusion.* The result is the same as in paragraph (c)(1)(vi)(T) of this section (*Example 20*). Even though Corporations P, Q, and R each are publicly held corporations, they comprise an affiliated group. Because Employee C is a covered employee of both Corporations P and Q, the amount disallowed as a deduction is prorated separately between Corporations P and R and between Corporations Q and R.

* * * * *

(2) * * *

(i) * * *

(C) Any individual who was a covered employee of the publicly held corporation (or any predecessor of a publicly held corporation, within the meaning of paragraph (c)(2)(ii) of this section) for any preceding taxable year beginning after December 31, 2016, other than an individual who was a covered employee in that year solely on account of paragraph (c)(2)(i)(D) of this section. For taxable years beginning prior to January 1, 2018, covered employees are identified in accordance with the rules in § 1.162–27(c)(2).

(D) The five highest compensated employees of the publicly held corporation for the taxable year regardless of whether the individual is serving at the end of the publicly held corporation’s taxable year, other than any individual described in paragraph (c)(2)(i)(A) or (B) of this section, determined in accordance with the rules in this paragraph (c)(2)(i)(D). See paragraph (c)(3)(iv) of this section for a special rule treating certain employees of a person other than the publicly held corporation as employees of the publicly held corporation.

(1) *Compensation.* The amount of compensation used to identify the five most highly compensated employees for the taxable year for purposes of paragraph (c)(2)(i)(D) of this section is the amount of compensation as defined in paragraph (c)(3) of this section, provided that, in determining compensation for purposes of applying this paragraph (c)(2)(i)(D), references to “covered employee” or “covered

employee (as defined in paragraphs (c)(2)(i) through (v) of this section)” in paragraph (c)(3) of this section shall be replaced with references to “employee.”

(2) *Employee.* For purposes of this paragraph (c)(2)(i)(D), the term “employee” means an employee as defined in section 3401(c).

(3) *Determining the employees eligible to be the five highest compensated employees with respect to an affiliated group with one publicly held corporation.* In the case of an affiliated group (as defined in paragraph (c)(1)(ii) of this section) that includes one publicly held corporation (as defined in paragraph (c)(1)(i) of this section), an employee of any member of the affiliated group is eligible to be one of the five highest compensated employees of the publicly held corporation regardless of whether the individual is an employee of the publicly held corporation itself or performs services for the publicly held corporation itself.

(4) *Determining the employees eligible to be the five highest compensated employees with respect to an affiliated group with more than one publicly held corporation.* In the case of an affiliated group (as defined in paragraph (c)(1)(ii) of this section) that includes more than one publicly held corporation (as defined in paragraph (c)(1)(i) of this section), the group of employees eligible to be the five highest compensated employees is determined separately with respect to the parent corporation (as defined below) and each publicly held corporation (as defined in paragraph (c)(1)(i) of this section) that is not the parent corporation (an additional publicly held corporation). For this purpose, the parent corporation is the highest corporation in the chain or chains of includible corporations (that comprise the affiliated group) that is a publicly held corporation as defined in paragraph (c)(1)(i) of this section. In the case of an affiliated group in which more than one member may be the parent corporation (such as where a common parent that is not publicly held owns multiple publicly held corporations), the affiliated group must choose which member to treat as the parent corporation for the taxable year. With respect to the parent corporation, an employee of any member of the affiliated group, excluding a member of an affiliated group of an additional publicly held corporation (as defined below), is eligible to be one of its five highest compensated employees regardless of whether the individual is an employee of the parent corporation itself or performs services for the parent corporation itself. Similarly, with respect to an additional publicly held

corporation, any employee of the affiliated group of the additional publicly held corporation is eligible to be one of its five highest compensated employees regardless of whether the individual is an employee of the additional publicly held corporation itself or performs services for the additional publicly held corporation itself. For this purpose, an affiliated group of an additional publicly held corporation means, with respect to any corporation, the affiliated group which would be determined under section 1504(a) if such corporation were the common parent and if section 1504(b) did not apply. These rules similarly apply to all additional publicly held corporations, beginning at the bottom of each chain of corporations and proceeding up until all members of the affiliated group that may be so allocated have been allocated to one (and only one) affiliated group of an additional publicly held corporation. If the affiliated group includes only publicly held corporations (as defined in paragraph (c)(1)(i) of this section), the affiliated group used to determine the employees eligible to be each publicly held corporation’s five highest compensated employees is that publicly held corporation itself.

(5) *Determining the five highest compensated employees in an affiliated group.* In determining whether an employee is one of the five highest compensated employees with respect to the parent corporation (as defined in paragraph (c)(2)(i)(D)(4) of this section) for the taxable year, compensation paid by each member of the affiliated group (as defined in paragraph (c)(1)(ii) of this section) in the taxable year, excluding any member of an affiliated group of an additional publicly held corporation (as defined in paragraph (c)(2)(i)(D)(4) of this section), is aggregated. In determining whether an employee is one of the five highest compensated employees with respect to a publicly held corporation (as defined in paragraph (c)(1)(i) of this section) in an affiliated group of an additional publicly held corporation, compensation paid by each member of the affiliated group of the additional publicly held corporation in the taxable year is aggregated.

(6) *Application of proration rules.* The proration rules in paragraph (c)(1)(ii)(B) of this section generally apply in the same way to covered employees determined under this paragraph (c)(2)(i)(D), except that a publicly held corporation or publicly held payor corporation refers to the portion of the affiliated group of which the publicly held corporation (as defined in

paragraph (c)(1)(i) of this section) is a part, as determined under paragraph (c)(2)(i)(D)(4) of this section.

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(vii) * * *

(CC) *Example 29 (Individual as one of the five highest compensated employees of a publicly held corporation that includes the affiliated group)—(1) Facts.* Corporation CO is a publicly held corporation for its 2026 and 2027 taxable years. Corporation CP is a foreign corporation and is a wholly-owned subsidiary of Corporation CO. Corporation CP is a controlled foreign corporation, but the only income it has is effectively connected with a U.S. trade or business. Corporation CO is a partner in Partnership CQ (a partnership for Federal tax purposes). Under the partnership agreement, Corporation CO has a 50% distributive share of the partnership’s income, gain, loss, deductions, and credits. These allocations comply with section 704(b) and its regulations. Employee E.O. is an employee of Corporation CO. In 2026, Employee E.O. is a covered employee of Corporation CO because Employee E.O. is one of the three highest compensated executive officers of Corporation CO. In 2027, Employee E.O. is not an executive officer of Corporation CO but performs services for and receives compensation from Corporations CO for services as its employee. Furthermore, in 2027, Employee E.O. performs services for and receives compensation from Corporation CP and Partnership CQ (Employee E.O. is not a partner of Partnership CQ). In 2027, the total compensation paid to Employee E.O. is \$3,600,000, of which Corporation CO pays \$1,500,000, Corporation CP pays \$900,000, and Partnership CQ pays \$1,200,000. For the 2027 taxable year, the total compensation paid to any employee of Corporations CO and CP did not exceed \$2,500,000.

(2) *Conclusion (Compensation paid by Corporation CO).* The \$1,500,000 in compensation paid by Corporation CO is taken into account to determine whether Employee E.O. is one of the five highest compensated employees of Corporation CO for its 2027 taxable year.

(3) *Conclusion (Compensation paid by Corporation CP).* Corporations CO and CP are an affiliated group as defined in paragraph (c)(1)(ii) of this section. Therefore, the \$900,000 in compensation paid by Corporation CP is taken into account to determine whether Employee E.O. is one of the five highest compensated employees of Corporation CO for its 2027 taxable year. Because a publicly held corporation includes an

affiliated group for purposes of paragraph (c)(3) of this section, the result would be the same even if there were intermediary privately held subsidiaries between Corporations CO and CP as long as all these corporations comprised an affiliated group.

(4) *Conclusion (Compensation paid by Partnership CQ).* Under paragraph (c)(3)(ii) of this section, Corporation CO's \$600,000 distributive share of Partnership CQ's deduction (50% of \$1,200,000) is compensation that is taken into account to determine whether Employee E.O. is one of the five highest compensated employees of Corporation CO for its 2027 taxable year. Because a publicly held corporation includes an affiliated group for purposes of paragraph (c)(3) of this section, the result would be the same even if there were an intermediary privately held subsidiary between Corporation CO and Partnership CQ (so that, instead of Corporation CO, an intermediary subsidiary was a partner in Partnership CQ), as long as Corporation CO and the intermediary subsidiary comprised an affiliated group.

(5) *Conclusion (Employee E.O. as a covered employee).* Because the aggregate compensation taken into account with respect to Employee E.O. is \$3,000,000 (\$1,500,000 + \$900,000 + \$600,000), Employee E.O. is a covered employee of Corporation CO for its 2027 taxable year by reason of being one of its five highest compensated employees for the taxable year as provided in paragraph (c)(2)(i)(D) of this section (even though Employee E.O. is also a covered employee of Corporation CO for its 2027 taxable year by reason of being a covered employee for its 2026 taxable year (as provided in paragraph (c)(2)(i)(C) of this section)).

(6) *Conclusion (Amount disallowed as a deduction).* Because the compensation paid by all affiliated group members is aggregated for purposes of section 162(m)(1), the aggregate compensation of \$3,000,000 exceeds the limitation in section 162(m)(1) and \$2,000,000 of the compensation paid to Employee E.O. is nondeductible. Corporations CO and CP each are treated as paying a ratable portion of the nondeductible compensation. Thus, two thirds of each corporation's payment will be nondeductible. Taking into account Corporation CO's \$600,000 distributive share of the Partnership CQ's deduction, Corporation CO has an otherwise allowable deduction of \$2,100,000 (\$1,500,000 + \$600,000). Therefore, Corporation CO has a nondeductible compensation expense of \$1,400,000 (\$2,100,000 × \$2,000,000/\$3,000,000). Corporation CP has an otherwise

allowable deduction of \$900,000, of which \$600,000 (\$900,000 × \$2,000,000/\$3,000,000) is a nondeductible compensation expense.

(DD) *Example 30 (Individual as one of the five highest compensated employees of a publicly held corporation that includes the affiliated group and affiliated groups of additional publicly held corporations)*—(1) *Facts.*

Corporations CR, CT, and CV are publicly held corporations for their 2027 taxable years. Corporations CS and CU are privately held for their 2027 taxable years. Corporation CT is a subsidiary of Corporation CS, which is a subsidiary of Corporation CR. Corporation CV is a subsidiary of Corporation CU, which is a subsidiary of Corporation CT. Corporations CR, CS, CT, CU, and CV are members of an affiliated group. Employee EP is an employee of Corporations CR, CS, CU, and CV. In 2027, Employee EP performs services for and receives compensation from Corporations CR, CS, CU, and CV. The total compensation paid to Employee EP from the affiliated group members is \$7,000,000 for the taxable year, of which Corporation CR pays \$1,200,000, Corporation CS pays \$1,800,000, Corporation CU pays \$1,500,000, and Corporation CV pays \$2,500,000.

(2) *Conclusion (Employee EP is eligible to be a covered employee of Corporation CR).* Because Employee EP is an employee of Corporation CR, Employee EP is eligible to be one of the five highest compensated employees of Corporation CR. Even though Corporations CR, CS, CT, CU, and CV comprise an affiliated group as defined in paragraph (c)(1)(ii) of this section, because Corporations CT and CV are additional publicly held corporations of the affiliated group, the affiliated group contains affiliated groups of these additional publicly held corporations (as defined in paragraph (c)(2)(i)(D)(4) of this section). Compensation paid by the affiliated groups of these additional publicly held corporations is not taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CR for its 2027 taxable year. Accordingly, Corporations CT and CU comprise an affiliated group of an additional publicly held corporation (Corporation CT), and compensation paid by Corporation CU is not taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CR for its 2027 taxable year. Furthermore, Corporation CV is an affiliated group of an additional publicly held corporation (Corporation

CV), and compensation paid by Corporation CV is not taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CR for its 2027 taxable year. Therefore, only the \$1,200,000 in compensation paid by Corporation CR and the \$1,800,000 paid by Corporation CS are taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CR for its 2027 taxable year.

(3) *Conclusion (Employee EP is eligible to be a covered employee of Corporation CT).* Because Corporation CT is a publicly held corporation, Corporations CT and CU comprise an affiliated group of an additional publicly held corporation (as defined in paragraph (c)(2)(i)(D)(4) of this section). Because an employee of any member of the affiliated group is eligible to be one of the five highest compensated employees of the publicly held corporation (regardless of whether the employee performs services for the publicly held corporation), Employee EP is eligible to be a covered employee of Corporation CT, even though Employee EP does not perform services for Corporation CT. Because only compensation paid by a member of the affiliated group of the additional publicly held corporation in the taxable year is taken into account to determine whether an individual is one of the five highest compensated employees with respect to the additional publicly held corporation, only compensation paid by Corporation CU is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CT for its 2027 taxable year. Accordingly, the \$1,500,000 in compensation paid by Corporation CU is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CT for its 2027 taxable year.

(4) *Conclusion (Employee EP is eligible to be a covered employee of Corporation CV).* Because Employee EP is an employee of Corporation CV, Employee EP is eligible to be one of the five highest compensated employees of Corporation CV. Because Corporation CV is a publicly held corporation, Corporation CV comprises an affiliated group of an additional publicly held corporation (as defined in paragraph (c)(2)(i)(D)(4) of this section). Because only compensation paid by a member of the affiliated group of the additional publicly held corporation in the taxable year is taken into account to determine whether an individual is one of the five highest compensated employees with

respect to the additional publicly held corporation, only compensation paid by Corporation CV is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CV for its 2027 taxable year. Accordingly, the \$2,500,000 in compensation paid by Corporation CV is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CV for its 2027 taxable year.

(5) *Conclusion (Employee EP as covered employee of Corporation CR).* The \$1,200,000 in compensation paid by Corporation CR and the \$1,800,000 in compensation paid by Corporation CS are taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CR for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Employee EP is a covered employee of Corporation CR, then Corporation CR's deduction for \$1,200,000 and Corporation CS's deduction for \$1,800,000 for the 2027 taxable year would be subject to the section 162(m)(1) limit. Because the compensation paid by the affiliated group members is aggregated for purposes of section 162(m)(1), the aggregate compensation of \$3,000,000 exceeds the limitation in section 162(m)(1) and \$2,000,000 of the compensation paid to Employee EP would be nondeductible. Corporations CR and CS each are treated as paying a ratable portion of the nondeductible compensation. Corporation CR has an otherwise allowable deduction of \$1,200,000, of which \$800,000 ($\$1,200,000 \times \$2,000,000 / \$3,000,000$) would be a nondeductible compensation expense. Corporation CS has an otherwise allowable deduction of \$1,800,000, of which \$1,200,000 ($\$1,800,000 \times \$2,000,000 / \$3,000,000$) would be a nondeductible compensation expense.

(6) *Conclusion (Employee EP as covered employee of Corporation CT).* The \$1,500,000 in compensation paid by Corporation CU is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CT for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Employee EP is a covered employee of Corporation CT, then Corporation CU's deduction for \$1,500,000 for the 2027 taxable year would be subject to the section 162(m)(1) limit. Accordingly, pursuant to paragraph (c)(2)(i)(D)(6) of this section, Corporation CU would have a nondeductible compensation expense of \$500,000.

(7) *Conclusion (Employee EP as covered employee of Corporation CV).* The \$2,500,000 in compensation paid by Corporation CV is taken into account to determine whether Employee EP is one of the five highest compensated employees of Corporation CV for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Employee EP is a covered employee of Corporation CV, then Corporation CV's deduction for \$2,500,000 for the 2027 taxable year would be subject to the section 162(m)(1) limit. Accordingly, Corporation CV would have a nondeductible compensation expense of \$1,500,000.

(EE) *Example 31 (Individual as one of the five highest compensated employees of a publicly held corporation that includes the affiliated group that chooses a parent corporation)—(1) Facts.* Corporations CX and CY are publicly held corporations for their 2027 taxable years. Corporations CW and CZ are privately held corporations for their 2027 taxable years. Corporations CX and CY are subsidiaries of Corporation CW. Corporations CX and CY each directly own 50% (by vote and value) of Corporation CZ's only class of stock. In 2027, Employee EQ performs services for and receives compensation from Corporations CW, CX, CY, and CZ. The total compensation paid to Employee EQ from all corporations is \$4,700,000 for the taxable year, of which Corporation CW pays \$1,500,000, Corporation CX pays \$900,000, Corporation CY pays \$1,700,000, and Corporation CZ pays \$600,000.

(2) *Conclusion (Employee EQ is eligible to be a covered employee of Corporations CX and CY).* Because Employee EQ is an employee of Corporations CX and CY, Employee EQ is eligible to be one of the five highest compensated employees of these publicly held corporations. Because both Corporations CX and CY are the highest publicly held corporations in the chain of includible corporations that comprise an affiliated group (composed of Corporations CW, CX, CY, and CZ) as defined in paragraph (c)(1)(ii) of this section, the affiliated group may choose to treat either Corporation CX or CY as the parent corporation for the 2027 taxable year. If the affiliated group chooses to treat Corporation CX as the parent corporation, then only compensation paid by Corporations CW, CX, and CZ is taken into account to determine whether Employee EQ is one of the five highest compensated employees of Corporation CX for the 2027 taxable year. Because Corporation CY is an affiliated group of the

additional publicly held corporation composed of one corporation (Corporation CY), only compensation paid by Corporation CY is taken into account to determine whether Employee EQ is one of the five highest compensated employees of Corporation CY. A similar analysis would apply if the affiliated group chose to treat Corporation CY as the parent.

(3) *Conclusion (Employee EQ as a covered employee of Corporation CX).* The \$1,500,000 in compensation paid by Corporation CW, the \$900,000 paid by Corporation CX, and the \$600,000 in compensation paid by Corporation CZ (that is, aggregate compensation of \$3,000,000) are taken into account to determine whether Employee EQ is one of the five highest compensated employees of Corporation CX for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Employee EQ is a covered employee of Corporation CX, then Corporation CW's deduction for \$1,500,000, Corporation CX's deduction for \$900,000, and Corporation CZ's deduction for \$600,000 for the 2027 taxable year would be subject to the section 162(m)(1) limit. Because the compensation paid by the affiliated group members is aggregated for purposes of section 162(m)(1), the aggregate compensation of \$3,000,000 exceeds the limitation in section 162(m)(1) and \$2,000,000 of the compensation paid to Employee EQ would be nondeductible. Corporations CW, CX, and CZ each are treated as paying a ratable portion of the nondeductible compensation. Corporation CW would have a nondeductible compensation expense of \$1,000,000 ($\$1,500,000 \times \$2,000,000 / \$3,000,000$). Corporation CX would have a nondeductible compensation expense of \$600,000 ($\$900,000 \times \$2,000,000 / \$3,000,000$). Corporation CZ would have a nondeductible compensation expense of \$400,000 ($\$600,000 \times \$2,000,000 / \$3,000,000$).

(4) *Conclusion (Employee EQ as a covered employee of Corporation CY).* The \$1,700,000 in compensation paid by Corporation CY is taken into account to determine whether Employee EQ is one of the five highest compensated employees of Corporation CY for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Employee EQ is a covered employee of Corporation CY, then Corporation CY's deduction for \$1,700,000 for the 2027 taxable year would be subject to the section 162(m)(1) limit. Accordingly, Corporation CY would have a nondeductible compensation expense of \$700,000.

(3) * * *

(iii) *Compensation paid by a controlled foreign corporation that is a member of an affiliated group.* For purposes of paragraph (c)(3)(i) of this section, compensation includes a publicly held corporation's pro rata share (as determined under the principles of sections 951(a)(2) and 951A(e)(1)) of the amounts that would be claimed by a controlled foreign corporation (as defined in section 957) that is a member of an affiliated group (as defined in paragraph (c)(1)(ii) of this section) as properly allocable to gross income included under sections 951(a)(1) and 951A(a) under sections 954(b)(5), 951A(c)(2)(A)(ii), and similar provisions, determined without regard to the disallowance of any such expenses by reason of section 162(m) and these regulations, for compensation expenses attributable to the remuneration paid by the controlled foreign corporation to a covered employee of a publicly held corporation for services performed by the covered employee.

(iv) *Amounts paid to individuals performing substantially all their services for a publicly held corporation.* Notwithstanding paragraph (c)(2)(i)(D)(2) of this section, for purposes of paragraph (c)(2)(i)(D) of this section, an employee of a publicly held corporation includes an individual who, pursuant to section 3401(c), is an employee of a person other than the publicly held corporation but performs substantially all the individual's services during the relevant taxable year for the publicly held corporation. Consequently, for purposes of paragraph (c)(3) of this section, compensation includes the aggregate amount allowable as a deduction to the publicly held corporation under chapter 1 of the Internal Revenue Code for the taxable year (determined without regard to section 162(m)(1)) to obtain the services performed by such individual, whether or not the particular services that give rise to the deduction were performed during the relevant taxable year. This rule applies regardless of how the amounts allowable as a deduction are paid or denominated, and regardless of whether the individual is compensated directly or by a third-party payor, including a related organization or certified professional employer organization under section 7705. The disallowance under paragraph (b) of this section likewise is applied to those amounts, however denominated, otherwise allowable as a deduction to obtain those services. Nothing in the previous sentence is intended to imply that such amounts paid to a third party

for services by a covered employee, however denominated, are not already treated as remuneration for those services and thus compensation for purposes of paragraph (c)(3) of this section.

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(D) *Example 4—(1) Facts.* Corporation U is a publicly held corporation for its 2027 taxable year and is not a member of an affiliated group. Corporation U has a services agreement with unrelated Corporation V. In Corporation U's 2027 taxable year, it pays \$1,500,000 to Corporation V pursuant to the agreement in exchange for the services of an interim chief accountant (Individual E) in the same year. The \$1,500,000 is otherwise deductible for Corporation U's 2027 taxable year. Individual E performs substantially all Individual E's services in 2027 for Corporation U.

(2) *Conclusion.* Pursuant to paragraph (c)(3)(iv) of this section, Individual E is treated as an employee of Corporation U for purposes of this section. The \$1,500,000 paid to Corporation V by Corporation U in 2027 is compensation within the meaning of paragraph (c)(3) of this section and is taken into account to determine whether Individual E is a covered employee as one of the five highest compensated employees of Corporation U for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Individual E is a covered employee of Corporation U, then Corporation U's deduction for \$1,500,000 for the 2027 taxable year is subject to the section 162(m)(1) limit. Because a publicly held corporation includes an affiliated group for purposes of paragraph (c)(3) of this section, the result would be the same even if Corporation U owned a privately held subsidiary, and Individual E performed substantially all Individual E's services for the subsidiary. In addition, the result would also be the same if Individual E performed substantially all Individual E's services for both Corporation U and its subsidiary, as long as Corporation U and its subsidiary comprised an affiliated group (regardless of whether Corporation U or its subsidiary paid the \$1,500,000 to Corporation V). In such case, pursuant to paragraph (c)(1)(ii) of this section, the amount disallowed as a deduction would be prorated between Corporation U and its subsidiary. Furthermore, the result would be the same even if Individual E were an employee of Corporation U (regardless of whether Individual E were also an employee of Corporation V).

(E) *Example 5—(1) Facts.* Corporation W is a publicly held corporation for its

2027 taxable year and is not a member of an affiliated group. Corporation W is a partner in Partnership X (a partnership for Federal tax purposes), that owns all the stock of Corporation Y. Under the partnership agreement, Corporation W has a 50% distributive share of the partnership's income, gain, loss, deductions, and credits. These allocations comply with section 704(b) and its regulations. Individual F is a partner of Partnership X. In 2027, Individual F performs services for the partnership, and the partnership pays \$1,000,000 to Individual F as a guaranteed payment for these services. With respect to the \$1,000,000 paid to Individual F, a deduction of \$500,000 is allocated to Corporation W. Corporation W's \$500,000 distributive share of the partnership's deduction is reported separately to Corporation W pursuant to § 1.702–1(a)(8)(iii). Individual F is also an employee (within the meaning of section 3401(c)) of Corporation Y. In Corporation W's 2027 taxable year, it pays \$8,000,000 to Corporation Y in exchange for Individual F's services. The \$8,000,000 is otherwise deductible for Corporation W's 2027 taxable year. Individual F performs substantially all Individual F's services in 2027 for Corporation W.

(2) *Conclusion.* Pursuant to paragraph (c)(3)(iv) of this section, Individual F is treated as an employee of Corporation W for purposes of this section. The entire \$8,000,000 paid to Corporation Y by Corporation W in 2027 is compensation within the meaning of paragraph (c)(3) of this section and is taken into account to determine whether Individual F is one of the five highest compensated employees of Corporation W for its 2027 taxable year. Because Corporation W's \$500,000 distributive share of the partnership's deduction is attributable to the compensation paid by the partnership for services performed by Individual F (who is treated as an employee of Corporation W), the \$500,000 is compensation within the meaning of paragraph (c)(3)(ii) of this section. Accordingly, Corporation W's \$500,000 distributive share of the partnership's deduction is aggregated with Corporation W's deduction for \$8,000,000 paid to Corporation Y in determining whether Individual F is a covered employee as one of the five highest compensated employees of Corporation W for its 2027 taxable year. If, pursuant to paragraph (c)(2)(i)(D) of this section, Individual F is a covered employee of Corporation W, then Corporation W's deduction for \$8,500,000 for its 2027 taxable year is subject to the section 162(m)(1) limit.

Because a publicly held corporation includes an affiliated group for purposes of paragraph (c)(3) of this section, the result would be the same even if there were an intermediary privately held subsidiary between Corporation W and Partnership X (so that, instead of Corporation W, an intermediary subsidiary was a partner in Partnership X), as long as Corporation W and the intermediary subsidiary comprised an affiliated group, and as long as Individual F performed substantially all Individual F's services for the intermediary subsidiary. Furthermore, the result would also be the same if Individual F performed substantially all Individual F's services for both Corporation W and the intermediary subsidiary (regardless of whether Corporation W or the intermediary subsidiary paid the \$8,000,000 to Corporation Y). In such case, pursuant to paragraph (c)(1)(ii) of this section, the amount disallowed as a deduction would be prorated between Corporation W and the intermediary subsidiary.

* * * * *

- (h) * * *
- (2) * * *
- (ii) * * *

(C) *Definition of compensation.* The definition of compensation provided in paragraph (c)(3)(ii) of this section (relating to distributive share of partnership deductions for compensation paid) applies to any deduction for compensation that is paid after December 18, 2020. The definition of compensation in paragraph (c)(3)(ii) of this section does not apply to compensation paid pursuant to a written binding contract that is in effect on December 20, 2019, and that is not materially modified after that date. For purposes of paragraph (h)(2)(C) of this section, written binding contract and material modification have the same meanings as provided in paragraphs (g)(1) and (2) of this section. The definition of compensation provided in paragraphs (c)(3)(iii) and (iv) of this section and the examples in paragraphs (c)(3)(vi)(D) and (E) of this section apply to any deduction for compensation that is otherwise deductible for taxable years beginning after the later of December 31, 2026, or the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

(F) *Five highest compensated employees.* Paragraph (c)(2)(i)(D) of this section (describing the five highest compensated employees of a publicly held corporation) and the examples in paragraphs (c)(2)(vii)(CC) through (EE)

of this section apply to taxable years beginning after the later of December 31, 2026, or the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(G) *Amendment to paragraph (c)(1)(vi)(W)(2) of this section.* The amendment to paragraph (c)(1)(vi)(W)(2) of this section (*Example 23*) to reference paragraph (c)(1)(vi)(T) of this section (*Example 20*) is proposed to apply to taxable years ending on or after January 16, 2025.

Douglas W. O'Donnell,
Deputy Commissioner.

[FR Doc. 2025-00728 Filed 1-14-25; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2024-0123]

RIN 1625-AA00

Safety Zone; San Pedro Bay, Los Angeles and Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish moving safety zones around vessels carrying oversized cargo within the Los Angeles-Long Beach Port Complex in San Pedro Bay. Safety zones around vessels carrying oversized cargo during movements within the port complex would ensure navigational safety and minimize mishaps disrupting the navigational channels. Entry of persons or vessels into these safety zones would be prohibited unless specifically authorized by the Captain of the Port (COTP) Los Angeles-Long Beach or their designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before February 18, 2025.

ADDRESSES: You may submit comments identified by docket number USCG-2024-0123 using the Federal Decision-Making Portal at <https://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-

word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LCDR Kevin Kinsella, Waterways Management, U.S. Coast Guard Sector Los Angeles-Long Beach; telephone (310) 357-1603, email D11-SMB-SectorLALB-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

Within the past two years, there have been six arrivals of vessels carrying a total of 16 ship-to-shore cranes to the Port Complex. The Coast Guard anticipates future deliveries of additional cranes and other oversized cargo. The Coast Guard previously established seven temporary safety zones and two extensions of those rules for past arrivals, shifts, and departures of oversized critical infrastructure cargo to the port complex. With this proposed rule, we propose establishing a permanent safety zone around all vessels moving oversized cargos that would be enforced only when the vessels are transiting into, out of, or within the port complex. The COTP has determined that potential hazards associated with the oversized cargo movements would be a safety concern for anyone within a 500-foot radius of the vessel carrying oversized cargo.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters during movements of oversized cargo within the port complex. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone for all vessels carrying oversized cargo inside the port complex. The safety zone would cover all navigable waters within a 500-foot radius of a vessel while it is in transit into, out of, and within the Los Angeles-Long Beach port complex. The duration of the zone is intended to ensure the safety of vessels and these navigable waters during scheduled movements. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The

regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the safety zone. This rule impacts an area of 500-feet surrounding cargo vessels while transiting into, out of, or within the area of the Los Angeles—Long Beach Port Complex for a limited duration. The safety zone will only be enforced for the duration of the vessels’ transits while carrying oversized cargo. Each transit is expected to last less than 24 hours, and that period will be announced via Broadcast Notice to Mariners. Vessel traffic will be able to safely transit around this 500-foot safety zone, which will impact a small, designated area of San Pedro Bay.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of

their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves safety zones lasting only during the duration of movements that would prohibit entry within a 500-foot radius of a vessel carrying oversized cargo into, out of, or within the port complex. Normally such actions are 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 preliminary 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. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

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

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

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2024–0123 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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 is proposing to amend 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 § 165.1153 to read as follows:

§ 165.1153 Safety Zones; San Pedro Bay, Los Angeles and Long Beach, CA.

(a) *Location.* The following area is a safety zone: all navigable waters of the Port of Los Angeles and Port of Long Beach, from surface to bottom, within a circle formed by connecting all points 500-feet out from vessels carrying oversized cargo into, out of, or within the Los Angeles-Long Beach Port Complex.

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

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.

(2) To seek permission to enter, contact the COTP or the COTP’s representative by hailing Coast Guard Sector Los Angeles-Long Beach on VHF–FM Channel 16 or calling at (310) 521–3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.

(d) *Enforcement period.* This section will be enforced only during movements of vessels carrying oversized cargo into, out of, or within the port complex.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement dates and times for safety zones via Broadcast Notice to Mariners or Local Notices to Mariners.

Dated: December 31, 2024.

S.L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2025–00398 Filed 1–15–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Parts 1, 2, and 4

[NPS–WASO–38853; GPO Deposit Account 4311H2]

RIN 1024–AE79

Powered Micromobility Devices

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service proposes a management framework for the use of powered micromobility devices within the National Park System. The proposed rule would define powered micromobility devices separately from motor vehicles, traditional bicycles, electric bicycles, and human powered coasting devices, and create rules for where and how they may be used in units of the National Park System. Examples of powered micromobility devices include electric scooters (e-scooters), hoverboards, and Segways.

DATES: Comments on the proposed rule must be received by 11:59 p.m. eastern time on March 17, 2025.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024–AE79, by either of the following methods:

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

(2) *By hard copy:* Mail to: Jay Calhoun, National Park Service, Division of Regulations, Jurisdiction and Special Park Uses, MS–2472, 1849 C Street NW, Washington, DC 20240.

Instructions: Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words “National Park Service” or “NPS” and must include the docket number or RIN (1024–AE79) for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read comments received, go to <https://www.regulations.gov> and search for “1024–AE79”.

FOR FURTHER INFORMATION CONTACT: Jay Calhoun, Division of Regulations, Jurisdiction and Special Park Uses, National Park Service; phone: (202) 513–7112; email: waso_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. In compliance with the Providing Accountability Through Transparency Act of 2023, the plain language summary of the proposal is available on <https://www.regulations.gov> in the docket for this rulemaking.

SUPPLEMENTARY INFORMATION:

Background

Powered micromobility devices, such as e-scooters, hoverboards and Segways, are appearing on lands administered by the National Park Service (NPS) with greater frequency, especially in urban locations. Units of the National Park System, such as the National Mall and Memorial Parks in Washington, DC, are filled with e-scooters on a daily basis as visitors use them to access, leave, and travel through the park, including on sidewalks and paths that are shared with pedestrians. Other System units with considerable use of e-scooters and other powered micromobility devices include Golden Gate National Recreation Area, San Antonio Missions National Historical Park, Mississippi National River and Recreation Area, and Cape Cod National Seashore. The U.S. Department of Transportation (DOT) Federal Highway Administration provides a fact sheet with an overview on micromobility, along with links to additional resources.¹ U.S. DOT also funds the Pedestrian and Bicycle Information Center (PBIC), which has a website containing a volume of information about active transportation, including micromobility devices. The information in this Background section is a basic overview of powered micromobility devices that is found on the PBIC website. Please visit <https://www.pedbikeinfo.org/> for more information.

The U.S. DOT and PBIC classify traditional and electric bicycles as micromobility devices; however, the use of traditional and electric bicycles in units of the National Park System is already governed by regulations in 36 CFR 4.30 and therefore is not addressed in this proposed rule. As used in the Background section of this proposed rule, the term “powered micromobility devices” does not refer to traditional bicycles, nor does it refer to electric bicycles, nor to human powered

coasting devices such as roller skates and skateboards, which are governed by NPS regulations at 36 CFR 2.20. It does refer to electric standing or sitting scooters (e-scooters) and devices such as electric skateboards, electric skates, and one-wheeled or two-wheeled electric self-balancing devices (e.g., balance wheels, hoverboards and Segways).

According to the PBIC, powered micromobility devices share three common characteristics.² First, powered micromobility devices are motorized. They can be fully motorized or motor-assisted, in which the rider can provide some human-powered propulsion, such as by kicking. They usually involve a battery-powered electric motor that provides 750 watts of maximum power. Second, powered micromobility devices are operated at low speed. Most powered micromobility devices are designed to travel at or below 20 miles per hour (mph), although some can reach 30 mph.³ Others may be regulated to lower maximum speeds, such as 8 mph or less, to be compatible with sidewalk use. Third, powered micromobility devices are small in size. Most powered micromobility devices are three feet wide or less to fit within the standard width of a bike lane or sidewalk. Most powered micromobility devices weigh less than 50 pounds. Due to their weight and size, most powered micromobility devices are designed to be used by single riders.

Users can own or rent powered micromobility devices. Rentals account for the majority of use in urban areas due to the deployment of shared fleets by private companies such as Uber, Lyft, Bird, and Lime. Shared fleets provide users with on-demand access to powered micromobility devices, which operators typically unlock using a smartphone application. Powered micromobility devices that are part of shared fleets are most commonly parked in public rights-of-way, such as sidewalks. In some cases, parking areas or docks may exist for grouping devices when they are not in use. Powered micromobility devices are mostly used in cities and serve a variety of transportation and public health goals. Shared powered micromobility devices provide communities with healthy, affordable, and low- or no-emission

transportation options.⁴ Powered micromobility devices can help close first- and last-mile gaps to transit and offer individuals greater access to jobs, health care, and other services.⁵ This may be particularly true for underserved communities.⁶ Powered and adaptive micromobility devices may increase mobility for older adults or individuals with disabilities because they are less strenuous to operate than traditional bicycles or scooters.⁷ San Francisco, Portland, Kansas City, and Washington, DC, expressly align e-scooter use with the goal of reducing carbon emissions and air pollution.⁸ Powered micromobility devices serve the NPS’s goal of promoting alternative transportation systems in System units that use modes of travel other than private motor vehicles. Alternative transportation systems can help connect communities to parks, manage congestion and ease parking shortages, improve air quality and soundscapes, and reduce collisions between automobiles and wildlife. Shared powered micromobility devices continue to become more prevalent and popular. The North American Bikeshare and Scootershare Association estimates that 62.2 million trips on e-scooters were taken in North America in 2021.⁹

Existing Regulatory Framework

The safety of powered micromobility devices, like other products sold in the United States, is regulated by the Consumer Product Safety Commission (CPSC) under the Consumer Product Safety Act. 15 U.S.C. 2051–2090. The CPSC does not regulate who may use powered micromobility devices and where they may be used.

The NPS has broad authority to regulate activities that occur within units of the National Park System. See 54 U.S.C. 100101 and 100751. NPS regulations addressing the use of motor vehicles, traditional bicycles, and electric bicycles are found in 36 CFR 4.30. Each of these devices is defined separately in 36 CFR 1.4 and has its own regulatory framework in 36 CFR part 4

⁴ U.S. Department of Transportation, Federal Highway Administration, Shared Micromobility and Equity Primer.

⁵ U.S. Department of Transportation, Federal Highway Administration, Fact Sheet on Micromobility.

⁶ Id. See also U.S. Department of Transportation, Federal Highway Administration, Shared Micromobility and Equity Primer.

⁷ U.S. Department of Transportation, Federal Highway Administration, Fact Sheet on Micromobility.

⁸ Blickstein, S. *et al.* (December 2019). E-Scooter Programs: Current State of Practice in US Cities.

⁹ NABSA 2021 Shared Micromobility State of the Industry Report.

² Sandt, L. (October 2019). The basics of micromobility and related motorized devices for personal transport. Pedestrian and Bicycle Information Center: Chapel Hill, NC.

³ The Society of Automotive Engineers classifies powered micromobility devices as those with a top speed of less than 30 mph. See Taxonomy and Classification of Powered Micromobility Vehicles J3194_201911 issued November 20, 2019.

¹ U.S. Department of Transportation, Federal Highway Administration, Fact Sheet on Micromobility.

that is tailored to the characteristics of each device and how they are used. Human powered coasting devices, such as roller skates and skateboards, are governed separately under 36 CFR 2.20. Motor vehicles are defined in 36 CFR 1.4 as “every vehicle that is self-propelled and every vehicle that is propelled by electric power, but not operated on rails or water, except an electric bicycle, a snowmobile, and a motorized wheelchair.” This definition is broad enough to include powered micromobility devices. As a result, powered micromobility devices fall within the NPS’s existing regulatory framework for motor vehicles, even though powered micromobility devices are lighter, smaller and used differently in System units. The differences between traditional motor vehicles and powered micromobility devices are numerous, but to highlight one that relates to the potential to cause impacts to resources and visitors in System units, the average weight of an automobile is 4,303 pounds while most powered micromobility devices weigh less than 50 pounds.¹⁰

Due to concerns about impacts to resources and visitors, NPS regulations at 36 CFR 4.10 generally limit motor vehicle use to public roads and parking areas within System units. See 52 FR 10679 (April 2, 1987). The NPS may allow off-road motor vehicle (ORV) use in national recreation areas, national seashores, national lakeshores and national preserves, but only after it completes a notice and comment rulemaking process that designates routes and areas for ORV use in special regulations that apply to the System unit. ORV use is not allowed in national parks or other types of System units (e.g., national monuments) that are managed by the NPS but not identified in 36 CFR 4.10. These regulatory requirements are consistent with the provisions of Executive Orders 11644 and 11989 (“Use of off-road vehicles on the public lands”) that were issued in 1972 and 1977. These Executive orders require Federal agencies to limit ORV use on public lands to designated routes or areas in a manner that protects resources, promotes visitor safety, and minimizes user conflicts. The Executive orders require Federal agencies to issue regulations providing for the designation of the specific areas and trails where ORV use is allowed on public lands. Unlike the NPS’s definition of “motor vehicle,” which is not limited to vehicles with off-road capabilities, the Executive orders apply

to “off-road vehicles” that are “designed for or capable of cross-country travel on or immediately over land, water, sand, snow, ice, marsh, swampland, or other natural terrain.”

Despite obvious differences in design, capability, and the potential to cause impacts to resources and visitors, current NPS regulations apply to powered micromobility devices and traditional motor vehicles in the same way. This has led to an undesired outcome where (1) NPS transportation goals to promote alternative transportation, protect the climate, and connect diverse communities;¹¹ (2) visitor expectations; and (3) on-the-ground use of powered micromobility devices are not served by outdated regulations meant to address a different type of visitor use activity within System units. On the one hand, NPS motor vehicle regulations are too limiting with respect to where powered micromobility devices may be used off park roads and parking areas, especially in System units located in or near cities. In these System units, visitors use powered micromobility devices, such as e-scooters and Segways, on paved and gravel sidewalks and paths in a manner that causes impacts to resources and visitors that are much less significant than would be caused by traditional motor vehicles (e.g., cars, trucks and vans) used in the same locations. On the other hand, NPS motor vehicle regulations are too lenient with respect to the use of powered micromobility devices on roads and parking areas. The existing regulations allow powered micromobility devices by default on all roads open to public motor vehicle use, many of which are not designed or suited to be shared with faster and heavier traditional motor vehicles. Roads without infrastructure that separates users who are not protected by an enclosed vehicle or safety restraints (such as seatbelts), which includes the vast majority of users of powered micromobility devices, can lead to user conflicts and increase the risk of injury.

One other existing regulatory framework is relevant to the use of shared powered micromobility devices in System units. NPS regulations at 36 CFR 5.3 (“Business operations.”) prohibit anyone from conducting a business in a System unit except in accordance with a permit, contract or other written agreement with the United States. Companies that operate shared fleets of e-scooters (e.g., Uber, Lyft, Bird, Lime) within System units must obtain written authorization to do so under

these regulations. The NPS may issue a commercial use authorization (CUA) or a concession contract to these businesses that contain terms and conditions governing how the business may be operated in the System unit. The NPS will continue to manage the operation of these shared fleets as a business through regulations and policies that apply to CUAs and concession contracts, and the terms and conditions of those instruments when they are issued to the CUA-holder or concessioner. This proposed rule would establish rules governing the use a powered micromobility device by the operator in the same way, whether the device is owned by the operator or rented from a company authorized to do business in the System unit.

Proposed Rule

This proposed rule would define powered micromobility devices separately from motor vehicles, bicycles, electric bicycles, and human powered coasting devices. This proposed rule would establish a distinct management framework for where powered micromobility devices are allowed in System units. This framework would provide flexibility to superintendents who believe that powered micromobility devices can be used by visitors and managed by the NPS in certain locations. At the same time, the proposed rule would ensure that powered micromobility devices capable of cross-country travel on or immediately over natural terrain may not be used in that manner without notice and comment rulemaking, consistent with Executive Orders 11644 and 11989.

The proposed rule would define a “powered micromobility device” as a human-operated, self-propelled device with a curb weight of less than 150 pounds and without an internal combustion engine. The definition would state that powered micromobility devices do not include an electric bicycle, motorized wheelchair, snowmobile, vessel, or motor vehicle (as those terms are defined in 36 CFR 1.4), or a non-bicycle coasting device that is solely human powered (as that term would be defined by this proposed rule).

The NPS intends the definition to include devices that are capable of self-propulsion even if they also may be propelled with human power. For example, the NPS intends the definition to include e-scooters that are primarily moved by an electric motor, even if they also may be propelled by kicking.

The proposed definition has a higher maximum weight (150 pounds) than the

¹⁰ The 2022 EPA Automotive Trends Report. EPA-420-R-23-033 December 2023.

¹¹ Current State of Transportation Needs and Priorities, NPS (2021).

typical weight for powered micromobility devices (less than 50 pounds) in order to include heavier devices such as Segways and adaptive devices designed for individuals with disabilities. Even though they are heavier than most powered micromobility devices, these devices are typically smaller and slower than traditional motor vehicles and are used similarly to lighter powered micromobility devices. One hundred and fifty pounds is well within range of the definition established by the Society of Automotive Engineers for powered micromobility vehicles, which includes devices weighing up to 500 pounds.¹² If powered micromobility devices above a certain weight would cause unacceptable impacts to resources or visitors, the proposed rule would authorize the superintendent to limit the maximum weight of powered micromobility devices below 150 pounds if necessary.

The proposed definition would exclude all devices with an internal combustion engine. In practice, most devices with an internal combustion engine would not qualify under the proposed definition because they weigh more than 150 pounds. Even the lightest versions, such as golf carts and mopeds, weigh at least 200 pounds and some can weigh more than 1,000 pounds.¹³ Although most devices with internal combustion engines would be excluded from the definition due to weight, the proposed rule would exclude all such devices from the definition due to their potential to cause adverse impacts to resources, including wildlife, caused by engine noise and exhaust.¹⁴

Under the proposed definition, powered micromobility devices would have a weight limit but no size limit. This would give superintendents the flexibility to allow larger than normal powered micromobility devices in locations that can accommodate their use. Neither would the proposed definition limit powered micromobility devices by maximum capable speed. The proposed rule would state that the regulations in 36 CFR 4.21 apply to the use of powered micromobility devices. These regulations set baseline speed limits on roads and apply to motor vehicles, traditional bicycles, and

electric bicycles, but also give the superintendent the discretion to designate different speed limits if the baseline limits are unreasonable, unsafe, or inconsistent with the purposes of the System unit. Under the proposed rule, superintendents also would have the authority to establish speed limits for powered micromobility devices off roads that are suitable for each designated location as a condition of use.

The NPS believes that defining powered micromobility devices by weight and engine type is sufficient because these characteristics are strongly correlated to potential for the device to cause impacts to resources and visitors. Weight and speed are the primary factors that determine the amount of kinetic energy transferred in a collision, which correlates to the severity of injuries caused by the collision;¹⁵ and internal combustion engines produce engine noise and exhaust that have the potential to cause adverse impacts to resources, including wildlife.

The proposed rule would prohibit the use of powered micromobility devices in System units except in designated locations. The proposed rule would require the NPS to complete notice and comment rulemaking to allow powered micromobility devices on natural terrain that is unimproved by artificial materials. Examples of natural terrain are sand, snow, rock, vegetation, and soil, and include natural terrain that has been designed, constructed or designated for other types of visitor use (e.g., hiking, bicycling, equestrian, ORV use) but remains natural because artificial materials that have been processed by humans, such as paving or gravel, have not been added to the surface. This rulemaking requirement is consistent with Executive Orders 11644 and 11989 that require federal agencies to issue regulations to manage the use of motorized vehicles designed for or capable of cross-country travel on or over natural terrain. This requirement will help ensure that the use of powered micromobility devices in System units will not create unacceptable impacts to soils, watershed, vegetation, wildlife, or other park resources; or create unacceptable visitor use conflicts or safety concerns.

Other locations, such as park roads, parking areas, administrative roads, and paved and gravel sidewalks and paths, could be designated by the superintendent pursuant to the

requirements in 36 CFR 1.5 and 1.7. These requirements apply to discretionary actions taken by superintendents to manage visitor use in System units. Superintendents would be required to prepare a written determination justifying the decision to allow powered micromobility devices in designated locations. Superintendents would be required to provide public notice of such actions, including by listing all designated locations in the superintendent's compendium for the System unit. The superintendent's compendium is a compilation of management actions about visitor use in a System unit that must be made available to the public under 36 CFR 1.7. Superintendents could designate these other locations without notice and comment rulemaking, except that notice and comment rulemaking would be required under 36 CFR 1.5(b) if the designated locations would be highly controversial or otherwise significant using the criteria in paragraph (b).¹⁶

Except for administrative actions taken by the NPS in limited circumstances, the Wilderness Act prohibits mechanical transport in wilderness areas designated by Congress. 16 U.S.C. 1133(c). Accordingly, the proposed rule would prohibit possessing a powered micromobility device in a wilderness area established by Federal statute, unless otherwise allowed under Federal law. The same prohibition applies to bicycles and electric bicycles under NPS regulations at 36 CFR 4.30. Superintendents would not have the authority to override this prohibition by designating locations in wilderness using the superintendent's compendium.

The proposed rule would authorize the superintendent to establish conditions for the use of powered micromobility devices in designated locations pursuant to the requirements in 36 CFR 1.5 and 1.7. Superintendents could tailor these conditions to the characteristics of the designated locations to minimize impacts to resources and other visitors. For example, superintendents could limit the size of powered micromobility devices on narrow sidewalks or require users to park powered micromobility devices in locations away from sensitive resources or public rights-of-way. As

¹² Society of Automotive Engineers Taxonomy and Classification of Powered Micromobility Vehicles J3194_201911 issued November 20, 2019.

¹³ Sandt, L. (October 2019). The basics of micromobility and related motorized devices for personal transport. Pedestrian and Bicycle Information Center: Chapel Hill, NC.

¹⁴ See Glen Canyon National Recreation Area Off-road Vehicle Management Plan/Final Environmental Impact Statement, Chapter 3: Affected Environment, January 2017.

¹⁵ Kumfer, *et al.* Speed, Kinetic Energy, and the Safe Systems Approach to Safer Roadways, ITE Journal, April 2019.

¹⁶ Rulemaking is required for an action "which is of a nature, magnitude and duration that will result in a significant alteration in the public use pattern of the park area, adversely affect the park's natural, aesthetic, scenic or cultural values, require a long-term or significant modification in the resource management objectives of the unit. . . ." 36 CFR 1.5(b).

another example, superintendents could limit the speed of powered micromobility devices to help reduce the number of crashes. And as a final example, superintendents could decide that only certain types of micromobility devices (e.g., e-scooters) are allowed in certain locations.

The proposed rule would state that the use of powered micromobility devices is governed by State and local law unless addressed by regulations in the proposed rule or by conditions established by the Superintendent. State and local laws address topics such as time of use, age limits, speed limits, helmets, and driver's license requirements.¹⁷ Adopting non-conflicting State law would promote consistency with rules promulgated by State and local governments for the use of powered micromobility devices in their jurisdictions. At the same time, the NPS would have the authority to preempt State or local laws in order to maintain responsibility for the management of System units in accordance with Federal laws and policies.

The proposed rule would state that the use of powered micromobility devices is subject to certain existing regulations that apply to the use of bicycles and electric bicycles. These regulations appear in §§ 4.12 (Traffic control devices), 4.13 (Obstructing traffic), 4.20 (Right of way), 4.21 (Speed limits), 4.22 (Unsafe operation), 4.23 (Operating under the influence of alcohol or drugs), and 4.30(h)(3) through (5) (Operating during periods of low visibility, abreast of another bicycle, and with an open container of alcohol).

Finally, the proposed rule would define the term "coasting device" and revise 36 CFR 2.20 to clarify that the regulations in section 2.20 apply to roller skates, skateboards, roller skis, scooters, or similar wheeled devices that are propelled solely by human power, except a bicycle. This would eliminate any potential for confusion about whether powered micromobility devices are subject to the regulations in § 2.20.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563 and 14094)

Executive Order (E.O.) 14094 amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations

that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866 and E.O. 13563. Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this proposed rule in a manner consistent with these requirements.

E.O. 12866, as reaffirmed by E.O. 13563 and amended and reaffirmed by E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA determined that this proposed rule is not significant.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

This proposed rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This certification is based on information contained in the economic analyses found in the report entitled "Regulatory Analysis of the Powered Micromobility Devices at National Park System Units Proposed Rule." The report may be viewed in the docket for this rulemaking action by visiting <https://www.regulations.gov/> and searching for "RIN 1024-AE79".

Congressional Review Act

This proposed rule is not a major rule under 5 U.S.C. 804(2). This proposed rule:

- (a) Does not have an annual effect on the economy of \$100 million or more.
- (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

This proposed rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than \$100 million per year. The proposed rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. It addresses public use of lands administered by the NPS and

imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.) is not required.

Takings (E.O. 12630)

This proposed rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. A takings implication assessment is not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, the proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This proposed rule only affects the use of federally administered lands. It has no direct effects on other areas. A federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This proposed rule complies with the requirements of E.O. 12988. This proposed rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The NPS has evaluated this proposed rule under the criteria in E.O. 13175 and under the Department's Tribal consultation policy and has determined that Tribal consultation is not required because the proposed rule will have no substantial direct effect on federally recognized Indian Tribes.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule contains no new information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The NPS may not conduct or sponsor, and you are not required to respond to a collection of information, unless it displays a currently valid Office of Management and Budget (OMB) control number.

¹⁷ Blickstein, S. et al. (December 2019). E-Scooter Programs: Current State of Practice in US Cities.

National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq.)

This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the proposed rule is covered by a categorical exclusion. The proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. The NPS has determined the proposed rule is categorically excluded under NPS NEPA Handbook section 3.3.D.3 that covers minor changes in regulations pertaining to visitor use activities.

Compared to the existing regulations in 36 CFR 4.10 that apply to motor vehicles (and to powered micromobility devices at present), this proposed rule would make four changes to existing regulations.

First, the proposed rule would allow superintendents to open park roads and parking areas to the use of powered micromobility devices, but only if they designate such locations for the use of powered micromobility devices in the superintendent's compendium. Under the existing regulations that apply to motor vehicles, powered micromobility devices are allowed on park roads and parking areas by default. This administrative change would require superintendents to consider the potential impacts to resources and visitors from allowing powered micromobility devices in these locations.

Second, the proposed rule would allow superintendents to designate paved and artificially improved sidewalks, paths and other locations for the use of powered micromobility devices. Under the existing regulations that apply to motor vehicles, superintendents have no authority to allow powered micromobility devices off roads and parking areas. Off-road locations must be designated through notice-and-comment rulemaking. The impact of this change compared to baseline conditions is reduced by the application of 36 CFR 1.5 to the superintendent's authority to manage powered micromobility devices in the proposed rule. Paragraph (b) of § 1.5 requires certain actions to be published as rulemaking in the **Federal Register**. To the extent designating paved and artificially improved sidewalks, paths and other locations for the use of powered micromobility devices would trigger this rulemaking requirement,

then the procedural result would be the same as baseline conditions which require rulemaking in every case.

Third, powered micromobility devices would be allowed off roads and parking areas in any System unit, either by designation in the superintendent's compendium (for artificially improved locations that do not meet the criteria for rulemaking in 36 CFR 1.5(b)) or through notice-and-comment rulemaking (for other locations). Under the existing regulations that apply to motor vehicles, powered micromobility devices may only be allowed off roads and parking areas in certain System units (national recreation areas, national seashores, national lakeshores and national preserves).

The NPS considers the cumulative effect of these changes to be minor because they would affect how the NPS manages a relatively small subset of "motor vehicles" in portions of System units where powered micromobility devices are present. In addition, according to the regulatory analysis report conducted by Industrial Economics (see the section entitled "Regulatory Flexibility Act" above), all surveyed superintendents at System units where powered micromobility devices are currently being used, indicated their intention to update the superintendent's compendium to allow for continued powered micromobility device use, resulting in very little on the ground change compared to current conditions. In addition to the fact that the changes are minor, decisions made under this proposed rule to allow powered micromobility devices within System units will be subject to compliance with NEPA at that time.

The fourth change to existing regulations would define coasting devices for clarity and result in no changes to visitor use under existing regulations.

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

This proposed rule is not a significant energy action under the definition in E.O. 13211; the proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the proposed rule has not otherwise been designated by the Administrator of Office of Information and Regulatory Affairs as a significant energy action. A statement of energy effects is not required.

Clarity of This Proposed Rule

The NPS is required by E.O.s 12866 (section 1(b)(12)) and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential memorandum of

June 1, 1998, to write all rules in plain language. This means that each rule the NPS publishes must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use common, everyday words and clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that the NPS has not met these requirements, send comments by one of the methods listed in the **ADDRESSES** section. To better help the NPS revise the proposed rule, your comments should be as specific as possible. For example, you should identify the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Participation

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section of this document.

Public Availability of Comments

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.

List of Subjects

36 CFR Part 1

National parks, Penalties, Reporting and recordkeeping requirements, Signs and symbols.

36 CFR Part 2

Environmental protection, National parks, Reporting and recordkeeping requirements.

36 CFR Part 4

National Parks, Traffic regulations.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR parts 1, 2, and 4 as set forth below:

PART 1—GENERAL PROVISIONS

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

Authority: 54 U.S.C. 100101, 100751, 320102.

- 2. Amend § 1.4 in paragraph (a) by:

- a. Adding, in alphabetical order, the definition for “Coasting device”;
- b. Revising the definition for “Motor vehicle”;
- c. Adding, in alphabetical order, the definition for “Powered micromobility device”.

The additions and revision read as follows:

§ 1.4 What terms do I need to know?

(a) * * *

Coasting devices means roller skates, skateboards, roller skis, scooters, or similar wheeled devices that are propelled solely by human power, except a bicycle.

* * * * *

Motor vehicle means every vehicle that is self-propelled and every vehicle that is propelled by electric power, but not operated on rails or water, except an electric bicycle, a snowmobile, a powered micromobility device, and a motorized wheelchair.

* * * * *

Powered micromobility device means a human-operated, self-propelled device with a curb weight of less than 150 pounds and without an internal combustion engine. This definition does not include an electric bicycle, motorized wheelchair, snowmobile, vessel, motor vehicle, or coasting device.

* * * * *

PART 2—RESOURCE PROTECTION, PUBLIC USE AND RECREATION

- 3. The authority citation for part 2 continues to read as follows:

Authority: 54 U.S.C. 100101, 100751, 320102.

- 4. Revise § 2.20 to read as follows:

§ 2.20 Skating, skateboards, and similar devices.

Using coasting devices is prohibited, except in designated areas.

PART 4—VEHICLES AND TRAFFIC SAFETY

- 5. The authority citation for part 4 continues to read as follows:

Authority: 5 4 U.S.C. 100101, 100751, 320102.

- 6. Add § 4.32 to read as follows:

§ 4.32 Powered micromobility devices.

(a) Operating a powered micromobility device is prohibited except in designated locations. Locations with a surface that is natural terrain, unimproved by artificial materials such as paving or gravel, must be designated by rulemaking in the **Federal Register**. Other locations, such

as park roads, parking areas, administrative roads, and paved and gravel sidewalks and paths, may be designated by the superintendent pursuant to §§ 1.5 and 1.7 of this chapter.

(b) The superintendent may establish conditions for the use of powered micromobility devices pursuant to §§ 1.5 and 1.7 of this chapter.

(c) Unless addressed by regulations in this section or by conditions established by the Superintendent, the use of powered micromobility devices is governed by State and local law.

(d) A person operating a powered micromobility device is subject to the following sections of this part that apply to bicycles and electric bicycles: §§ 4.12, 4.13, 4.20, 4.21, 4.22, 4.23, and 4.30(h)(3) through (5).

(e) Possessing a powered micromobility device in a wilderness area established by Federal statute is prohibited, unless otherwise allowed by Federal law.

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–31578 Filed 1–15–25; 8:45 am]

BILLING CODE 4312–52–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 257

[EPA–HQ–OLEM–2020–0107; FRL–7814.1–03–OLEM]

RIN 2050–AH34

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Legacy CCR Surface Impoundments; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to correct errors and clarify several provisions published in the **Federal Register** on May 8, 2024. This May 8, 2024 rule (Legacy Final Rule) established regulatory requirements for legacy coal combustion residuals (CCR) surface impoundments and CCR management units, among other things, under the Resource Conservation and Recovery Act (RCRA). This proposal seeks comment on issues discussed in a direct final rule to correct errors and clarify in the Legacy Final Rule.

DATES: Comments must be received on or before March 17, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2020–0107, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.

- **Mail:** U.S. Environmental Protection Agency, EPA Docket Center, Office of Land and Emergency Management (OLEM) Docket, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

- **Hand Delivery or Courier** (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center’s hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions concerning this proposal, contact Frank Behan, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, MC: 5304T, Washington, DC 20460; telephone number: (202) 566–0531; email address: behan.frank@epa.gov, or Taylor Holt, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, MC: 5304T, Washington, DC 20460; telephone number: (202) 566–1439; email address: Holt.Taylor@epa.gov. For more information on this rulemaking please visit <https://www.epa.gov/coalash>.

SUPPLEMENTARY INFORMATION:

I. Public Participation—Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2020–0107, at <https://www.regulations.gov/> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not

submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. General Information

A. Does this action apply to me?

This rule may be of interest to electric utilities and independent power producers that fall within the North American Industry Classification System (NAICS) code 221112. The reference to NAICS code 221112 is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This discussion lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not described here could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR 257.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

EPA is proposing to correct errors and conform the regulatory text to the decisions articulated in the Legacy Final Rule published in the **Federal Register** on May 8, 2024, which established regulatory requirements for legacy CCR surface impoundments and CCR management units (CCRMU). 89 FR 38950. In addition, EPA is proposing a number of revisions to clarify the final requirements, such as consolidating the compliance deadlines for CCRMU into a single section and providing a deadline for the initial fugitive dust plan for CCRMU at facilities without a regulated unit.

In the "Rules and Regulations" section of this **Federal Register**, EPA has also published a direct final rule for this same action because the Agency views this as a noncontroversial action and anticipates no adverse comment. EPA has explained the reasons for this in the preamble to the direct final rule. This proposed rule provides an opportunity for the public to comment on the issues discussed in the preamble to the direct final rule.

In light of the narrow purpose of this rule to conform the regulatory text to the final actions described in the Legacy Final Rule, EPA is only soliciting comment on whether the changes in the direct final rule conform the text to EPA's stated intent in the Legacy Final Rule preamble. EPA is not reconsidering, proposing to reopen, or otherwise soliciting comment on any provisions of the Legacy Final Rule itself. For the reader's convenience, EPA has provided a background description of individual provisions in the Legacy Final Rule in several places throughout the direct final rule preamble. These descriptions do not reopen the underlying described provisions, but merely explain the context to inform the public of the basis for this action's technical corrections. EPA will not respond to comments submitted on any issues other than those specifically identified in the direct final rule, and such comments will not be considered part of the rulemaking record.

If EPA receives no adverse comment on the corrections in the direct final rule, the Agency will not take further action on this proposed rule and the direct final rule will become effective as provided in that action. If EPA does receive adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public about the specific regulatory paragraph(s) or amendment(s) in the direct final rule that will not take effect. The corrections in the direct final rule that are not withdrawn will become effective on the date set out above. EPA will address all public comments in any subsequent final rule based on this proposed rule.

EPA does not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this proposed rule see the **ADDRESSES** section of this document.

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

EPA is publishing this rulemaking under the authority of sections 1008(a)(3), 2002(a), 4004, and 4005(a),

(d) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, 42 U.S.C. 6907(a), 6912(a), 6944, 6945(a) and (d).

D. Where is the location of regulatory text for this proposal?

The regulatory text for this proposal is identical to that for the direct final rule published in the Rules and Regulations section of this **Federal Register**. For further supplemental information, the detailed rationale for the proposal, and the regulatory revisions, see the information provided in the direct final rule published in the Rules and Regulations section of this **Federal Register**.

III. Statutory and Executive Order (E.O.) Reviews

For a complete discussion of all of the administrative requirements applicable to this action, see the direct final rule in the Rules and Regulations section of this **Federal Register**.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Jane Nishida,

Acting Administrator.

[FR Doc. 2025-00847 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2017-0183; FRL-5120-05-OAR]

RIN 2060-AO18

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Large Municipal Waste Combustors Voluntary Remand Response and 5-Year Review; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; request for comment; reopening of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is reopening the comment period on the proposed Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Large Municipal Waste Combustors Voluntary Remand Response and 5-Year Review. The original proposed rule was published on January 23, 2024, with a 60-day comment period closing March 25, 2024. With this notification, EPA is reopening the public comment period for an additional 6 months, from January 16, 2025, to July 16, 2025.

DATES: The comment period for the proposed rule published at 89 FR 4243 on January 23, 2024, is reopened. Comments must be received on or before July 16, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2017-0183, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- **Email:** a-and-r-docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2017-0183 in the subject line of the message.
- **Fax:** (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2017-0183.
- **Mail:** U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2017-0183, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- **Hand/Courier Delivery:** EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact U.S. EPA, Attn: Noel Cope, Mail Drop: E143-02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North

Carolina 27711; telephone number: (919) 541-2128; and email address: cope.noel@epa.gov.

SUPPLEMENTARY INFORMATION:

Rationale. On January 23, 2024, the EPA proposed amendments to 40 Code of Federal Regulations (CFR) part 60, subparts Cb and Eb, the Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Large Municipal Waste Combustors (89 FR 4243). The comment period for this proposed rule closed on March 25, 2024. The EPA has decided to reopen the comment period for an additional 6 months for the EPA to gather additional information on the proposed amendments to the Large Municipal Waste Combustor regulations. Specifically, the EPA seeks additional information and documentation on verifiable historic pollutant emission concentration information (e.g., stack test reports, waste characterization reports and continuous emission monitor records) for the industry so that we can further assess the proposed maximum achievable control technology (“MACT”) requirements, including operation of the control technologies over time. The public comment period will now end on July 16, 2025.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2017-0183. All documents in the docket are listed in <https://www.regulations.gov/>. 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. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov*.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2017-0183. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <https://www.regulations.gov/>, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to <https://www.regulations.gov/> any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to its public docket.

Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

The <https://www.regulations.gov/> website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <https://www.regulations.gov/>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

Submitting CBI. Do not submit information containing CBI to the EPA through <https://www.regulations.gov/>. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and

note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (e.g., Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address oaqps_cbi@epa.gov, and as described above, should include clear CBI markings, and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email oaqps_cbi@epa.gov to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, P.O. Box 12055, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2017-0183. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Penny Lassiter,
Director, Sector Policies and Programs
Division.

[FR Doc. 2025-00648 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 216 and 300

[Docket Number 250108-008]

RIN 0648-BG11

Implementation of Provisions of the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015, the Ensuring Access to Pacific Fisheries Act, and the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023

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

ACTION: Proposed rule; withdrawal.

SUMMARY: NMFS formally withdraws a proposed rule on the Implementation of

Provisions of the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015 and the Ensuring Access to Pacific Fisheries Act, which was published in the **Federal Register** on July 8, 2022. This proposed rule would have implemented certain provisions of the two acts and amended the definition of illegal, unreported, or unregulated (IUU) fishing in the regulations that implement the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act). After the proposed rule was issued, Congress amended the Moratorium Protection Act by the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (NDAA). NMFS has been developing a revised proposed rule in light of the NDAA to conform to the statutory changes, but does not have sufficient time to finalize the rule in this Administration.

DATES: The National Marine Fisheries Service is withdrawing the proposed rule published July 8, 2022 (87 FR 40763) as of January 16, 2025.

ADDRESSES: Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service, 1315 East-West Highway (F/IS5), Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:

Terra Lederhouse, Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service (phone: 301-427-8360; or email: terra.lederhouse@noaa.gov).

SUPPLEMENTARY INFORMATION:

Background

On July 8, 2022, NMFS published a proposed rule (87 FR 40763) on the Implementation of Provisions of the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015 and the Ensuring Access to Pacific Fisheries Act. The proposed rule would have implemented the Agreement on Port State Measures to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing (PSMA) and certain other provisions of the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015, Public Law 114-81 (November 15, 2015), as well as certain provisions of the Ensuring Access to Pacific Fisheries Act, Public Law 114-327 (December 16, 2016). The purpose of this proposed rule was to establish or amend procedures intended to assist the United States in combatting IUU fishing. It would have implemented the PSMA, which is intended to enhance regional and international cooperation and the ability of nations to detect and intercept products of IUU fishing before they enter into national

and international markets. It would have amended the definition of IUU fishing in the regulations that implement the High Seas Driftnet Fishing Moratorium Protection Act as well as procedures to identify nations whose vessels undertake IUU fishing and other unsustainable fishing practices and negatively certify nations when they fail to take appropriate corrective actions. Finally, this proposed rule would also have amended the fisheries enforcement mechanisms of a number of existing statutes implementing U.S. obligations to regional fisheries management organizations and other international conservation organizations.

After the proposed rule was issued, President Biden signed the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (NDAA), Public Law 117-263 (December 23, 2022). NMFS has been revising the July 8, 2022, proposed rule in light of amendments made to the Moratorium Protection Act by the NDAA to conform to the statutory changes. Combatting IUU fishing has been a top priority for NMFS, and NMFS has actively engaged with interagency partners and constituents on how best to address this critical issue through rulemaking and other means since the passage of the NDAA. Despite its best efforts, NMFS does not have sufficient time to finalize before the end of this Administration a revised version of the regulation that would appropriately address the statutory changes or to seek public input on those potential changes.

Accordingly, NMFS hereby withdraws the July 2022 proposed rule and terminates this rulemaking proceeding. If, in the future, NMFS decides it is appropriate to issue regulations on this topic, it will do so via a new notice of proposed rulemaking, subject to the requirements of the Administrative Procedure Act, 5 U.S.C. 551, *et seq.*

Authority: Pub. L. 114-81 (November 15, 2015); Pub. L. 114-327 (December 16, 2016); Pub. L. 117-263 (December 23, 2022); 16 U.S.C. 1826d-k; 16 U.S.C. 1801 *et seq.*; 16 U.S.C. 5501 *et seq.*; 16 U.S.C. 2431 *et seq.*; 31 U.S.C. 9701 *et seq.*; 16 U.S.C. 1826a-1826c; 16 U.S.C. 1361 *et seq.*; 16 U.S.C. 971 *et seq.*; 16 U.S.C. 5601 *et seq.*; the Pacific Salmon Treaty Act, 16 U.S.C. 3631 *et seq.*; 16 U.S.C. 951 *et seq.*, 16 U.S.C. 5501 *et seq.*

Dated: January 8, 2025.

Samuel D. Rauch, III,
Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.

[FR Doc. 2025-00716 Filed 1-15-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 224**

[Docket No. 250108–0009]

RIN 0648–BI88

North Atlantic Right Whale Vessel Strike Reduction Rule

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

ACTION: Proposed rule; withdrawal.

SUMMARY: NMFS withdraws a proposed rule published in the **Federal Register** on August 1, 2022 to amend the North Atlantic right whale (*Eubalaena glacialis*) vessel speed regulations. NMFS withdraws this proposed rule in light of numerous and ongoing requests from the public for further opportunity to review and engage with the Agency on the proposal. NMFS's existing vessel speed regulations remain in effect.

DATES: The National Marine Fisheries Service is withdrawing the proposed rule published August 1, 2022 (87 FR 46921) as of January 16, 2025.

ADDRESSES: The August 1, 2022 proposed rule, and the comments received, are available at <https://www.regulations.gov>, Docket No. NOAA–NMFS–2022–0022.

FOR FURTHER INFORMATION CONTACT: Caroline Good, NMFS Office of Protected Resources, caroline.good@noaa.gov, 301–427–8402.

SUPPLEMENTARY INFORMATION:**Background**

The proposed rule (87 FR 46921, August 1, 2022) was intended to further reduce the likelihood of mortalities and serious injuries to endangered North Atlantic right whales from vessel collisions, which are impeding the species' recovery and are a primary factor in an ongoing Unusual Mortality Event. The proposed rule would have expanded the size class of regulated vessels subject to applicable vessel speed restrictions, enlarged the boundaries and extended the timing of seasonal speed zones, introduced mandatory dynamic (*i.e.*, temporary) speed zones when right whales were known to be present outside of active seasonal zones, clarified language related to enforcement of the rule, and updated the safety deviation provision and reporting requirements.

NMFS received approximately 90,000 public comments on the proposed rule.

The comments received addressed many different aspects of the rule and reflected views on all sides of the issues addressed. Despite its best efforts, NMFS does not have sufficient time to finalize this regulation in this Administration due to the scope and volume of public comments. NMFS hereby withdraws the August 2022 proposed rule and terminates this rulemaking proceeding. NMFS' existing North Atlantic right whale vessel speed regulations (50 CFR 224.105) remain in effect.

Withdrawal of the proposed rule does not preclude NMFS from taking future action, including but not limited to initiating a new rulemaking, to address ongoing lethal right whale vessel strikes. If, in the future, NMFS decides it is appropriate to issue regulations on this topic, NMFS will do so via a new rulemaking, in accordance with the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*

Authority: 16 U.S.C. 1531 *et seq.*; 16 U.S.C. 1361 *et seq.*

Dated: January 8, 2025.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2025–00718 Filed 1–15–25; 8:45 am]

BILLING CODE 3510–22–P

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS-LP-24-0072]

United States Classes, Standards, and Grades for Poultry

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice, request for comments.

SUMMARY: The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is seeking public comment on revisions to the United States Classes, Standards, and Grades for Poultry (the Poultry Standards). The last minor revision to the Poultry Standards occurred in 2018, but the last substantial revision prior to that occurred in 1998. Since then, poultry production and quality assessment methods have changed significantly, as have consumer preferences.

DATES: Submit comments on or before March 17, 2025.

ADDRESSES: Interested persons are invited to submit comments electronically at <https://www.regulations.gov>. Written comments should be sent to: Poultry Standards Revisions, Standards and Specifications Division; Livestock and Poultry Program, AMS, USDA; 1400 Independence Avenue SW, STOP 0258; Washington, DC 20250-0258. Comments may also be emailed to AMSPoultryResources@usda.gov. All comments should reference document number AMS-LP-24-0072, the date of submission, and the page number of this issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, and will be made available for public inspection at the above physical address during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Samantha Rhoderick, National Poultry Supervisor, Livestock and Poultry Program, phone (202) 603-9025; or email at Samantha.Rhoderick@usda.gov.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*), directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices." AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities. While the Poultry Standards do not appear in the Code of Federal Regulations, they—along with other official Standards—are maintained by USDA and can be found at <https://www.ams.usda.gov/grades-standards>. Copies of official Poultry Standards are also available upon request. To propose changes to the Poultry Standards, AMS utilizes the procedures published in the August 13, 1997, **Federal Register** (62 FR 43439) and in 7 CFR part 36.

Background

Official USDA grade Standards and associated voluntary, fee-for-service grading programs are authorized under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*). The primary purpose of USDA grade Standards, including the Poultry Standards, is to divide the population of a commodity into uniform groups (of similar quality, value, etc.) to facilitate marketing. In concert, the Federal voluntary, fee-for-service grading programs are designed to provide an independent, objective determination as to whether a given product is in conformance with the applicable USDA grade standard. USDA quality grades provide a simple, effective means of describing product that is easily understood by both buyers and sellers.

To ensure the Poultry Standards maintain relevance in a dynamic industry, USDA accepts recommendations for changes from interested parties at any time. The Poultry Standards were first developed in the 1930s, and periodic revisions were made to reflect industry

improvements or changes in the marketplace. The current Poultry Standards were last updated in 2018, to align the definition of "roaster" class with the 2013 Food Safety Inspection Service definition. Prior to that, the last substantial revisions occurred in 1998 when tolerances for the number and length of feathers were established and Standards were implemented for additional boneless, boneless skinless, and size reduced poultry parts.

The poultry industry has continued to evolve by incorporating camera quality assessment systems, robotics, artificial intelligence, machine learning, and other technological advancements. These tools will continue to impact how products are sorted for quality allowing much greater efficiency with decreased reliance on manual labor performed by authorized plant graders. AMS strives to ensure that the Poultry Standards keep pace with modernization and continue to serve the needs of industry and consumers.

Market trends have also shifted, and consumers are increasingly aware of industry marketing claims. Easy-to-prepare poultry products that require minimal preparation steps have grown increasingly popular. The overwhelming majority of poultry marketing is for further processed ready-to-eat items, as well as ready-to-cook poultry parts (bone-in, skin-on or boneless skinless), instead of whole carcasses. Therefore, AMS is inviting comments for revisions to the Poultry Standards that will better serve the needs of modern consumers.

According to the National Chicken Council, the average U.S. broiler weight at 47 days of age has increased about 30% from the year 2000 to the year 2023. New poultry myopathies such as woody breast, white striping, spaghetti breast, and deep pectoral myopathy have presented additional quality assessment challenges. Multiple studies have provided possible industry solutions for detection and segregation of affected product. Generally, AMS allows time for industry and academia to develop solutions to address such changes before implementing a revision to the Standards. Currently in addition to the requests mentioned above, AMS is also requesting input from industry whether a revision to the Poultry Standards to address these myopathies is necessary.

Request for Comments

AMS is soliciting comments including data, recommendations, and other information from stakeholders about potential changes to the U.S. Classes, Standards, and Grades for Poultry. Comments may include any current and/or ongoing research or industry practice that has relevance to this Poultry Standard. AMS also invites comments about how those changes would be implemented in the Federal voluntary, fee-for-service grading programs.

After reviewing the recommendations and information submitted in response to this notice, AMS will consult with other relevant government agencies, academia, industry, and stakeholders, to determine how updates to the Poultry Standards should be made. When updates are made, a draft of the updated Poultry Standards with all changes will be published in the **Federal Register** for an additional comment period. Any comments not directly related to updates or recommendations that are not accompanied by data and other information will not be considered.

AMS invites responses to the following questions:

1. How could the Poultry Standards be updated to better align with current and future advances in technology?
2. Are the current Poultry Standards and supplemental resources easily interpreted by industry employees, particularly the authorized plant graders actively applying them in facilities? If not, what updates to the Poultry Standards, additional resources, or training material are recommended?
3. Are there any defect categories that have become irrelevant or new defect categories that should be added?
4. How could the tolerances for existing defect categories be updated to better suit the needs of stakeholders?
5. Is there information in general which should be added to or removed from the current Poultry Standards?
6. How could the Poultry Standards be updated to reflect current marketing of Poultry? Could U.S. Grade B or U.S. Grade C be updated to be more useful in the marketing of poultry products, similar to how USDA Choice or USDA Select are useful marketing terms for red meat commodities?
7. How could the Poultry Standards be updated to be more useful to smaller poultry operations?
8. How could the Poultry Standards be updated to be more useful to volume food buyers and those engaged in institutional purchases?
9. How could the Poultry Standards be updated to be more meaningful to end consumers?

10. High quality poultry products are procured through the Federal Nutrition Assistance and Child Nutrition Programs using the Poultry Standards. How could the Poultry Standards be updated to improve the effectiveness of the purchase program in regard to value and quality?

11. Are there any other recommendations, suggestions, or ideas that would be relevant for AMS to consider?

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2025–01029 Filed 1–15–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2024–0028]

Addition of Nicaragua to the List of Regions Affected With Screwworm

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Nicaragua to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS website of regions considered affected with screwworm. We took this action because of the confirmation of screwworm in this region.

DATES: Nicaragua was added to the list of regions considered affected with screwworm effective March 29, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Heather Sriranganathan, APHIS Veterinary Services, Regionalization Evaluation Services, 4700 River Road, Riverdale, MD 20737; phone: (717) 818–3582; email: AskRegionalization@usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases and pests of livestock. Subparts C, D, E, and F of the regulations govern the importation of horses, ruminants, swine, and dogs, respectively.

Horses, ruminants, swine, and dogs may be imported into the United States from the regions where screwworm is considered to exist only if they are inspected and, if necessary, treated for screwworm according to the conditions outlined in the regulations for each type

of animal. The requirements for horses are set out in § 93.308(a)(3) and include not only pre-embarkation and post-arrival inspection and treatment requirements, but also quarantine in the United States for 7 days after arrival, and examination by a veterinarian before release from quarantine. The requirements for ruminants and swine are set out in §§ 93.405(a)(3) and 93.505(b) and are the same as for horses, other than the 7-day quarantine and final examination of the animal. The requirements for dogs are set out in § 93.600 and require that all dogs from affected regions be inspected and, if necessary, treated before importation.

The Animal and Plant Health Inspection Service (APHIS) maintains a list of regions APHIS considers affected with screwworm on its website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/>. APHIS will add a region to the list upon determining that screwworm exists in the region based on reports we receive of detections of the pest from veterinary officials of the exporting country, from the World Organization for Animal Health (WOAH), or from other sources the Administrator determines to be reliable.

On March 22, 2024, APHIS received a report from the U.S. Department of Agriculture, Trade and Foreign Agricultural Affairs office documenting an outbreak of screwworm in cattle in Nicaragua. This detection was confirmed by the Panama-United States Commission for the Eradication and Prevention of Screwworm on March 14, 2024. Accordingly, on March 29, 2024, APHIS added Nicaragua to the list of regions APHIS considers affected with screwworm. As a result, horses, ruminants, swine, and dogs from Nicaragua are subject to APHIS import restrictions designed to mitigate risk of screwworm introduction into the United States. This notice serves as an official record and public notification of this action.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 13th day of January 2025.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2025–01000 Filed 1–15–25; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS–2024–0066]

Addition of Guatemala and Honduras to the List of Regions Affected With Screwworm**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Notice.

SUMMARY: We are advising the public that we have added Guatemala and Honduras to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS website of regions considered affected with screwworm. We took this action because of the confirmation of screwworm in these regions.

DATES: Guatemala was added to the list of regions considered affected with screwworm effective November 1, 2024. Honduras was added to the list of regions considered affected with screwworm effective October 25, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Amber Kerk, APHIS Veterinary Services, Regionalization Evaluation Services, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; phone: (608) 662–0625; email: AskRegionalization@usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases and pests of livestock. Subparts C, D, E, and F of the regulations govern the importation of horses, ruminants, swine, and dogs, respectively.

Horses, ruminants, swine, and dogs may be imported into the United States from the regions where screwworm is considered to exist only if they are inspected and, if necessary, treated for screwworm according to the conditions outlined in the regulations for each type of animal. The requirements for horses are set out in § 93.308(a)(3) and include not only pre-embarkation and post-arrival inspection and treatment requirements, but also quarantine in the United States for 7 days after arrival, and examination by a veterinarian before release from quarantine. The requirements for ruminants and swine are set out in §§ 93.405(a)(3) and 93.505(b), respectively, and are the same as for horses, other than the 7-day quarantine and final examination of the animal. The requirements for dogs are

set out in § 93.600 and require that all dogs from affected regions be inspected and, if necessary, treated before importation.

The Animal and Plant Health Inspection Service (APHIS) maintains a list of regions it considers affected with screwworm on its website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/>. APHIS will add a region to the list upon determining that screwworm exists in the region based on reports we receive of detections of the pest from veterinary officials of the exporting country, from the World Organization for Animal Health (WOAH), or from other sources the Administrator determines to be reliable.

On October 29, 2024, WOAH received a report from Guatemala documenting an outbreak of New World screwworm (*Cochliomyia hominivorax*) in cattle with no recent import history. Accordingly, on November 1, 2024, APHIS added Guatemala to the list of regions APHIS considers affected with screwworm.

On September 16, 2024, WOAH also received a report from Honduras documenting an outbreak of New World screwworm in illegally imported horses in that country. APHIS responded by adding Honduras to the Temporary Restrictions list for the import of animal commodities from or transiting Honduras. Soon after, Honduras reported further detections of screwworm in livestock, including cattle and swine, to WOAH on October 25, 2024. Therefore, on October 25, 2024, APHIS added Honduras to the list of regions APHIS considers affected with screwworm.

As a result, horses, ruminants, swine, and dogs from Guatemala and Honduras are subject to APHIS import restrictions designed to mitigate risk of screwworm introduction into the United States. This notice serves as an official record and public notification of these actions.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 10th day of January 2025.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2025–00939 Filed 1–15–25; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS–2024–0068]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Rhizomes of Wasabi from Indonesia Into the United States**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with the importation of fresh rhizomes of wasabi, *Eutrema japonicum* (Miq.) Koidz. (Brassicaceae), for consumption from Indonesia into the United States. Based on the analysis, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh rhizomes of wasabi from Indonesia into the United States. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before March 17, 2025.

ADDRESSES: You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to www.regulations.gov. Enter APHIS–2024–0068 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS–2024–0068, Regulatory Analysis and Development, PPD, APHIS, Station 2C–10.16, 4700 River Road Unit 25, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Hesham Abuelnaga, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2010; Hesham.A.Abuelnaga@USDA.gov.

SUPPLEMENTARY INFORMATION:**Background**

Under the regulations in “Subpart L—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization of Indonesia to allow the importation of fresh rhizomes (underground stems) of wasabi, *Eutrema japonicum* (Miq.) Koidz. (Brassicaceae), for consumption from Indonesia into the United States. As part of our evaluation of Indonesia’s request, we have prepared a pest risk assessment to identify the pests of quarantine significance that could follow the pathway of the importation of fresh rhizomes of wasabi for consumption from Indonesia into the United States. Based on the pest risk assessment, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to fresh rhizomes of wasabi to mitigate the pest risk.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our pest risk assessment and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh rhizomes of wasabi for consumption from Indonesia into the United States, may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may request paper copies of the pest risk assessment and RMD by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh rhizomes of wasabi for consumption from Indonesia into the United States in a subsequent notice. If the overall

conclusions of our analysis and the Administrator’s determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh rhizomes of wasabi for consumption from Indonesia into the United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 10th day of January 2025.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2025–00952 Filed 1–15–25; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS–2023–0062]

Addition of Panama and Costa Rica to the List of Regions Affected With Screwworm

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Panama and Costa Rica to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS website of regions considered affected with screwworm. We took this action because of the confirmation of screwworm in these regions.

DATES: Panama was added to the list of regions considered affected with screwworm effective July 12, 2021. Costa Rica was added to the list of regions considered affected with screwworm effective August 21, 2023.

FOR FURTHER INFORMATION CONTACT:

For information on Panama, contact: Dr. Michael Ray, Regionalization Evaluation Services, Strategy and Policy, APHIS Veterinary Services, 920 Main Campus Drive, Venture II Suite 200, Raleigh, NC 27606; phone: (919) 855–7225; email: AskRegionalization@usda.gov.

For information on Costa Rica, contact: Dr. Rebecca Gordon, APHIS Veterinary Services, Regionalization Evaluation Services, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; phone: (919) 338–4972; email: AskRegionalization@usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 (referred to

below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock. Subparts C, D, E, and F of the regulations govern the importation of horses, ruminants, swine, and dogs, respectively.

Horses, ruminants, swine, and dogs may be imported into the United States from the regions where screwworm is considered to exist only if they are inspected and, if necessary, treated for screwworm according to the conditions outlined in the regulations for each type of animal. The requirements for horses are set out in § 93.308(a)(3) and include not only pre-embarkation and post-arrival inspection and treatment requirements, but also quarantine in the United States for 7 days after arrival, and examination by a veterinarian before release from quarantine. The requirements for ruminants and swine are set out in §§ 93.405(a)(3) and 93.505(b), respectively, and are the same as for horses, other than the 7-day quarantine and final examination of the animal. The requirements for dogs are set out in § 93.600 and require that all dogs from affected regions be inspected and, if necessary, treated before importation.

The Animal and Plant Health Inspection Service (APHIS) maintains a list of regions APHIS considers affected with screwworm on its website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/>. APHIS will add a region to the list upon determining that screwworm exists in the region based on reports we receive of detections of the pest from veterinary officials of the exporting country, from the World Organization for Animal Health (WOAH), or from other sources the Administrator determines to be reliable.

On July 2, 2021, Panama reported a detection of New World screwworm (*Cochliomyia hominivorax*) to WOAH. After that report, and after confirming that the screwworm occurred in livestock, on July 12, 2021, APHIS added Panama to the list of regions APHIS considers affected with screwworm. In 2022, Panama requested that APHIS evaluate the country for New World screwworm. APHIS concluded the evaluation in 2022 after Panama reported additional detections of screwworm throughout the country.

On July 17, 2023, Costa Rica reported a detection of New World screwworm in a dog to WOAH. On July 24, 2023, APHIS responded by adding Costa Rica

to the Temporary Restrictions list for the import of animal commodities imported from or transiting Costa Rica. Subsequent follow-up reports to WOA, as well as epidemiological reports submitted to APHIS from Costa Rica's National Service for Animal Health, indicated further detections of screwworm in livestock, including cattle and sheep. Therefore, on August 21, 2023, APHIS added Costa Rica to the list of regions APHIS considers affected with screwworm.

As a result, horses, ruminants, swine, and dogs from Panama and Costa Rica are subject to APHIS import restrictions designed to mitigate risk of screwworm introduction into the United States. This notice serves as an official record and public notification of these actions.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 13th day of January 2025.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2025–00995 Filed 1–15–25; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

The U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Committee on Fresh Fruits and Vegetables

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S. Codex Office is sponsoring a public meeting on Feb 5, 2025. The objective of the public meeting is to provide information and receive public comments on agenda items and draft U.S. positions to be discussed at the 22nd Session of the Codex Committee on Fresh Fruits and Vegetables (CCFFV), which will meet in Mexico City, Mexico, from February 25–March 1, 2025. The U.S. Manager for Codex Alimentarius and the Under Secretary for Trade and Foreign Agricultural Affairs recognize the importance of providing interested parties the opportunity to obtain background information on the 23rd Session of the CCFFV and to address items on the agenda.

DATES: The public meeting is scheduled for February 5, 2025, from 11 a.m.–12:30 p.m. eastern time.

ADDRESSES: The public meeting will take place via video teleconference only. Documents related to the 23rd Session

of the CCFFV will be accessible via the internet at the following address:

<https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFFV&session=23>.

Mr. Dorian LaFond, U.S. Delegate to the 23rd Session of CCFFV, invites interested U.S. parties to submit their comments electronically to the following email address: Dorian.LaFond@usda.gov.

Registration: Attendees may register to attend the public meeting at the following link: https://www.zoomgov.com/meeting/register/vJscOihrD8uGX42lENyIB4gIMrirpf_SE.

After registering, you will receive a confirmation email containing information about joining the meeting.

For further information about the 23rd Session of the CCFFV, contact U.S. Delegate, Mr. Dorian LaFond, International Food Standards Coordinator, Fruits and Vegetables Program, Specialty Crops Division, Agricultural Marketing Service, U.S. Department of Agriculture, phone: +1 (202) 690–4944, email: Dorian.LaFond@usda.gov. For additional information regarding the public meeting, contact the U.S. Codex Office by email at: uscodex@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through the adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The Terms of Reference of the Codex Committee on Fresh Fruits and Vegetables (CCFFV) are:

(a) To elaborate worldwide standards and codes of practice as may be appropriate for fresh fruits and vegetables

(b) to consult, as necessary, with other international organizations in the standards development to avoid duplication

The CCFFV is hosted by Mexico. The United States attends the CCFFV as a member country of Codex.

Issues To Be Discussed at the Public Meeting

The following items from the Provisional Agenda for the 23rd Session of the CCFFV will be discussed during the public meeting:

- Matters arising from the Codex Alimentarius Commission and other committees;

- Matters arising from other international organizations on the standardization of fresh fruits and vegetables;

- Draft standard for fresh dates;
- Proposed draft standard for fresh curry leaves;

- Discussion paper on the review of existing FFV standards;

- Consideration for proposals for new work;

- Other Business.

Public Meeting

At the February 5, 2025, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Mr. Dorian LaFond, U.S. Delegate to the 23rd Session of the CCFFV, at dorian.lafond@usda.gov. Written comments should state that they relate to activities of the 23rd Session of the CCFFV.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication online through the USDA Codex web page located at: <https://www.usda.gov/codex>, a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscriptions themselves and have the option to password-protect their accounts.

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Done at Washington, DC, on January 13, 2025.

Julie A. Chao,

Deputy U.S. Manager for Codex Alimentarius.

[FR Doc. 2025-01035 Filed 1-15-25; 8:45 am]

BILLING CODE 3420-3F-P

DEPARTMENT OF AGRICULTURE

The U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Committee on Food Additives

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S. Codex Office is sponsoring a public meeting on February 18, 2025, from 9 a.m. to 12 p.m. eastern time (ET). The objective of the public meeting is to provide information and receive public comments on agenda items and draft U.S. positions to be discussed at the 55th Session of the Codex Committee on Food Additives (CCFA) of the Codex Alimentarius Commission, which is scheduled to be held in Seoul, Republic of Korea, from March 24–28, 2025. The U.S. Manager for Codex Alimentarius and the Under Secretary for Trade and Foreign Agricultural Affairs recognize the importance of providing interested parties the opportunity to obtain background information on the 55th Session of the CCFA and to address items on the agenda.

DATES: The public meeting is scheduled for February 18, 2025, from 9 a.m. to 12 p.m. ET.

ADDRESSES: The public meeting will take place in a hybrid format. The on-site location is Meeting Room 1A-001 and 1A-002 at the U.S. Food and Drug Administration, Harvey Wiley Federal Building, 5001 Campus Drive, College Park, MD 20740-3835. Documents related to the 55th Session of the CCFA will be accessible via the internet at the following address: <https://www.fao.org/fao-who-codexalimentarius/detail/it/meeting=CCFA&session=55>.

Dr. Daniel Folmer, U.S. Delegate to the 55th Session of the CCFA, invites interested U.S. parties to submit their comments electronically to the following email address:

Daniel.Folmer@fda.hhs.gov.

Registration: In-person attendees may register to attend the public meeting at the following email address: ccfa@cfsan.fda.gov. Virtual attendees may register to attend the public meeting at the following link: <https://fda.zoomgov.com/meeting/register/vJltcOmnpj4iHgEoL7A3kCqQesR5F9ClcMQ>. Both in-person and virtual attendees should register by February 14, 2025. After registering, you will receive a confirmation email containing information about joining the meeting. For further information about the public meeting, contact Dr.

LaShonda Cureton, U.S. Alternate Delegate to the 55th Session of the CCFA, by phone at: +1 (240) 402-1351 or by email at: Lashonda.Cureton@fda.hhs.gov.

For further information about the 55th session of the CCFA, contact U.S. Delegate, Dr. Daniel Folmer, by phone at: +1 (240) 402-1274 or by email at: Daniel.Folmer@fda.hhs.gov, or U.S. Alternate Delegate, Dr. LaShonda Cureton, by phone at: +1 (240) 402-1351 or by email at: Lashonda.Cureton@fda.hhs.gov. For additional information regarding the public meeting, contact the U.S. Codex Office by email at: uscodex@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through the adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The Terms of Reference of the Codex Committee on Food Additives (CCFA) are:

(a) to establish or endorse permitted maximum levels for individual food additives;

(b) to prepare priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;

(c) to assign functional classes to individual food additives;

(d) to recommend specifications of identity and purity for food additives for adoption by the Commission;

(e) to consider methods of analysis for the determination of additives in food; and

(f) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.

The CCFA is hosted by China. The United States attends the CCFA as a member country of the Codex Alimentarius. The 55th session of the CCFA will be co-hosted by the Republic of Korea.

Issues To Be Discussed at the Public Meeting

The following items from the Provisional Agenda for the 55th Session of the CCFA will be discussed during the public meeting:

- Matters Referred by the Codex Alimentarius Commission and other subsidiary bodies;
- Matters of Interest arising from FAO/WHO and from the 99th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA);
- Proposed draft specifications for identity and purity of food additives arising from the 99th JECFA meeting;
- Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards;
- Alignment of the food additive provisions of commodity standards: Report of the Electronic Working Group (EWG) on Alignment;
- *General Standard for Food Additives* (GSFA): Report of the EWG on the GSFA;
- *General Standard for Food Additives* (GSFA): Proposals for new and/or revision of food additive provisions (replies to circular letter (CL) 2024/58-FA);
- Proposed draft revision to the *Class Names and the International Numbering System for Food Additives* (CXG 36-1989);
- Proposals for additions and changes to the Priority List of Substances proposed for evaluation by JECFA (replies to CL 2024/59-FA);
- Standard for baker's yeast (Step 4);
- Discussion paper on the working practices and the engagement plan to avoid divergence between the GSFA, commodity standards and other related Codex texts;
- Other business and future work.

Public Meeting

At the public meeting on February 18, 2025, the draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Dr.

Daniel Folmer, U.S. Delegate to the 55th Session of the CCFA, at Daniel.Folmer@fda.hhs.gov. Written comments should state that they relate to activities of the 55th Session of the CCFA.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the USDA Codex web page located at: <https://www.usda.gov/codex>, a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscriptions themselves and have the option to password protect their accounts.

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Done at Washington, DC, on January 13, 2025.

Julie A. Chao,

Deputy U.S. Manager for Codex Alimentarius.

[FR Doc. 2025-01036 Filed 1-15-25; 8:45 am]

BILLING CODE 3420-3F-P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS-2024-0021]

Notice of Intent To Prepare an Environmental Impact Statement for the Owyhee Irrigation District Infrastructure Modernization Project, Malheur County, OR

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Natural Resources Conservation Service (NRCS) Oregon State Office, in coordination with the U.S. Bureau of Reclamation, announces its intent to prepare an EIS for the Owyhee Irrigation District (OID) Infrastructure Modernization Project (Modernization Project). The project area is located along the Owyhee and Snake rivers in Eastern Oregon 50 miles west of Boise, Idaho in proximity to the town of Nyssa, Oregon. The proposed EIS will examine alternative solutions to improve the OID agricultural water management. OID is the sponsoring local organization for the project. NRCS is requesting comments to identify significant issues, potential alternatives, information, and analyses relevant to the proposed action from all interested individuals, Federal and State agencies, and Tribes.

DATES: We will consider comments that we receive by February 18, 2025. We will consider comments received after close of the comment period to the extent possible.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through the method below:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov> and search for docket ID NRCS-2024-0021. Follow the online instructions for submitting comments.

All comments received will be posted without change and made publicly available on www.regulations.gov.

Individuals who require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202) 720-2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Purpose and Need

The purpose of the OID Modernization Project is to improve agricultural water management by making the delivery of irrigation water for agricultural lands within OID more reliable and efficient. Watershed planning is authorized under the Watershed Protection and Flood Prevention Act of 1954 (Pub. L. 83-566), as amended, and the Flood Control Act of 1944 (Pub. L. 78-534).

This action is needed to alleviate inefficient and unreliable access to irrigation water which causes agricultural damages for farmers in OID. Agriculture is an essential part of the Malheur County economy which only receives 10.1 inches of precipitation a year, with only 1.5 inches falling during the months of June, July, and August. The insignificant amounts of precipitation limit the ability of agricultural production. OID was formed with the primary purpose of providing the delivery of Owyhee River and Snake River water within Malheur County. Access to this irrigation water has allowed development of the agricultural community within the area. The OID area has been reliant on irrigation water delivery for over 100 years. The OID supplies water to approximately 312,000 acres during a normal water year.

OID operates and maintains more than 400 miles of canals, laterals, and siphons through the Bureau of Reclamation's Owyhee Project. OID delivers water to 1,012 patrons and 1,364 parcels from three primary diversions: the Owyhee River via the Owyhee Reservoir and two pumping stations located along the Snake River. The OID conveyance system irrigates approximately 67,000 total acres of onions, sugar beets, corn, alfalfa, and other crops.

Due to rising temperatures and decreasing snowpack, supply shortages are expected to worsen in the coming decades. Between 2013 and 2023, the State issued drought declarations six times in Malheur County. The ability to deliver water efficiently and effectively, especially during drought years, is essential. The majority of the OID infrastructure is approximately 90 years old, which has reduced the water delivery reliability for agricultural use and is at risk of failure. Catastrophic failure of the OID infrastructure would stop water deliveries while the conveyance system is fixed, which would have large impacts to crops and users that rely on water supplied by OID.

The proposed project would modernize the OID system through a series of projects including canal piping; canal lining; siphon improvements; headgate and diversion improvements; and installation of supervisory control and data acquisition (SCADA) systems. During the irrigation season, the current OID system loses water due to seepage, evaporation, and operational inefficiencies. The water that is lost enters the OID system, but never reaches the farms.

In accordance with the regulation in 7 CFR 650.7(a)(2), an EIS is required for projects requiring congressional action such as this proposed project, where estimated federal funds required for construction may exceed \$25 million. 16 U.S.C. 1002.

Preliminary Proposed Action and Alternatives, Including No Action

The EIS objective is to formulate and evaluate alternatives that would decrease agricultural damages due to the unreliable and inefficient access to irrigation water within OID. The EIS is expected to evaluate two alternatives: one no action alternative and one action alternative.

The alternatives that may be considered for detailed analysis include:

- **Alternative 1—No Action**

Alternative: Taking no action would consist of activities conducted if no Federal action or funding were provided. No watershed project would be implemented, and the OID infrastructure would not be modernized. OID would continue operating and maintaining its system in its current state. The No Action Alternative would not meet the OID Modernization Project's purpose and need.

- **Alternative 2—Proposed Action**

Alternative: The proposed action is to evaluate a suite of system improvement measures across OID including: piping 74.8 miles of canal; lining 8.5 miles of canal; installing 13 SCADA sites; upgrading 2 headgates; and upgrading 13 siphons. The projects included in the Proposed Action would serve 67,134.5 acres within OID.

Summary of Expected Impacts

As mentioned above, the estimated Federal contribution to construction cost will exceed \$25 million.

The EIS will be prepared as required by section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA); the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508); and NRCS regulations that implement NEPA in 7 CFR part 650.

Resource concerns for scoping were identified and categorized as relevant or not relevant to the proposed OID Modernization Project action. OID and NRCS evaluated the current infrastructure conditions in addition to relevant resource concerns for each proposed solution. Environmental resources in the project area consist of the natural and human-made environment. Resource concerns to be identified and addressed in the EIS include: cultural resources; economics; soils; land use; environmental justice; endangered and threatened species; wildlife, hydrology, wetlands, vegetation, and climate change. Other resources may be identified through the scoping process.

Anticipated Permits and Authorizations

The following permits and authorizations are anticipated to be required:

- **Endangered Species Act (ESA).** Consultation with the U.S. Fish and Wildlife Service and National Marine Fisheries Service will be conducted as required by the ESA of 1973.
- **National Historic Preservation Act (NHPA) Section 106.** Consultation with Tribal Nations and interested parties would be conducted as required by the NHPA.
- **Clean Water Act (CWA) and National Pollutant Discharge Elimination System (NPDES).** The project would require water quality certification under section 401 of CWA; permitting under section 402 of NPDES; and section 404 of CWA for potential wetland impacts.

Schedule of Decision-Making Process

A Draft EIS (DEIS) will be prepared and circulated for review and comment by agencies, Tribes, consulting parties, and the public for 45 days as required by the regulations in 40 CFR 1503.1, 1502.20, 1506.11, and 1502.17, and 7 CFR 650.13. The DEIS is anticipated to be published in the **Federal Register**, approximately 16 months after publication of this NOI. A Final EIS is anticipated to be published within 6 months of completion of the public comment period for the DEIS.

NRCS will decide whether to implement one of the action alternatives as evaluated in the EIS. A Record of Decision will be completed after the required 30-day waiting period and will be publicly available. The Responsible Federal Official (RFO) and decision maker for NRCS is the Oregon NRCS State Conservationist.

Public Scoping Process

A public scoping meeting is scheduled to occur early 2025 and will be held at a public venue near the OID project area. Exact meeting locations and times will be determined closer to the dates of the events. Public notices will be placed in local newspapers and on the NRCS, OID, and the U.S. Bureau of Reclamation websites. Additionally, a letter providing details on the public meetings and the scoping comment and objection processes will be sent to Federal and State agencies, Tribes, local landowners, and interested parties. Scoping meeting presentation materials will be available on the project website: <https://project.com/watershed-project/>.

Public scoping meetings provide an opportunity to review and evaluate the alternatives, express concern or support, and gain further information regarding the project. Comments received, including the names and addresses of those who comment, will be part of the public record. Comments submitted anonymously will be accepted and considered.

Identification of Potential Alternatives, Information, and Analyses

NRCS, OID, and the U.S. Bureau of Reclamation invite agencies, Tribes, and individuals that have special expertise, legal jurisdiction, or interest, to provide comments concerning the scope of the analysis and identification of potential alternatives, information, and analyses relevant to the Proposed Action.

NRCS, OID, and the U.S. Bureau of Reclamation will use the scoping process to help fulfill the public involvement process under section 106 of NHPA (54 U.S.C. 306108), as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed project will assist NRCS in identifying and evaluating impacts to resources in the context of both NEPA and NHPA.

NRCS will consult with Native American tribes on a government-to-government basis in accordance with the regulations in 36 CFR 800.2 and 800.3, Executive Order 13175, and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources and historic properties, will be given due consideration.

Authorities

This document is published as specified by the NEPA regulations regarding publication of an NOI to issue an EIS (40 CFR 1501.9(d)). Watershed planning is authorized under the

Watershed Protection and Flood Prevention Act of 1954, as amended, and the Flood Control Act of 1944.

Federal Assistance Programs

The title and number of the Federal Assistance Program as found in the Assistance Listing¹ to which this document applies is 10.904, Watershed Protection and Flood Prevention.

Executive Order 12372

Executive Order 12372, “Intergovernmental Review of Federal Programs,” requires consultation with State and local officials that would be directly affected by proposed Federal financial assistance. The objectives of the Executive Order are to foster an intergovernmental partnership and a strengthened federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance and direct Federal development. This proposed project is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720-2600 (voice and telephone) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program

Discrimination Complaint Form, AD-3027, found online at: <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) Fax: (202)690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Greggory Becker,

Oregon State Conservationist, Natural Resources Conservation Service.

[FR Doc. 2025-00958 Filed 1-15-25; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-172]

Vanillin From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that vanillin from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through March 31, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Claudia Cott or Bryan Hansen, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4270 or (202) 482-3683, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended

(the Act). Commerce published the notice of initiation of this investigation on July 1, 2024.¹ On July 22, 2024, Commerce tolled certain deadlines in this investigation by seven days.² On October 22, 2024, Commerce postponed the preliminary determination of this investigation.³ The deadline for the preliminary determination is now January 8, 2025.

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.⁴ A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is vanillin from China. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,⁵ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, *i.e.*, scope.⁶ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*. As a result, Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice*. See the scope in Appendix I to this notice.

¹ See *Vanillin from the People's Republic of China: Initiation of Less-Than-Fair Value Investigation*, 89 FR 54424 (July 1, 2024) (*Initiation Notice*).

² See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

³ See *Vanillin from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair Value Investigation*, 89 FR 84330 (October 22, 2024).

⁴ See Memorandum, “Decision Memorandum for the Preliminary Affirmative Determination in the Investigation of Sales at Less Than Fair Value of Vanillin from People's Republic of China,” dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

⁵ See *Antidumping Duties, Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

⁶ See *Initiation Notice*, 89 FR at 54424.

¹ See <https://sam.gov/content/assistance-listings>.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices and constructed export prices in accordance with sections 772(a) and (b) of the Act, respectively. Because China is a non-market economy (NME) within the meaning of section 771(18) of the Act, Commerce has calculated normal value (NV) in accordance with section 773(c) of the Act. Furthermore, pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily relied upon facts otherwise available, with adverse inferences, for the China-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, see the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice*,⁷ Commerce stated that it would calculate producer/

exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.⁸ In this investigation, we assigned a producer/exporter combination rate for the companies that are listed in the "Preliminary Determination" and eligible for separate rates.

Separate Rates

We preliminarily granted a separate rate to certain separate rate respondents that we did not select for individual examination.⁹ In calculating the rate for non-individually examined separate rate respondents in an NME LTFV investigation, Commerce normally looks to section 735(c)(5)(A) of the Act, which pertains to the calculation of the all-others rate in a market economy LTFV investigation, for guidance. Pursuant to section 735(c)(5)(A) of the Act, normally this rate shall be an amount equal to the weighted-average of the estimated

weighted-average dumping margins established for those companies individually examined, excluding zero and *de minimis* dumping margins, and any dumping margins based entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Jiangxi Brother Pharmaceutical Co., Ltd. (Jiangxi Brother) that is not zero, *de minimis*, or based entirely on facts otherwise available. Thus, the weighted-average dumping margin calculated for Jiangxi Brother is the basis to determine the weighted-average dumping margin for the non-examined, separate rate companies in this investigation.¹⁰ See the table below in the "Preliminary Determination" section of this notice.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Jiangxi Brother Pharmaceutical Co., Ltd	Jiangxi Brother Pharmaceutical Co., Ltd	186.20	186.15
Chongqing Thrive Fine Chemicals Co., Ltd	Chongqing Thrive Fine Chemicals Co., Ltd	186.20	186.15
HongKong Wictive Merchants Co., Ltd	Kunshan Asia Aroma Corp., Ltd	186.20	186.15
Kunshan Asia Aroma Corp., Ltd	Kunshan Asia Aroma Corp., Ltd	186.20	186.15
Mianyang Sunshine Bio-Tech Co., Ltd	Mianyang Sunshine Bio-Tech Co., Ltd	186.20	186.15
Shanghai Fuxin Fine Chemical Co., Ltd	Jiaying Zhonghua Chemical Co., Ltd	186.20	186.15
Shenzhen Siyomicro Bio-Tech Co., Ltd	Shenzhen Siyomicro Bio-Tech Co., Ltd	186.20	186.15
Wuxi Lotus Essence Co., Ltd	Jiaying Zhonghua Chemical Co., Ltd	186.20	186.15
Xiamen Bestally Biotechnology Co., Ltd	Xiamen Oamic Biotech Co., Ltd	186.20	186.15
China-Wide Entity		* 379.87	379.82

* This rate is based on facts available with adverse inferences.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the

estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-country exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping

margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the "Preliminary Determination" section's table of estimated weighted-average dumping margins above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation,

⁷ *Id.*

⁸ See Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, "Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non-Market

Economy Countries," (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at [enforcement.trade.gov/policy/bull05-1.pdf](https://www.enforcement.trade.gov/policy/bull05-1.pdf).

⁹ See the Preliminary Decision memorandum for additional details.

¹⁰ See Memorandum, "Calculation of the Dumping Margin for Respondents Not Selected for Individual Examination," dated January 8, 2025.

Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis it performed in connection with this preliminary determination within five days of the public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.¹¹ A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹² Interested parties who submit

case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹³

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹⁴ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁵

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice in the **Federal Register**. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days

after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping duty determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On December 24, 2024, Jiangxi Brother requested that Commerce postpone the final determination and that the provisional measures be extended to a period not to exceed six months, respectively.¹⁶ In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This preliminary determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

¹⁶ See Jiangxi Brother's Letter, "Request to Postpone Final Determination," dated December 24, 2024.

¹¹ Case and rebuttal briefs submitted in response to this preliminary determination should not include scope-related issues. See 19 CFR 351.309(c)(1)(i); see also 19 CFR 351.303 (for general filing requirements).

¹² See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in*

Antidumping and Countervailing Duty Proceedings, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹³ See 19 CFR 351.309(c)(2) and (d)(2).

¹⁴ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁵ See *APO and Service Final Rule*.

Dated: January 8, 2025.

Steven Presing,

Acting Deputy Assistant Secretary for Policy and Negotiations.

Appendix I

Scope of the Investigation

The merchandise covered by the investigation is vanillin, with the molecular formula $C_8H_8O_3$ or $C_9H_{10}O_3$. For purposes of this investigation, vanillin consists of natural vanillin, synthetic vanillin, bio-sourced synthetic vanillin (biovanillin) (each also known as 4-Hydroxy-3-methoxybenzaldehyde), and ethylvanillin (also known as 3-Ethoxy-4-hydroxybenzaldehyde). Vanillin covered by this investigation is a chemical compound with the Chemical Abstracts Service (CAS) number 121–33–5 or 121–32–4. Vanillin is covered by the investigation regardless of whether it is in a crystalline powder or crystal form. Vanillin is covered by the scope of the investigation, irrespective of purity, particle size, or physical form.

Merchandise subject to the investigation is specified within the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 2912.41.0000 and 2912.42.0000. The HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes only. The written description of the merchandise covered by the investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Discussion of the Methodology
- V. Adjustment Under Section 777(A)(f) of the Act
- VI. Adjustment to Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
- VII. Recommendation

[FR Doc. 2025–00865 Filed 1–15–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–875]

Non-Malleable Cast Iron Pipe Fittings From the People's Republic of China: Continuation of Antidumping Duty Order

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

SUMMARY: As a result of the determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) order on non-malleable cast iron pipe fittings (pipe fittings) from the

People's Republic of China (China) would likely lead to continuation or recurrence of dumping, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the AD order.

DATES: Applicable January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Thomas Martin, 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) 482–3936.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2003, Commerce published in the **Federal Register** the AD order on pipe fittings from China.¹ On June 3, 2024, the ITC instituted,² and Commerce initiated,³ the fourth sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its review, Commerce determined that revocation of the *AD Order* would likely lead to continuation or recurrence of dumping, and therefore, notified the ITC of the magnitude of the margins of dumping rates likely to prevail should the *Order* be revoked.⁴

On January 10, 2025, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Order* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.⁵

Scope of the Order

The merchandise subject to the *Order* are finished and unfinished non-malleable cast iron pipe fittings. *See* the appendix to this notice for the full scope of the *Order*.

Continuation of the Order on Non-Malleable Cast Iron Pipe Fittings From China

As a result of the determinations by Commerce and the ITC that revocation

¹ See *Notice of Antidumping Duty Order: Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China*, 68 FR 16765 (April 7, 2003) (*Order*).

² See *Non-Malleable Cast Iron Pipe Fittings from China; Institution of a Five-Year Review*, 89 FR 47610 (June 3, 2024).

³ See *Initiation of Five-Year (Sunset) Review*, 89 FR 47525 (June 3, 2024).

⁴ See *Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China: Final Results of the Expedited Fourth Sunset Review of the Antidumping Duty Order*, 89 FR 81424 (October 8, 2024), and accompanying Issues and Decision Memorandum.

⁵ See *Non-Malleable Cast Iron Pipe Fittings from China Determination*, 90 FR 2022 (January 10, 2025) (*ITC Final Determination*).

of the *Order* would likely lead to continuation or recurrence of dumping, and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Order*. U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the *Order* will be January 10, 2025.⁶ Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next sunset review of the *Order* not later than 30 days prior to the fifth anniversary of the effective date of this continuation.

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return, destruction, or conversion to judicial protective order 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 with this request is a violation of the APO which may be subject to sanctions.

Notification to Interested Parties

This five-year sunset review and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and this notice is published pursuant to section 777(i) of the Act and 19 CFR 351.218(f)(4).

Dated: January 10, 2025.

Steven Presing,

Acting Deputy Assistant Secretary for Policy and Negotiations.

Appendix

The merchandise subject of the *Order* are finished and unfinished non-malleable cast iron pipe fittings with an inside diameter ranging from 1/4 inch to 6 inches, whether threaded or unthreaded, regardless of industry or proprietary specifications. The subject fittings include elbows, tees, crosses, and reducers as well as flanged fittings. These pipe fittings are also known as “cast iron pipe fittings” or “gray iron pipe fittings.” These cast iron pipe fittings are normally produced to ASTM A–126 and ASME B.16.4 specifications and are threaded to ASME B1.20.1 specifications. Most building codes require that these products are Underwriters Laboratories (UL) certified. The scope does not include cast iron soil pipe fittings or grooved fittings or grooved couplings. Also, certain brake fluid tube connectors are excluded from the scope of

⁶ See *ITC Final Determination*.

the *Order*.⁷ Commerce did not include the certain brake fluid tube connectors exclusion scope language in the 2019 continuation notice.

Fittings that are made out of ductile iron that have the same physical characteristics as the gray or cast iron fittings subject to the scope above or which have the same physical characteristics and are produced to ASME B.16.3, ASME B.16.4, or ASTM A-395 specifications, threaded to ASME B1.20.1 specifications and UL certified, regardless of metallurgical differences between gray and ductile iron, are also included in the scope of the *Order*. These ductile fittings do not include grooved fittings or grooved couplings. Ductile cast iron fittings with mechanical joint ends (MJ), or push on ends (PO), or flanged ends and produced to American Water Works Association (AWWA) specifications AWWA C110 or AWWA C153 are not included. Imports of covered merchandise are classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers

7307.11.00.30, 7307.11.00.60, 7307.19.30.60 and 7307.19.30.85. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the *Order* is dispositive.

[FR Doc. 2025–00991 Filed 1–15–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID: 0648–XE607]

Southeast Regional Office,
Amendment 59 to the Fishery
Management Plan for the Snapper-
Grouper Fishery of the South Atlantic;
Public Hearings

AGENCY: National Marine Fisheries
Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA),
Commerce.

ACTION: Notice of public hearings.

SUMMARY: The NMFS Southeast Regional Office will hold a series of public hearings on Amendment 59 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic (Amendment 59). NMFS will review Amendment 59 and the proposed measures for management of red snapper and snapper-grouper species in South Atlantic Federal waters.

DATES: The public hearing meetings will be held on February 5, 2025, February 6, 2025, February 24, 2025, February 25, 2025, and March 5, 2025.

See **SUPPLEMENTARY INFORMATION** for additional details.

ADDRESSES: Meeting locations:

Date and time	Location
February 5, 2025; 4:00–8:00 p.m	Hilton Garden Inn, Charleston, Airport 5265 International Boulevard, North Charleston, SC 29418, 843–308–9330.
February 6, 2025; 4:00–8:00 p.m	The Crystal Coast Civic Center, 3505 Arendell Street, Morehead City, NC 28557, 252–247–3883.
February 24, 2025; 4:00–8:00 p.m	Crowne Plaza Jacksonville Airport, 14670 Duval Rd., Jacksonville, FL 32218, 904–741–4404.
February 25, 2025; 4:00–8:00 p.m	Hilton Cocoa Beach, 1550 N Atlantic Avenue, Cocoa Beach, FL 32931, 321–613–9023.
March 5, 2025; 4:00 p.m. during the scheduled South Atlantic Fishery Management Council meeting.	Villa By the Sea, 1175 Beachview Drive N, Jekyll Island, GA 31527, 912–635–2521.

FOR FURTHER INFORMATION CONTACT:
Karla Gore, Southeast Regional Office,
telephone: (727) 824–5305, karla.gore@noaa.gov.

SUPPLEMENTARY INFORMATION: As part of the development of Amendment 59, the NMFS Southeast Regional Office will host a series of public hearings. During these public hearings, NMFS will review Amendment 59 and the proposed options for management of red snapper and snapper-grouper species in South Atlantic Federal waters. The structure of the public hearings will allow for a presentation on the amendment and proposed rule at 4:30 p.m. and 6:00 p.m. on February 5, 6, 24, and 25, 2025. There will be separate breakout rooms for the public to ask questions, obtain more information on the amendment and proposed rule, and

formally submit public comments to NMFS.

The March 5, 2025, public hearing will be held in conjunction with the scheduled March meeting of the South Atlantic Fishery Management Council (Council). A presentation on the measures proposed in Amendment 59 will be provided by NMFS at 1:00 p.m. and comments on Amendment 59 will be accepted during the Council’s scheduled public comment period starting at 4:00 p.m.

A detailed public hearing agenda and Amendment 59 background documents will be made available on the NMFS Amendment 59 website prior to the public hearing. The website for information about Amendment 59 is located at: [https://www.fisheries.noaa.gov/action/amendment-59-fishery-management-](https://www.fisheries.noaa.gov/action/amendment-59-fishery-management)

plan-snapper-grouper-fishery-south-atlantic-region/.

Special Accommodations

These public hearings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Karla Gore, (727) 824–5305, karla.gore@noaa.gov at least 5 days prior to the meeting date.

Note: The times and sequence specified in the agenda are subject to change.

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

Dated: January 10, 2025.

Karen H. Abrams,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2025–00853 Filed 1–15–25; 8:45 am]
BILLING CODE 3510–22–P

⁷ See *Non-Malleable Cast Iron Pipe Fittings From The People’s Republic of China: Continuation of Antidumping Duty Order*, 79 FR 8437 (February 12, 2014). To be excluded, the connector must meet the following description: The connector is a “joint block” for brake fluid tubes and is made of non-

malleable cast iron to Society of Automotive Engineers (SAE) automotive standard J431. The tubes have an inside diameter of 3.44 millimeters (0.1355 inches) and the inside diameters of the fluid flow channels of the connector are 3.2 millimeters (0.1260 inches) and 3.8 millimeters (0.1496 inches).

The end of the tube is forced by pressure over the end of a flared opening in the connector also known as “flared joint.” The flared joint, once made fast, permits brake fluid to flow through channels that never exceed 3.8 millimeters (0.1496 inches) in diameter.

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648–XE521]

Deepwater Horizon Natural Resource Damage Assessment Texas Trustee Implementation Group Draft Restoration Plan/Environmental Assessment #3: Wetlands, Coastal, and Nearshore Habitats

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

ACTION: Notice of availability; request for public comments.

SUMMARY: The Deepwater Horizon (DWH) natural resource Trustees for the Texas Trustee Implementation Group (Texas TIG) have prepared the Draft Restoration Plan/Environmental Assessment #3: Wetlands, Coastal, and Nearshore Habitats (Draft RP/EA #3). The Draft RP/EA #3 proposes alternatives to help restore wetlands, coastal, and nearshore habitats impacted by the DWH oil spill. The Draft RP/EA #3 evaluates eight restoration alternatives under the Oil Pollution Act of 1990 (OPA), including criteria set forth in the OPA Natural Resource Damage Assessment (NRDA) regulations and the National Environmental Policy Act (NEPA) and its implementing regulations. A No Action Alternative is also evaluated pursuant to the NEPA. The total estimated cost to implement the Texas TIG's seven preferred alternatives is approximately \$40 million. The Texas TIG invites the public to comment on the Draft RP/EA #3.

DATES: *Submitting Comments:* The Texas TIG will consider public comments on the Draft RP/EA #3 received on or before February 18, 2025.

Public meeting: The Texas TIG will host a public meeting to facilitate public review and comment on the Draft RP/EA #3. The public meeting date and time are as follows:

- Tuesday, January 28, 2025. An open house will be begin at 5 p.m. central time (CT). The public meeting will be held at 5:30 CT. See **ADDRESSES** below for meeting location.

ADDRESSES: *Meeting location:* The meeting will be held at Rosenberg Library in the Wortham Auditorium, 2310 Sealy Avenue, Galveston, TX 77550.

Obtaining Documents: You may view and download the Draft RP/EA #3 at <https://>

www.gulfspillrestoration.noaa.gov/restoration-areas/texas. You may also request a flash drive containing the Draft RP/EA #3 (see **FOR FURTHER INFORMATION CONTACT**).

Submitting comments: You may submit comments on the Draft RP/EA #3 by any of the following methods:

- *Website:* <https://parkplanning.nps.gov/TXTIGRP3>. Follow the online instructions for submitting comments.

- *In person:* Comments may be provided at the public meeting. See **DATES**.

- *Mail:* U.S. Fish and Wildlife Service Gulf Restoration Office, 1875 Century Blvd., Atlanta, GA 30345. To be considered, mailed comments must be postmarked on or before the comment deadline given in **DATES**.

Please note that personal identifying information included in the submitted comments (such as name, address, phone number, and email address) may be made publicly available at any time. Personal information is not required to submit comments.

FOR FURTHER INFORMATION CONTACT:

National Oceanic and Atmospheric Administration—Jamie Schubert, NOAA Restoration Center, (409) 679–3237, jamie.schubert@noaa.gov.

SUPPLEMENTARY INFORMATION:**Introduction**

On April 20, 2010, the mobile offshore drilling unit Deepwater Horizon, which was drilling a well for BP Exploration and Production, Inc. (BP), experienced a significant explosion, fire and subsequent sinking in the Gulf of Mexico, resulting in the release of millions of barrels of oil and other discharges into the Gulf. Under the authority of the OPA, designated Federal and state Trustees, acting on behalf of the public, assessed the injuries to natural resources and prepared the Deepwater Horizon Oil Spill Final Programmatic Damage Assessment and Restoration Plan and Final Programmatic Environmental Impact Statement (Final PDARP/PEIS), and the Record of Decision for the Deepwater Horizon Oil Spill Final Programmatic Damage Assessment and Restoration Plan and Final Programmatic Environmental Impact Statement (ROD), which set forth the governance structure and process for DWH restoration planning under the OPA NRDA regulations. On April 4, 2016, the United States District Court for the Eastern District of Louisiana entered a Consent Decree resolving civil claims by the Trustees against BP.

The Texas TIG, which is composed of the NOAA, U.S. Department of the

Interior, the U.S. Environmental Protection Agency, the U.S. Department of Agriculture, the Texas General Land Office, the Texas Parks and Wildlife Department, and the Texas Commission on Environmental Quality, selects and implements restoration projects under the Texas TIG's management authority in accordance with the Consent Decree. The Final PDARP/PEIS, ROD, Consent Decree, and information on the DWH natural resource Trustees can be found at <https://www.gulfspillrestoration.noaa.gov/restoration-planning/gulf-plan>.

Background

On August 5, 2024, the Texas TIG announced on the Gulf Spill Restoration website that they were initiating preparation of the Draft RP/EA #3, which tiers from the Final PDARP/PEIS and includes a reasonable range of restoration project alternatives to provide compensatory restoration toward meeting the Restore and Conserve Habitats restoration goal identified in the Final PDARP/PEIS under the Wetlands, Coastal, and Nearshore Habitats (WCNH) Restoration Type.

Overview of the Texas TIG Draft RP/EA #3

This Draft RP/EA #3 focuses on the beneficial use of dredged material (BUDM) to restore and conserve wetlands, coastal, and nearshore habitats. The Texas TIG proposes the allocation of \$40 million toward the use of BUDM to construct wetland habitat along the Texas coast through the projects included in the Draft RP/EA #3. The \$40 million will be divided among the selected projects to provide the incremental cost for the U.S. Army Corps of Engineers or to fund other viable sources to beneficially use dredged sediments to construct the preferred restoration alternatives. This Draft RP/EA #3 includes a description and evaluation of eight restoration projects, also called restoration alternatives, which compensate for the WCNH Restoration Type injury described in the Final PDARP/PEIS. Seven alternatives are preferred and one of the alternatives is not preferred by the Texas TIG at this time. Pursuant to NEPA, a No Action alternative is also evaluated. Funding to implement any of the alternatives ultimately selected by the Texas TIG would come from the WCNH Restoration Type allocation. The reasonable range of project alternatives evaluated by the Texas TIG are listed below:

- Anahuac National Wildlife Refuge Roberts Mueller Tract Wetland Restoration (preferred);
- Goose Island Wetland Restoration (preferred);
- Guadalupe River Old Delta Wetland Restoration (not preferred);
- Lower Neches Wildlife Management Area Old River Unit Wetland Restoration (preferred);
- McFaddin National Wildlife Refuge Willow Lake Terraces Wetland Restoration (preferred);
- San Bernard National Wildlife Refuge Sargent Oil Field Wetland Restoration (preferred);
- Schicke Point Wetland Restoration (preferred); and
- Texas Point National Wildlife Refuge Wetland Restoration (preferred).

The total estimated cost to implement the seven preferred alternatives is \$40 million.

Next Steps

After the public comment period ends, the Texas TIG will consider and address all substantive comments received before making a final decision on which, if any, alternatives to fund and implement. A Final RP/EA #3 and Finding of No Significant Impact, as appropriate, identifying the selected alternatives will be made publicly available on <https://www.gulfspillrestoration.noaa.gov/restoration-areas/texas>.

Administrative Record

The Administrative Record for the Draft RP/EA #3 can be viewed electronically at <https://www.doi.gov/deepwaterhorizon/adminrecord> under the folder 6.5.7.2.3.

Authority

The authority for this action is the OPA of 1990 (33 U.S.C. 2701 *et seq.*), its implementing NRDA regulations found at 15 CFR part 990, and the NEPA of 1969 (42 U.S.C. 4321 *et seq.*), its implementing regulations found at 40 CFR parts 1500 through 1508.

Dated: January 10, 2025.

Carrie Diane Robinson,

*Director, Office of Habitat Conservation,
National Marine Fisheries Service.*

[FR Doc. 2025-00942 Filed 1-15-25; 8:45 am]

BILLING CODE 3510-12-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Public Meeting of the National Sea Grant Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the National Sea Grant Advisory Board (Board), a Federal Advisory Committee. Board members will discuss and provide advice on the National Sea Grant College Program (Sea Grant) in the areas of program evaluation, strategic planning, education and extension, science and technology programs, and other matters as described in the agenda found on the Sea Grant website.

DATES: The announced meeting is scheduled for Monday March 3, 2025 from 9 a.m.–6 p.m. and Tuesday March 4, 2025 from 9 a.m.–3 p.m. (eastern standard time).

ADDRESSES: The meeting will be held at the Yours Truly Hotel in Washington, DC. For more information about the public meeting see below in the **FOR FURTHER INFORMATION CONTACT** section.

For more information on this Federal Advisory Committee please visit the Federal Advisory Committee database: <https://www.facadatabase.gov/FACA/FACAPublicPage>.

FOR FURTHER INFORMATION CONTACT: For any questions concerning the meeting, please contact Ms. Donna Brown, National Sea Grant College Program. Email: oar.sg-feedback@noaa.gov. Phone Number 301-734-1088.

SUPPLEMENTARY INFORMATION:

Status: The meeting will be open to public participation with a public comment period on Monday, March 3 at 9:10 a.m. The Board expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by Ms. Donna Brown by Monday, February 24, 2025 to provide sufficient time for Board review. Written comments received after the deadline will be distributed to the Board, but may not be reviewed prior to the meeting date.

Special Accommodations: The Board meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Donna Brown by Monday, February 24, 2025.

The Board, which consists of a balanced representation from academia, industry, State government and citizens groups, was established in 1976 by section 209 of the Sea Grant Improvement Act (Pub. L. 94-461, 33 U.S.C. 1128). The Board advises the Secretary of Commerce and the Director of the National Sea Grant College Program with respect to operations under the Act, and such other matters as the Secretary refers to them for review and advice.

Matters To Be Considered: Board members will discuss and vote on the selection of new committee memberships as well as Board participation of Sea Grant Network Groups and other topics that need Board feedback: <https://seagrants.noaa.gov/About/Advisory-Board>.

David Holst,

Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2025-01020 Filed 1-15-25; 8:45 am]

BILLING CODE 3510-22-P

COMMISSION OF FINE ARTS

Notice of Meeting

Per 45 CFR Chapter XXI § 2102.3, the next meeting of the U.S. Commission of Fine Arts is scheduled for January 16, 2025, at 9:00 a.m. and will be held via online videoconference. Items of discussion may include buildings, infrastructure, parks, memorials, and public art.

Draft agendas, the link to register for the online public meeting, and additional information regarding the Commission are available on our website: www.cfa.gov. Inquiries regarding the agenda, as well as any public testimony, should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing cfastaff@cfa.gov; or by calling 202-504-2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated January 6, 2025, in Washington, DC.
Zakiya N. Walters,
Administrative Officer.
[FR Doc. 2025–00418 Filed 1–14–25; 11:15 am]
BILLING CODE 6330–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0128]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Mandatory Civil Rights Data Collection

AGENCY: Office for Civil Rights (OCR), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before February 18, 2025.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sala Green at Sala.Green@ed.gov, (202) 900–8558.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the

respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Mandatory Civil Rights Data Collection.

OMB Control Number: 1870–0504.

Type of Review: A revision of an existing information collection request.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 17,717.

Total Estimated Number of Annual Burden Hours: 2,378,410.

Abstract: The collection, use, and reporting of education data is an integral component of the mission of the U.S. Department of Education (Department). The Department has collected civil rights data about the nation’s public schools via the Civil Rights Data Collection (CRDC) since 1968. As with previous CRDC collections, the purpose of the 2025–26 and 2027–28 CRDCs is to obtain vital data related to the civil rights laws’ requirement that public local educational agencies (LEA) and elementary and secondary schools provide equal educational opportunity. The Department has analyzed the uses of many data elements collected in the 2020–21 CRDC and sought advice from experts across the Department to refine, improve, and where appropriate, add or remove data elements from the collection. CRDC data definitions and metrics are consistent with other mandatory collections across the Department wherever possible. The Department seeks the Office of Management and Budget’s approval under the Paperwork Reduction Act to collect from LEAs the elementary and secondary education data described in the sections of Attachment A. The Department requests that LEAs and other stakeholders review and comment on the proposed changes (detailed in Supporting Statement A, Attachments A–1, A–2, A–3, and A–4, and Attachment B).

Dated: January 13, 2025.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025–01058 Filed 1–15–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Application of the Revised Version of the Uniform Guidance to Department Grants

AGENCY: Office of Planning, Evaluation and Policy Development, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces updates to awardees’ Grant Award Notices (GANs) to apply the 2024 revision of the Uniform Administrative Requirements, Cost Principles, And Audit Requirements for Federal Awards the Uniform Guidance to all Department grants that are subject to the Uniform Guidance.

DATES: This change is effective January 16, 2025.

SUPPLEMENTARY INFORMATION: On April 22, 2024, the Office of Management and Budget (OMB) published a final rule in the **Federal Register** that revised the Uniform Guidance (89 FR 30046). This final rule, effective as of October 1, 2024, provided new flexibilities and due process protections to grantees, and also clarified several grant requirements. In order to ensure that the new flexibilities and due process protections for grantees set out in that revised 2024 guidance apply uniformly to Department grantees, we have updated the terms and conditions of Department grants to clarify that the revised Uniform Guidance (89 FR 30136, April 22, 2024) is the version that applies to all Department grants that are subject to the Uniform Guidance.

Specifically, the Department is adding the following condition to Box 10 of its Grant Award Notifications (GANs):

By the drawdown of funds under this GAN, the grantee accepts that this award is subject to the requirements of the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards; Title 2 CFR part 200 as revised at 89 FR 30136–30208 (April 22, 2024).

While grantees will not automatically receive a new printed GAN, the updated Box 10 and this notice supersede any previous GAN or notice that applied an earlier version of the Uniform Guidance. Grantees are not required to take any action other than continuing to draw down funds to take advantage of this change but are encouraged to maintain a copy of this notice within their grant files as documentation for grant management and auditing purposes.

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 Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at this 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.

Program Authority: 2 CFR part 200 as adopted at 89 FR 30046 (April 22, 2024); 2 CFR 3474.

Roberto Rodriguez,

Assistant Secretary of Planning, Evaluation and Policy Development.

[FR Doc. 2025-01050 Filed 1-14-25; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Request for Information Regarding Treatment and Disposal of Elemental Mercury

AGENCY: Office of Environmental Management, U.S. Department of Energy.

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy's (DOE) Environmental Management Consolidated Business Center and Office of Environmental Management are currently in the acquisition planning and regulatory planning stages for a potential future treatment and disposal (T&D) acquisition activity and fee rulemaking activities for elemental mercury waste. This planning supports DOE's efforts to implement the requirements of the Mercury Export Ban Act of 2008, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. DOE's Office of Environmental Management is issuing this RFI for the purpose of conducting market research in accordance with the Federal Acquisition Regulation (FAR). This RFI is also being issued to potentially support a future rulemaking action that would establish a fee to provide long-term management and storage of elemental mercury. No contract solicitation is available through this RFI.

DATES: Written comments and information are requested on or before March 3, 2025.

ADDRESSES: Interested parties may submit comments via any of the following methods:

Email: mercury.mgt.fee@em.doe.gov. Please include "Treatment and Disposal of Elemental Mercury RFI" in the subject line, and submit comments in Microsoft Word, or PDF file format, and avoid the use of encryption.

Postal Mail: Timothy Herald, U.S. Department of Energy, Office of Environmental Management, Office of Waste Disposal (EM-4.22), 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Timothy Herald, U.S. Department of Energy, Office of Environmental Management, Office of Waste Disposal (EM-4.22), 1000 Independence Avenue SW, Washington, DC 20585, Telephone: (240) 243-8753, Email: mercury.mgt.fee@em.doe.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose and Introduction

The purpose of this RFI is to identify entities capable of providing (1) infrastructure, capabilities, and capacities for the treatment and/or disposal of elemental mercury, (2) documentation of permits held, or viable strategies for obtaining permits and regulatory approval for the T&D methods identified, and (3) physical and administrative methods to segregate and control the elemental mercury considered under this RFI separately from other hazardous wastes managed at the facility or facilities.

To that end, this RFI solicits input via capability statements from interested parties with the specialized capabilities necessary to meet all, or part of, the major elements of scope for the T&D of elemental mercury. Within these capability statements, DOE is seeking feedback from contractors, small business concerns, and other interested parties regarding options for innovative approaches to perform the work scope elements of this RFI. This feedback will assist DOE with identifying interested and capable sources, and with advancing development of DOE's acquisition strategy and future rulemaking action.

This RFI is issued as part of DOE's implementation of the requirements of the Mercury Export Ban Act of 2008 (Pub. L. 110-414), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182) (collectively identified herein as MEBA). Within MEBA, DOE interprets "long-term management" to include T&D. Elemental mercury managed under MEBA is a hazardous waste and

thus must be treated and disposed of in accordance with applicable statutory and regulatory requirements.

DOE is aware that Land Disposal Restrictions (LDRs) described in the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 *et seq.*) (RCRA) at 40 CFR part 268, subpart D—Treatment Standards, do not currently include an approved treatment standard for non-radioactively contaminated elemental mercury waste that provides an LDR-compliant waste form acceptable for shallow land disposal. However, a treatment and land disposal path for non-radioactively contaminated elemental mercury would be available if the U.S. Environmental Protection Agency promulgated a new rulemaking (per 40 CFR 260.20) or approved a site-specific No Migration Variance (NMV) (per 40 CFR 268.6) or a site-specific Determination of Equivalent Treatment (DET) (per 40 CFR 268.42(b)). Recently, DOE received information that could provide other potential T&D options (e.g., deep well injection) to disposition elemental mercury. Also, RCRA may allow for intermediary treatment methods that convert elemental mercury to a more stable form (e.g., cinnabar/mercury sulfide) suitable for longer duration storage pending disposal availability. DOE therefore encourages all interested parties to identify their T&D methods for DOE consideration.

II. Performance Work Statement

DOE requires services for the T&D of elemental mercury conveyed to DOE pursuant to MEBA. DOE may initially seek T&D services for up to 120 metric tons (MT) of elemental mercury to which DOE holds title as established in an August 2020 settlement agreement with Nevada Gold Mines, LLC (NGM), whereby DOE agreed to accept title to and all further responsibility for 112 MT of elemental mercury that was in temporary storage at certain NGM facilities as of December 31, 2019.

DOE is considering additional contract options that could increase the quantity of elemental mercury T&D capacity over a 5-year contract period of performance. The potential need for additional T&D capacity is based on the expectation that additional quantities of elemental mercury would be conveyed to DOE, and such options would afford DOE the capability to disposition a much larger volume of elemental mercury waste. Interested parties' responses to this RFI should address their capabilities and capacities to treat and/or dispose of the following three volumes of elemental mercury waste during a base period of performance

(estimated) through a maximum 5-year period of performance (PoP):

- 120 metric tons (MT) elemental mercury—base period proposed by responding entity.
- 1,500–2,000 MT elemental mercury (includes base 120 MT)—maximum 5-year PoP.
- 2,000–3,000 MT elemental mercury (includes base 120 MT)—maximum 5-year PoP.

III. Request for Information

Within the context of the information contained in this RFI request, interested parties may provide responses to the following information requested below as deemed appropriate and applicable by the respondent, and to the extent the information is available:

1. Describe your experience managing hazardous materials and hazardous waste, including elemental mercury as a material and as a waste. Discuss roles and responsibilities of your company and any contemplated teaming partners specific to the performance work statement (PWS) elements of this RFI.

2. Describe your approach to meeting the PWS elements of this RFI in providing T&D services for elemental mercury waste. Specifically, discuss:

a. The permits you hold or your regulatory status/proposed strategy for obtaining regulatory approval (*i.e.*, DET, NMV, other RCRA T&D method, export to Organization for Economic Cooperation and Development country, etc.) to treat and dispose of elemental mercury waste.

b. Your expected (existing or planned) annual throughput capacity (*i.e.*, metric tons of elemental mercury per year treated and disposed). Describe your ability to scale up processes, if required, to achieve T&D of (a) 1,500–2,000 MT during a 5-year PoP, or (b) 2,500–3,000 MT during a 5-year PoP.

c. For the existing (or planned) capacity identified in 2(b) above, describe the proposed facilities and processes and whether new construction or modifications would be required to treat and dispose of the requested quantities.

d. Capabilities to safely manage compromised (*e.g.*, leaking, damaged) containers of elemental mercury, including the ability to open containers for transfer to new containers, as well as interim products (*e.g.*, cinnabar).

e. Capabilities to process off-specification waste forms to allow disposal.

f. Management and disposition of secondary wastes generated during processing or handling.

g. Disposal facility receipt, handling, staging, and emplacement of the

equivalent of the masses of elemental mercury identified above, accounting for volume increase due to treatment to produce an acceptable waste form for disposal.

h. Capabilities to monitor the performance of disposal (*e.g.*, monitoring wells, leachate collection and treatment, etc.) in accordance with regulatory requirements to identify and mitigate potential leak/release paths.

3. Identify any challenges and risks in meeting the PWS elements of this RFI in providing T&D service for elemental mercury waste and any actions your organization would take to address those challenges and risks.

4. Describe your approach to managing the infrastructure at the planned facility or facilities to provide segregation and control processes (*e.g.*, administrative, procedural, and physical) of DOE MEBA elemental mercury through all activities, including transportation, handling, treatment, and disposal.

5. Discuss your experience in implementation of environmental, safety, and health plans related to your (and any teaming partner's) work, including any prior relevant experience with work on or with DOE facilities, and your approach to addressing the requirements under 10 CFR part 851, Worker Safety and Health Program, as applicable.

6. Provide a brief Experience and Performance Record (within the past 15 years). Identify all DOE, other Government, or other commercial experience relevant to this RFI (include dollar value, contract type, role in the effort [*i.e.*, prime contractor or subcontractor] date, scope, duration, and client).

7. DOE may require a leasehold interest in the real property or properties offering T&D services. Discuss any impacts this may have to your ability to respond to a request for proposal. Discuss any relevant experience with leasehold arrangements.

8. Highlight any factors that would make competing for this contract desirable or undesirable for your firm, including input on proposal evaluation criteria. Discuss any issues that DOE should consider when developing the solicitation for this proposal. Identify any Organizational Conflicts of Interest (OCI) concerns and/or potential OCI's that you or your teaming partners may have pertaining to the work described in this RFI. Additionally, please identify and describe any areas in the major elements of scope believed to be missing or in need of clarification.

Any additional information that would assist in the evaluation of the RFI.

IV. Response Guidelines

All interested parties are invited to submit a capability statement/response to this RFI. Responses to the RFI must be in writing and submitted no later than March 3, 2025 via one of the methods provided in the **ADDRESSES** section. Electronic responses are preferred and can be provided as an attachment to an email. Please provide submittals as Microsoft Word (.docx), or PDF files. Respondents may use formatting that best presents the information, but submittals of 15 pages or less are requested. Respondents may answer as many or as few topics as they wish. A response to this RFI will not be viewed as a binding commitment to develop or pursue projects, ideas, or proposals discussed.

This RFI is solely a request for information and is not a request for quote or proposal. DOE will not pay for any information that is provided in response to this announcement, nor will it compensate any respondents for the development of such information. DOE may contact firms responding to this announcement to clarify a respondent's responses or capabilities and other matters as part of this regulatory research process.

DOE reserves the right to use any, and all, information submitted by the responding party in any manner. DOE intends to utilize the information provided in response to this RFI to inform potential future T&D acquisition activity and fee rulemaking planning activities. Respondents are advised to avoid including any information that might be considered business confidential and/or proprietary information (CBI), if possible, in their submission. DOE will endeavor to protect such information to the extent legally permissible. If required to do so as part of the regulatory process, DOE would try to make the information available to the public in a manner that is not directly attributable to the responding party.

Confidential Business Information

Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be

confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on January 8, 2025, by Candice Trummell, Senior Advisor for Environmental Management, pursuant to delegated authority from the Secretary of Energy. The document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2025.

Treana V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025-01034 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an online virtual combined meeting of the Consent Order Subcommittee, Public Outreach Subcommittee and Risk Evaluation and Management Subcommittee of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, February 12, 2025; 1 to 3 p.m. MST.

ADDRESSES: This meeting will be held virtually via WebEx. To attend, please contact the Northern New Mexico Citizens Advisory Board (NNMCAB) Executive Director (below), no later than 5 p.m. MST on Monday, February 10, 2025.

FOR FURTHER INFORMATION CONTACT: Bridget Maestas, NNMCAB Executive

Director, by phone: 505-709-7466 or email: bridget.maestas@em.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Purpose of the Consent Order Subcommittee: The subcommittee reviews the *2016 Compliance Order on Consent*, evaluate its strengths and weaknesses, and draft recommendations for the full Board's consideration as to how to improve it.

Purpose of the Public Outreach Subcommittee: The subcommittee involves stakeholders more directly in EM cleanup decisions, by reaching out to them to share their opinions by becoming involved in cleanup discussions and federal decision-making regarding clean-up.

Purpose of the Risk Evaluation and Management Subcommittee: The subcommittee drafts external citizen-based recommendations for the full Board's consideration on human and ecological health risk resulting from historical, current, and future hazardous and radioactive legacy waste operations at Los Alamos National Laboratory.

Tentative Agenda:

- Presentation on the Budget Process and Fiscal Year 2026 Budget
- Discussion on NNMCAB Recommendation on Fiscal Year 2026 Budget

Public Participation: The online virtual meeting is open to the public. To sign up for public comment, please contact Bridget Maestas at Bridget.Maestas@em.doe.gov, no later than 5 p.m. MST on Friday, February 7, 2025. Written public comments may be filed with the Committees either before or within five days after the meeting by sending them to Bridget Maestas at the aforementioned email address. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by emailing or calling Bridget Maestas, NNMCAB Executive Director, at bridget.maestas@em.doe.gov or at (505) 709-7466.

Signing Authority: This document of the Department of Energy was signed on January 13, 2025, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2025.

Jennifer Hartzell,

Alternate Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025-01052 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho Cleanup Project (ICP). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, February 20, 2025; 9 a.m.–3:30 p.m. MST.

ADDRESSES: TownePlace Suites, 175 Avenida Del Rio Drive, Twin Falls, Idaho 83301. This meeting will be open to the public in-person at the TownePlace Suites and virtually via Zoom. To attend virtually, please contact Danielle Miller, ICP Citizens Advisory Board (CAB) Administrator, by email at millerdc@id.doe.gov or phone (208) 526-5709, no later than 5 p.m. MST on Tuesday, February 18, 2025.

FOR FURTHER INFORMATION CONTACT: Danielle Miller, ICP CAB Administrator, by email at millerdc@id.doe.gov or phone (208) 526-5709 or visit the Board's internet homepage at <https://energy.gov/em/icpcab>.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda (agenda topics may change up to the day of the meeting; please contact Danielle Miller for the most current agenda):

1. Recent Public Outreach
2. ICP Progress Update
3. Program Presentations to the Board
4. Budget Update and ICP CAB Recommendation Discussion
5. Program Presentation to the Board

Public Participation: The in-person/online virtual hybrid meeting is open to the public in-person at the TownePlace Suites and via Zoom. To sign-up for public comment, please contact the ICP CAB Administrator (above) no later than 5 p.m. MST on Tuesday, February 18, 2025. In addition to participation in the live public comment sessions identified above, written statements may be filed with the Board either five days before or five days after the meeting by sending them to the ICP CAB Administrator at the aforementioned email address. Written public comment received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Danielle Miller, ICP Administrator, phone (208) 526-5709 or email millerdc@id.doe.gov. Minutes will also be available at the following website: <https://www.energy.gov/em/icpcab/listings/cab-meetings>.

Signing Authority: This document of the Department of Energy was signed on January 10, 2025, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the

document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2025.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025-00967 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years an information collection request with the Office of Management and Budget (OMB).

DATES: Comments regarding this proposed information collection must be received on or before March 17, 2025. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

ADDRESSES: Written comments may be sent to Phillip Harmonick, Office of Hearings and Appeals, U.S. Department of Energy, 1000 Independence Avenue SW, 8G-090, Washington, DC 20585, or by email at Phillip.Harmonick@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Phillip Harmonick, Office of Hearings and Appeals, U.S. Department of Energy, 1000 Independence Avenue SW, 8G-090, Washington, DC 20585, (202) 287-1566, Phillip.Harmonick@hq.doe.gov.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1910-5118.

(2) *Information Collection Request Titled:* Technology Partnerships Ombudsmen Reporting Requirements;

(3) *Type of Review:* Extension;

(4) *Purpose:* DOE's Alternative Dispute Resolution Office is required to collect reports, pursuant to the Technology Transfer Commercialization Act of 2000, from technology partnership ombudsmen at each DOE national laboratory. These reports are intended to demonstrate the extent to which each national laboratory has incorporated alternative dispute resolution techniques into its respective technology transfer program.

(5) *Annual Estimated Number of Respondents:* 17;

(6) *Annual Estimated Number of Total Responses:* 68;

(7) *Annual Estimated Number of Burden Hours:* 23;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$3,220.

Statutory Authority: Section 11 of the Technology Transfer Commercialization Act of 2000, Public Law 106-404, codified at 42 U.S.C. 7261c(c)(3)(C).

Signing Authority

This document of the Department of Energy was signed on January 13, 2025, by Policarpio A. Marmolejos, Director, Office of Hearings and Appeals, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2025.

Jennifer Hartzell,

Alternate Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025-01054 Filed 1-15-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Project No. 2905–035]****Village of Enosburg Falls, Vermont; Notice of Meeting**

a. *Project Name and Number:* Enosburg Falls Hydroelectric Project No. 2905.

b. *Applicant:* Village of Enosburg Falls, Vermont.

c. *Date and Time of Meeting:* Tuesday, February 18, 2025, from 1 p.m. to 2 p.m. eastern standard time.

d. *FERC Contact:* Arash Barsari, telephone at (202) 502–6207, or email at Arash.JalaliBarsari@ferc.gov.

e. *Purpose of Meeting:* Commission staff will hold a meeting with representatives from the Vermont Division for Historic Preservation (Vermont SHPO) and the Village of Enosburg Falls, Vermont (Village) to discuss Commission staff's draft Programmatic Agreement and the Area of Potential Effects for the project, pursuant to section 106 of the National Historic Preservation Act. The meeting will be held virtually via Microsoft Teams.

f. All local, State, and Federal agencies, Indian Tribes, and other interested parties are invited to participate. If meeting attendees decide to disclose information about a specific location that could create a risk or harm to an archaeological site or Native American cultural resource, attendees other than Vermont SHPO, Tribal representatives, and Commission staff will be excused for that portion of the meeting.

g. A summary of the meeting will be placed in the public record of this proceeding. As appropriate, the meeting summary will include both a public, redacted version that excludes any information about the specific location of any archaeological site or Native American cultural resource; and an unredacted privileged version. Parties planning to attend the meeting should notify Arash Barsari, using the contact information provided above in paragraph (d), by Tuesday, February 11, 2025, to RSVP and to receive specific instructions for logging in to the meeting.

Dated: January 10, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–01046 Filed 1–15–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #2**

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–43–000.

Applicants: Wild Plains Wind Project, LLC.

Description: Wild Plains Wind Project, LLC submits Amendment of Exempt Wholesale Generator Status Notice of Self-certification and Request for Shortened Comment Period.

Filed Date: 1/10/25.

Accession Number: 20250110–5372.

Comment Date: 5 p.m. ET 1/17/25.

Docket Numbers: EG25–70–000.

Applicants: Rio Lago Solar, LLC.

Description: Rio Lago Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/20/24.

Accession Number: 20241220–5531.

Comment Date: 5 p.m. ET 1/31/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–730–004.

Applicants: Linden VFT, LLC.

Description: Amendment to Transmission Scheduling Rights Purchase Agreement and Request for Confidential Treatment of Linden VFT, LLC.

Filed Date: 1/10/25.

Accession Number: 20250110–5317.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–895–001.

Applicants: BOCA bn, LLC.

Description: Tariff Amendment: Errata Amendment to MBR Filing ER25–895 to be effective 1/24/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5288.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–902–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original GIA Service Agreement No. 7461; Project Identifier No. AG1–156 to be effective 12/12/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5297.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–903–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original CSA, SA No. 7456; Project Identifier No. AE2–048 to be effective 12/11/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5314.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–904–000.

Applicants: Georgia Power Company.

Description: Initial rate filing:

Pineview Affected System Construction Agreement Filing to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5319.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–905–000.

Applicants: BCD 2024 Fund 4 Lessee, LLC.

Description: Tariff Amendment: BCD 2024 Fund 4 Lessee, LLC Notice of Cancellation of MBR Tariff to be effective 1/11/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5331.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–906–000.

Applicants: ISO New England Inc., The Connecticut Light and Power Company.

Description: ISO New England, Inc. and Eversource Energy Service Company submits a Notice of Termination of Small Generator Interconnection Agreement of the ISO–NE's OATT.

Filed Date: 1/10/25.

Accession Number: 20250110–5341.

Comment Date: 5 p.m. ET 1/31/25.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and

assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or *OPP@ferc.gov*.

Dated: January 10, 2025.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2025-00990 Filed 1-15-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC25-37-000.

Applicants: Norton Rose Fulbright US LLP, Cataract Coast, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Cataract Coast, LLC, et al.

Filed Date: 1/7/25.

Accession Number: 20250107-5201.

Comment Date: 5 p.m. ET 1/28/25.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25-72-000.

Applicants: PGR 2023 Lessee 1, LLC.

Description: PGR 2023 Lessee 1, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/10/25.

Accession Number: 20250110-5060.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: EG25-73-000.

Applicants: Catalina Solar, LLC.

Description: Catalina Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/10/25.

Accession Number: 20250110-5064.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: EG25-74-000.

Applicants: East Atmore Solar, LLC.

Description: East Atmore Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/10/25.

Accession Number: 20250110-5189.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: EG25-75-000.

Applicants: BOCA bn, LLC.

Description: BOCA bn, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/10/25.

Accession Number: 20250110-5252.

Comment Date: 5 p.m. ET 1/31/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15-1332-012;

ER10-2401-012; ER10-2402-011;

ER11-3414-012; ER10-2403-012;

ER18-1188-007; ER17-1318-008;

ER13-1816-024; ER15-1333-011.

Applicants: Waverly Wind Farm LLC, Sustaining Power Solutions LLC, Redbed Plains Wind Farm LLC, Prairie Queen Wind Farm LLC, Cloud County Wind Farm, LLC, Blue Canyon Windpower VI LLC, Blue Canyon Windpower V LLC, Blue Canyon Windpower II LLC, Arbuckle Mountain Wind Farm LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Arbuckle Mountain Wind Farm LLC, et al. under ER15-1332 et al.

Filed Date: 12/31/24.

Accession Number: 20241231-5479.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER18-471-014;

ER23-2234-003; ER23-2233-003;

ER23-2236-003; ER23-2235-003;

ER23-647-004; ER23-2238-003; ER23-

2237-003; ER23-2241-003; ER23-2240-

003; ER23-2243-003; ER23-2242-003;

ER23-2245-003; ER23-2244-003;

ER23-645-003; ER23-646-004.

Applicants: Wagon Wheel Wind Project Holdings LLC, Wagon Wheel Wind Project, LLC, Pixley Solar Energy Holdings LLC, Pixley Solar Energy LLC, Lazbuddie Wind Energy Holdings LLC, Lazbuddie Wind Energy LLC, Flat Ridge 5 Wind Energy Holdings LLC, Flat Ridge 5 Wind Energy LLC, Flat Ridge 4 Wind Holdings LLC, Flat Ridge 4 Wind, LLC, Diversion Wind Energy Holdings LLC, Chisholm Trail Solar Energy Holdings LLC, Chisholm Trail Solar Energy LLC, Algodon Solar Energy Holdings LLC, Algodon Solar Energy LLC, States Edge Wind I LLC.

Description: Triennial Market Power Analysis for the Southwest Power Pool Inc. Region of States Edge Wind I LLC, et al.

Filed Date: 12/31/24.

Accession Number: 20241231-5480.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER21-204-004.

Applicants: Commonwealth Edison Company, PJM Interconnection, L.L.C.

Description: Compliance filing: Commonwealth Edison Company submits tariff filing per 35: ComEd Clean-Up Filing to Adopt Certain Approved Updates into Att H-13A to be effective 5/1/2020.

Filed Date: 1/10/25.

Accession Number: 20250110-5246.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER22-2360-002.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Compliance filing: Further Compliance Filing Regarding Order No. 881 to be effective N/A.

Filed Date: 1/10/25.

Accession Number: 20250110-5257.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER24-2431-002.

Applicants: Duke Energy Progress, LLC, Energy Carolinas, LLC.

Description: Tariff Amendment: Duke Energy Carolinas, LLC submits tariff filing per 35.17(b): Response to Deficiency Letter (Provisional Interconnection) to be effective 4/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110-5013.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-151-001.

Applicants: Duff Solar Park LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 12/18/2024.

Filed Date: 1/10/25.

Accession Number: 20250110-5017.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-152-001.

Applicants: Pleasantville Solar Park LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 12/18/2024.

Filed Date: 1/10/25.

Accession Number: 20250110-5018.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-153-001.

Applicants: Riverstart Solar Park IV LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 12/18/2024.

Filed Date: 1/10/25.

Accession Number: 20250110-5019.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-154-001.

Applicants: Sandrini BESS Storage LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 12/18/2024.

Filed Date: 1/10/25.

Accession Number: 20250110-5020.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-300-002.

Applicants: ITC Great Plains, LLC, Southwest Power Pool, Inc.

Description: Tariff Amendment: ITC Great Plains, LLC submits tariff filing per 35.17(b): ITC Great Plains, LLC Second Amendment to Formula Rate Revisions Filing to be effective 1/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110-5006.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25-883-000.

Applicants: Duke Energy Indiana, LLC.

Description: § 205(d) Rate Filing: 2025-01-09_SA 4429_Duke Energy-

Vermillion E&P (J1518) to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5001.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–884–000.

Applicants: Duke Energy Indiana, LLC.

Description: § 205(d) Rate Filing: DEI—AES Indiana Construction Agmt Rate Schedule No. 284 to be effective 3/11/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5002.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–885–000.

Applicants: New York Independent System Operator, Inc., New York Transco, LLC.

Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): NY Transco 205: proposed revisions to formula rate re: ROE and O&M accounts to be effective 3/11/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5003.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–886–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3221R1 Grain Belt Express/ITC Great Plains Int Agr to be effective 3/11/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5004.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–887–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Calpine NITSA Rev 19 (SA No. 299) to be effective 1/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5007.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–888–000.

Applicants: Peoples Natural Gas.

Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5011.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–889–000.

Applicants: The Connecticut Light and Power Company.

Description: Tariff Amendment: Cancel—Design and Engineering Agreement—WE 400 Groton Road, LLC to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5012.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–890–000.

Applicants: Catalina Solar, LLC.

Description: § 205(d) Rate Filing: Catalina Solar, LLC MBR Tariff to be effective 2/23/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5014.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–891–000.

Applicants: PGR 2023 Lessee 1, LLC.

Description: § 205(d) Rate Filing: PGR 2023 Lessee 1 MBR Tariff to be effective 2/23/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5015.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–892–000.

Applicants: American Electric Power Service Corporation.

Description: § 205(d) Rate Filing: AEP submits one FA with City of Niles and MPPA–SA No. 5677 to be effective 4/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5024.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–893–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Service Agreement FERC No. 891 to be effective 12/11/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5195.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–894–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Service Agreement FERC No. 804 to be effective 10/10/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5231.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–895–000.

Applicants: BOCA bn, LLC.

Description: Initial Rate Filing: MBR Tariff Application Filing to be effective 1/24/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5233.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–896–000.

Applicants: East Atmore Solar, LLC.

Description: § 205(d) Rate Filing: East Atmore Solar, LLC MBR Tariff to be effective 3/12/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5259.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–897–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule Nos. 392 and 393 to be effective 10/1/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5273.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–898–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Shelby Solar Park LGIA Termination Filing to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5275.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–899–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Hancock County Solar Project LGIA Termination Filing to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5276.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–900–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Sable Solar LGIA Termination Filing to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110–5279.

Comment Date: 5 p.m. ET 1/31/25.

Docket Numbers: ER25–901–000.

Applicants: Cheyenne Light, Fuel and Power Company.

Description: § 205(d) Rate Filing: Filing of LGIA with NextEra Energy Resources Interconnection Holdings, LLC to be effective 12/13/2024.

Filed Date: 1/10/25.

Accession Number: 20250110–5280.

Comment Date: 5 p.m. ET 1/31/25.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES25–26–000.

Applicants: Consumers Energy Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Consumers Energy Company.

Filed Date: 1/6/25.

Accession Number: 20250106–5249.

Comment Date: 5 p.m. ET 1/27/25.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the

specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: January 10, 2025.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2025-00983 Filed 1-15-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP25-346-000.

Applicants: Carolina Gas

Transmission, LLC.

Description: Compliance filing: CGT—2024 Interruptible Revenue Sharing Report to be effective N/A.

Filed Date: 1/10/25.

Accession Number: 20250110-5000.

Comment Date: 5 p.m. ET 1/22/25.

Docket Numbers: RP25-347-000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: SNG 2025 Housekeeping Filing to be effective 1/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110-5005.

Comment Date: 5 p.m. ET 1/22/25.

Docket Numbers: RP25-348-000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Venice Extension Full In-Service—NRA and

Non-conforming Agrmt to be effective 1/10/2025.

Filed Date: 1/10/25.

Accession Number: 20250110-5021.

Comment Date: 5 p.m. ET 1/22/25.

Docket Numbers: RP25-349-000.

Applicants: Black Hills Shoshone Pipeline, LLC.

Description: Compliance filing: BHS NAESB Compliance Filing—Order No. 587—AA to be effective 2/1/2025.

Filed Date: 1/10/25.

Accession Number: 20250110-5283.

Comment Date: 5 p.m. ET 1/22/25.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP23-930-000.

Applicants: Saltville Gas Storage Company L.L.C.

Description: Refund Report: Saltville RP23-930 Refund Report to be effective N/A.

Filed Date: 1/10/25.

Accession Number: 20250110-5009.

Comment Date: 5 p.m. ET 1/22/25.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <https://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

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contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: January 10, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025-01045 Filed 1-15-25; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-12498-01-R9]

Approval of Clean Air Act General Permit Request for Coverage for New Minor Source Gasoline Dispensing Facility in Indian Country Within California for Viejas Pit Stop

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: This notice announces that the U.S. Environmental Protection Agency (EPA), Region 9, issued an approval to the Viejas Band of Kumeyaay Indians under the Clean Air Act's Tribal Minor New Source Review (NSR) Program. The EPA approved the Viejas Band of Kumeyaay Indians' Request for Coverage under the General Air Quality Permit for New or Modified Minor Source Gasoline Dispensing Facilities in Indian Country within California for the Viejas Pit Stop. This approval authorizes the construction of the Viejas Pit Stop under the Tribal Minor NSR Program.

DATES: The EPA's approval of the Request for Coverage for the Viejas Pit Stop was issued by the EPA and became effective on September 18, 2024. Pursuant to section 307(b)(1) of the Clean Air Act, judicial review of this final agency decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Ninth Circuit within 60 days of March 17, 2025.

FOR FURTHER INFORMATION CONTACT: Ashley Miller, EPA Region 9, (415) 972-3829, Miller.ashley01@epa.gov. The EPA's final approval decision, the Technical Support Document for this action, and all other supporting information are available through www.regulations.gov under Docket ID No. EPA-R09-OAR-2024-0084.

SUPPLEMENTARY INFORMATION:

Notice of Final Action

The EPA approved the Viejas Band of Kumeyaay Indians' Request for Coverage under the General Air Quality Permit for New or Modified Minor Source Gasoline Dispensing Facilities in

Indian Country (Gasoline Dispensing Facility General Permit) on September 18, 2024.¹ This approval pertains to the construction and operation of the Viejas Pit Stop (Source), a gasoline dispensing facility, to be located on the Viejas Band of Kumeyaay Indians Reservation, in Alpine, California. The EPA issued the approval pursuant to the provisions of Clean Air Act sections 110(a) and 301(d) and the EPA's Tribal Minor NSR Program at 40 CFR 49.151–49.164. The EPA based its approval on its determination that the Source meets the criteria qualifying it for coverage and that the Source is eligible for coverage under the Gasoline Dispensing Facility General Permit.

The EPA's Clean Air Act approval for the Source is a final agency action for purposes of judicial review only for the issue of whether the Source qualifies for coverage under the Gasoline Dispensing Facility General Permit. 40 CFR 49.156(e)(6).

Dated: January 8, 2025.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2025–00887 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0415; FRL–12559–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Implementation of the 8-Hour National Ambient Air Quality Standards for Ozone (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Implementation of the 8-hour National Ambient Air Quality Standards for Ozone (EPA ICR Number 2347.05, OMB Control Number 2060–0695) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2025.

Public comments were previously requested, via the **Federal Register**, on August 15, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 18, 2025.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0415, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Mr. Francis Oggeri, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (919) 541–3255; email address: oggeri.francis@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2025. 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. Public comments were previously requested via the **Federal Register** on August 15, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments. Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional

information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Abstract: This ICR that estimates the burden on states for implementation-related activities associated with the 2008 and 2015 ozone NAAQS. States with nonattainment areas for the 2008 and 2015 ozone NAAQS are implementing the NAAQS under the CAA and implementation regulations issued for that NAAQS. The state activities include, but are not limited to, developing and submitting attainment demonstrations, reasonable further progress plans, and reasonably available control technology (RACT) determinations. This ICR renewal estimates the burden for states to meet the ongoing planning requirements that apply to their remaining nonattainment areas for the 2008 and 2015 NAAQS. These requirements primarily affect 2015 ozone nonattainment areas that may fail to attain the NAAQS by their attainment date during this period and be reclassified to a higher classification with new SIP revisions required from the states. In addition, this ICR renewal includes burden estimates for state and EPA activities related to implementing second Maintenance Plans for the 2008 8-hour ozone standard.

The estimates included in this ICR renewal include both the state burden to develop and submit attainment plans to meet the requirements prescribed in CAA sections 110 and Part D, subparts 1 and 2 of Title I as interpreted by EPA's SIP requirements rules. An ozone NAAQS attainment plan contains state rules and other measures designed to improve air quality and achieve the NAAQS by the deadlines established under the CAA. It also must address several additional CAA requirements related to demonstrating timely attainment and contain contingency measures if the nonattainment area does not achieve reasonable further progress throughout the attainment period or if the area does not attain the NAAQS by its attainment date. States that have attained by the applicable attainment date may be eligible to submit a redesignation request and maintenance plan to receive a redesignation from “nonattainment to “attainment”.

Form Numbers: None.

Respondents/affected entities: State and Local Governments.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 97 (total).

Frequency of response: Once per triggering event, e.g., an air agency is required to revise and submit a SIP revision when the area is designated nonattainment or reclassified to a higher

¹ The Gasoline Dispensing Facility General Permit was issued by the EPA under the Tribal Minor NSR Program on May 1, 2019, and the permit became effective June 12, 2019. 84 FR 20879 (May 13, 2019). This permit is available at <https://www.epa.gov/caa-permitting/air-permits-gas-stations-tribal-lands-california>.

classification or if it is in an OTR member state to determine if RACT is satisfied by the previously approved state SIP. An air agency is also required to submit a second 10-year maintenance plan for maintenance areas or portions of maintenance areas for the 2008 ozone NAAQS.

Total estimated burden: 53,667 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$4,540,200 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease in the annual burden of 65,466 hours below the 119,133 hours estimated from the last approved ICR for 8-hour ozone NAAQS implementation. The primary reason for this decrease is that the previous ICR accounted for some respondents continuing to submit information for the 2008 NAAQS, respondents continuing to report on the revoked 1997 NAAQS, and respondents submitting initial information for all 52 nonattainment areas for the 2015 NAAQS. The estimates provided in this supporting statement differ from the prior 2015/2008/1997 combined NAAQS estimate due to decreases resulting from: the total state respondents reduced from 96 NAAs for the 2015/2008/1997 ozone NAAQS to 66 NAAs for the combined 2008 and 2015 ozone NAAQS, removal of the burden estimate for the states in the Ozone Transport Regions to certify the current state SIPs meet CAA section 184(b)(1)(B) RACT requirements; no 1997 8-hour ozone second maintenance plans due during the next three years; no 2008 8-hour ozone NAAQS needing to be reclassified to a higher class.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2025–01037 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEJECR–2024–0235; FRL–12561–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Environmental and Climate Justice Community Change Grant Program: Post-Award Reporting (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Environmental and Climate Justice Community Change Grant Program: Post-Award Reporting (EPA ICR Number 7781.01, OMB Control Number 2035–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on August 6, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 18, 2025.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OEJECR–2024–0235, to EPA online using www.regulations.gov (our preferred method), by email to Docket_OMS@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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:

Aarti Iyer, Office of the Chief Financial Officer, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; email address: iyer.aarti@epa.gov; phone: 202–564–0214.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. 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.

Public comments were previously requested via the **Federal Register** on August 6, 2024 during a 60-day comment period (89 FR 63940). This

notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Abstract: The U.S. Environmental Protection Agency (EPA) makes competitive financial assistance awards to support projects that tackle environmental, public health, and energy challenges across the country. Historically, these investments have not reached communities and groups who are overburdened by the effects of pollution, environmental hazards, and climate change. To help get resources and funding to underserved and overburdened communities, the Inflation Reduction Act (IRA) created the Environmental and Climate Justice Block Grant Program (ECJP)—the largest investment in environmental and climate justice in U.S. history—when it was signed into law by President Biden on August 16, 2022. The Community Change Grants (CCG) are the final and most comprehensive piece of EPA's implementation of ECJP IRA funding. The CCG program will provide funding to communities and their partners to design, develop, and implement multifaceted, community-driven projects to protect public health and the environment. With this Information Collection Request (ICR), EPA seeks approval to collect performance information from CCG grantees via progress reports and final reports. Collection of this information enables EPA to assess and manage the CCG program, which ensures responsible stewardship of public funds; rigorous evidence-based learning and improvement; and transparent accountability to the American public.

Form Numbers: None.

Respondents/affected entities: Recipients of financial assistance awards

Respondent's obligation to respond: Mandatory for recipients of financial awards to obtain or retain a benefit (2 CFR parts 200 and 1500).

Estimated number of respondents: 105.

Frequency of response: Varies.

Total estimated burden: 9,100 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$521,339 (per year), including \$0 annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection, and so does not involve any program changes or burden adjustments.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2025-01040 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OCFO-2024-0072; FRL-12560-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Environmental Justice Collaborative Problem Solving and Government to Government Programs: Progress and Final Reporting Information Collections (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Environmental Justice CPS and G2G Programs: Progress and Final Reporting Information Collections (EPA ICR Number 2807.01, OMB Control Number 2035-NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on February 21, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 18, 2025.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OEJECR-2023-0531, to EPA online using www.regulations.gov (our preferred method), by email to Docket_OMS@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential

Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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:

Aarti Iyer, Office of the Chief Financial Officer, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; email address: iyer.aarti@epa.gov; phone: 202-564-0214.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. 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.

Public comments were previously requested via the **Federal Register** on February 21, 2024 during a 60-day comment period (89 FR 13079). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Abstract: The U.S. Environmental Protection Agency (EPA) makes competitive financial assistance awards to support projects that tackle environmental, public health, and energy challenges across the country. This is accomplished by working directly with community-based organizations (CBOs) and state, local, territorial, and tribal governments that have strong ties to the communities in which they are working. EPA fosters a collaborative approach to tackling some of the most critical challenges in the most overburdened communities by encouraging projects that involve multiple stakeholders including States, local governments, and tribal governments. To help get resources and funding to underserved and overburdened communities EPA offers Environmental Justice Collaborative Problem Solving (EJCPS) and

Environmental Justice Government to Government (EJG2G) cooperative agreement programs. With this Information Collection Request (ICR), EPA seeks authorization to collect post-award information in the form of semi-annual progress reports and final reports from each grantee to track their progress, with respect to effectiveness (e.g., the extent to which projects achieved their objectives, goals, and targets), efficiency (e.g., the extent to which projects delivered activities and outputs on schedule and within budget), and equity (e.g., the extent to which investments and benefits flowed to disadvantaged communities that are marginalized, underserved, and overburdened by pollution). Collection of this information enables EPA to assess and manage the EJCPS and EJG2G programs, which ensures responsible stewardship of public funds; rigorous evidence-based learning and improvement; and transparent accountability to the American public.

Form Numbers: None.

Respondents/affected entities: Recipients of financial assistance awards.

Respondent's obligation to respond: Mandatory for recipients of financial awards to obtain or retain a benefit (2 CFR parts 200 and 1500).

Estimated number of respondents: 217.

Frequency of response: Varies.

Total estimated burden: 17,360 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$994,554 (per year), including \$0 annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection, and so does not involve any program changes or burden adjustments.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2025-01041 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0448; FRL-12439-01-OCSP]

Vinyl Chloride; Draft Scope of the Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on the draft scope of the risk evaluation to be conducted under the Toxic Substances Control Act (TSCA) for vinyl chloride (ethene, chloro-; CASRN 75-01-4). Under TSCA, the scope documents must include the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA expects to consider in conducting the risk evaluation for this chemical substance. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors.

DATES: Comments must be received on or before March 3, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0448, online 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:

For technical information: Marcy Card, Existing Chemicals Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1202; email address: VinylChloride.TSCA@epa.gov.

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and

disposal of vinyl chloride, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

The draft scope of the risk evaluation is issued pursuant to TSCA section 6(b)(4)(D), 15 U.S.C. 2605(b)(4)(D), and EPA's implementing regulations at 40 CFR 702.39(b).

C. What action is the Agency taking?

EPA is announcing the availability of and seeking public comment on the draft scope of the risk evaluation to be conducted under TSCA for vinyl chloride (ethene, chloro-; CASRN 75-01-4). Under TSCA, the scope documents must include the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA expects to consider in conducting the risk evaluation for this chemical substance. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors.

D. What should I consider as I prepare my comments?

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

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>.

II. Background

A. What is vinyl chloride?

Vinyl chloride (ethene, chloro-), also known as chloroethylene, is a chlorinated ethene that does not occur naturally in the environment. Its primary use is as a reactant (monomer) in the production of polyvinyl chloride (PVC) in consumer, commercial, and industrial applications. Since 1986, the national aggregate production volume of vinyl chloride, as reported under the Chemical Data Reporting (CDR) rule, formerly known as the Inventory Update Rule (IUR) (40 CFR part 711), has been consistently over 1 billion pounds. In 2011, over 16 billion pounds were reported to CDR and since 2012 production volume has been reported between 10 billion and 20 billion pounds.

Due to its physical state as a gas at room temperature and pressure, vinyl chloride is expected to be primarily present in the atmosphere in vapor phase and is not expected to partition to airborne particles. Exposure to vinyl chloride may result in a range of harmful health effects such as liver toxicity, neurotoxicity, immunotoxicity, and developmental toxicity. EPA previously determined that vinyl chloride is a "known human carcinogen."

B. Draft Scope for the Risk Evaluation of Vinyl Chloride

In December 2024, EPA announced its designation of vinyl chloride as a high priority substance for risk evaluation under TSCA (Ref. 1), which initiated the risk evaluation phase and started the 3 to 3.5 year statutory timeframe in which the risk evaluation is to be completed. The draft scope of the risk evaluation for this chemical substance (Ref. 2) includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA expects to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)). Development of the scope is the first step of a risk evaluation, and includes the following components (40 CFR 702.39(b)):

- The conditions of use, as determined by the Administrator, that EPA expects to consider in the risk evaluation;
- The potentially exposed populations, including any potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA under the conditions of use that EPA expects to evaluate;
- The ecological receptors that EPA expects to evaluate;

- The hazards to health and the environment that EPA expects to evaluate;
- A description of the reasonably available information and the science approaches that the Agency expects to use;
- A conceptual model that describes the actual or predicted relationships between the chemical substance, its associated conditions of use through predicted exposure scenarios, and the identified human and environmental receptors and human and ecological health hazards;
- An analysis plan that describes how EPA intends to assess hazards and exposures, and characterize risks; and
- A plan for peer review.

III. Request for Comment

EPA seeks feedback on the approaches presented in the draft scope of the risk evaluation, use profile (Ref. 3), and draft chemistry and fate technical support document (Ref. 4), copies of which are available in the docket. EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that supports the comments provided, and, to the extent permissible, describe any supporting data that is not publicly available.

IV. Next Steps

EPA will consider comments received and prepare the final scope of the risk evaluation for vinyl chloride. EPA intends to publish a notice in the **Federal Register** announcing the availability of the final scope of the risk evaluation within six months of the designation of vinyl chloride as a high-priority substance for risk evaluation under TSCA (Ref. 1), *i.e.*, by June 2025.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. **Federal Register**. 89 FR 102900, December 18, 2024 (FRL-11581-07-OCSPP)
2. EPA. Vinyl Chloride; Draft Scope of the Risk Evaluation under the Toxic Substances Control Act (TSCA). January 2025.
3. EPA. Use Report for Vinyl Chloride. January 2025.
4. EPA. Draft Chemistry and Fate Technical Support Document for Vinyl Chloride, January 2025.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: January 10, 2025.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025-00948 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2020-0530; FRL 12558-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Unregulated Contaminant Monitoring Rule (UCMR 5) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Unregulated Contaminant Monitoring Rule (UCMR 5) (EPA ICR Number 2683.03, OMB Control Number 2040-0304) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the original UCMR 5 ICR, which is currently approved through January 31, 2025. Public comments on the ICR renewal were previously requested during a 60-day comment period via the **Federal Register** on July 30, 2024. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 18, 2025.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OW-2020-0530, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is

that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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:

Brenda Bowden, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268; telephone number: (513) 569-7961; email address: bowden.brenda@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2025. 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.

Public comments on the ICR renewal were previously requested during a 60-day comment period via the **Federal Register** on July 30, 2024 (89 FR 61112). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: Section 1445(a)(2) of the Safe Drinking Water Act (SDWA) requires that once every five years, beginning in 1999, EPA issue a new list of not more than 30 priority unregulated contaminants in drinking water to be monitored by public water systems (PWSs). Information collected under the program informs EPA's decision making regarding whether or not to regulate particular contaminants in drinking water. UCMR 5 requires monitoring for 30 chemical contaminants and was published in the **Federal Register** on

December 27, 2021 (86 FR 73131). The information collection associated with UCMR 5 does not require respondents to disclose confidential information.

Form Numbers: None.

Respondents/affected entities: Data associated with this ICR will be collected and maintained by PWSs subject to the rule. UCMR is a federally-implemented program; however, States, territories, and Tribes (herein after referred to as “States” for simplicity) can choose to participate in UCMR 5 implementation through a Partnership Agreement with EPA. These States will sometimes choose to collect samples and maintain records on behalf of PWSs.

Respondent's obligation to respond: Mandatory (section 1445(a) of SDWA).

Estimated number of respondents: Approximately 3,493 respondents (total among PWSs and States) participate in UCMR 5 sample collection during the ICR years 2025–2027. There are approximately 10,367 respondents to UCMR 5 during the five-year program period.

Frequency of response: The frequency and number of responses varies across respondents. PWSs that rely on surface water and ground water under the direct influence of surface water will sample quarterly (four sampling events), and PWSs that rely on ground water will sample twice (at 6-month intervals). All sample collection will take place during a continuous 12-month period during the sampling timeframe. UCMR 5 sampling takes place at the entry point to the distribution system (EPTDS). The number of samples collected by PWSs also differs based on the size of the PWS, and the number of entry points within each PWS. Over the three ICR years of 2025 through 2027, the total number of responses per respondent averages 3.0, or an average of 1.0 responses per respondent per year.

Total estimated burden: EPA estimates the labor burden at 21,275 hours (per year) during the ICR renewal years of 2025 through 2027 for States and PWSs. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: During the ICR renewal years of 2025 through 2027, EPA estimates the total cost for States and PWSs at \$5,633,415 (per year), which includes \$4,702,003 annualized capital or operation & maintenance costs. The total costs include labor costs and laboratory analysis (non-labor) costs. EPA pays for the analytical and sample shipping costs for small PWSs (i.e., serving 10,000 or fewer people).

Changes in the Estimates: There is a decrease of 27,193 hours in the total estimated respondent burden for PWSs

and States during the ICR renewal years of 2025 through 2027 compared with the original UCMR 5 ICR currently approved by OMB. This decrease is due to:

- Fewer PWSs participate during the ICR renewal period of 2025–2027 than in 2022–2024 period addressed by the original ICR. Only one-third of PWSs monitor for UCMR 5 contaminants in 2025–2027; two-thirds of PWS will have monitored for UCMR 5 contaminants in 2023 or 2024.
- Some initial, pre-monitoring activities were conducted by all systems during the original ICR period. These activities will not take place during 2025–2027.
- States are expected to incur less burden during 2025–2027, since their support is associated with monitoring and less monitoring is occurring during the renewal period.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2025–01038 Filed 1–15–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0611; FRL–12562–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Toxic Substances Control Act (TSCA) Existing Chemical Risk Evaluation and Management: Generic Information Collection Request for Surveys (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), TSCA Existing Chemical Risk Evaluation and Management; Generic ICR for Surveys, (EPA ICR Number 2585.02 and OMB Control Number 2070–0218) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through February 28, 2025. Public comments were previously requested via the **Federal Register** on May 15, 2024. This notice allows for an additional 30 days for public comments.

DATES: Comments must be received on or before February 18, 2025.

ADDRESSES: Submit your comments to EPA, identified by docket identification (ID) number Docket ID No. EPA–HQ–OPPT–2018–0612, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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:

Katherine Sleasman, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is approved through February 28, 2025. 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. Public comments were previously requested via the **Federal Register** on May 15, 2024, establishing a 60-day comment period (89 FR 42467). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information collection activities and related estimated burden and costs that are summarized in this document, are available in the docket. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. Additional instructions on commenting and visiting the docket is available at <https://www.epa.gov/dockets>.

Abstract: EPA will use this generic ICR to survey chemical users, processors, distributors, manufacturers

(including importers), and recyclers, chemical waste handlers, consumers of chemical-containing products, employees exposed to the chemical evaluated (including unions), state and local regulators, non-governmental organizations, industry experts, and knowledgeable members of the public (including potentially exposed or susceptible subpopulations) who may have relevant information and are not covered by current information collection requests. The Agency will use the information collected to inform the development of any future regulatory efforts and to integrate consistent, meaningful, and transparent information into risk evaluation and risk management actions. This information is critical for adequately identifying conditions of use, conducting hazard and exposure assessments, characterizing risks, ascertaining benefits of and substitutes for each substance, estimating the economic consequences of regulation, and developing appropriate regulatory actions. Surveys are important information-gathering tools that will allow EPA to collect information that is necessary to inform the risk evaluation and management efforts and support unreasonable risk determinations from existing chemicals under TSCA.

Form number(s): None.

Respondents/affected entities: Entities potentially affected by this include chemical manufacturers (including importers), chemical users (including government agencies), processors, distributors, product manufacturers, recyclers, chemical waste handlers, consumers, employees, and others with important information about the chemical being evaluated or considered for risk evaluation and management under TSCA. North American Industrial Classification System (NAICS) codes identified in question 12 of the ICR.

Respondent's obligation to respond: Voluntary.

Estimated number of potential respondents: 2,400.

Frequency of response: On occasion.

Total estimated burden: 22,080 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: \$1,960,086, includes \$0 annualized capital investment or maintenance and operational costs.

Changes in the estimates: There are adjustments to the burden hours and responses currently approved by OMB. There is an increase in 20,880 burden hours and an increase in 1,800

responses. There changes are corrections to reflect three-year totals.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2025-01039 Filed 1-15-25; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

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 question whether the proposal complies with the standards of section 4 of the BHC Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Unless otherwise noted, comments regarding the 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 January 31, 2025.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org:

1. *Magnolia Banking Corporation, Magnolia, Arkansas*; to engage de novo in extending credit and servicing loans pursuant to section 225.28(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-01033 Filed 1-15-25; 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 received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

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 January 31, 2025.

A. *Federal Reserve Bank of Minneapolis* (Mark Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *Gabrielle Pogatchnik, Philadelphia, Pennsylvania*; to join the Pogatchnik Family Control Group, a group acting in concert, to retain voting shares of Finlayson Bancshares, Inc., Finlayson, Minnesota, and thereby indirectly retain voting shares of First Independent Bank, Russell, Minnesota, and Northview Bank, Sandstone, Minnesota.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-01032 Filed 1-15-25; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0112; Docket No. 2025-0001; Sequence No. 3]

Information Collection; Federal Management Regulation; State Agency Monthly Donation Report of Surplus Property, GSA Form 3040

AGENCY: Federal Acquisition Service, General Services Administration (GSA).

ACTION: Notice; request for public comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding State Agency Monthly Donation Report of Surplus Property, GSA Form 3040.

DATES: Submit comments on or before March 17, 2025.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to <https://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for Information Collection 3090-0112. Select the link “Comment Now” that corresponds with “Information Collection 3090-0112; State Agency Monthly Donation Report of Surplus Personal Property” under the heading “Enter Keyword or ID” and select “Search”. Select the link “Submit a Comment” that corresponds with

“Information Collection 3090-0112, State Agency Monthly Donation Report of Surplus Personal Property”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 3090-0112, State Agency Monthly Donation Report of Surplus Personal Property” on your attached document.

Instructions: Comments received generally will be posted without change to [regulations.gov](https://www.regulations.gov), including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [regulations.gov](https://www.regulations.gov), approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Christopher Willett, Property Disposal Specialist, GSA Office of Personal Property Management, at telephone 703-605-2873 or via email to christopher.willett@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

This report complies with 41 CFR 102-37.360, which requires a State Agency for Surplus Property (SASP) to submit annual reports of personal property donated to public agencies for use in carrying out such purposes as conservation, economic development, education, parks and recreation, public health, and public safety.

B. Annual Reporting Burden

Respondents: 56.
Responses per Respondent: 4.
Total Responses: 224.
Hours per Response: 1.5.
Total Burden Hours: 336.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov.

Lois Mandell,

Director, Regulatory Secretariat Division, General Services Administration.

[FR Doc. 2025-00994 Filed 1-15-25; 8:45 am]

BILLING CODE 6820-34-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0014; Docket No. 2025-0001; Sequence No. 2]

Information Collection; Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123

AGENCY: Federal Acquisition Service, General Services Administration (GSA).

ACTION: Notice; request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding the Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123.

DATES: Submit comments on or before: March 17, 2025.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to <https://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number.

Select the link “Comment Now” that corresponds with “Information Collection 3090-0014, Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123”. Follow the instructions provided on the screen.

Please include your name, company name (if any), and “Information Collection 3090-0014, Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123”. on your attached document.

If your comment cannot be submitted using [regulations.gov](https://www.regulations.gov), call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite “Information Collection 3090-0014, Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123”, in all correspondence related to this collection. Comments received generally will be posted without change to [regulations.gov](https://www.regulations.gov), including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [regulations.gov](https://www.regulations.gov), approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Willett, Property Disposal Specialist, GSA Office of Personal Property Management, at telephone 703-605-2873 or via email to christopher.willett@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Transfer Order-Surplus Personal Property and Continuation Sheet, Standard form (SF) 123, is used by a State Agency for Surplus Property (SASP) to donate Federal surplus personal property to public agencies, nonprofit educational or public health activities, programs for the elderly, service educational activities, and public airports. The SF 123 serves as the transfer instrument and includes item descriptions, transportation instructions, nondiscrimination assurances, and approval signatures.

B. Annual Reporting Burden

Electronic

Responses: 23,211.

Burden Hours (at .017 Hours per Response): 394.59.

Manual

Responses: 153.

Burden Hours (at .13 Hours per Response): 19.89.

Total Annual Responses: 23,364.

Total Burden Hours: 414.48.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0014, Transfer Order-Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, in all correspondence.

Lois Mandell,

Director, Regulatory Secretariat Division, General Services Administration.

[FR Doc. 2025-00993 Filed 1-15-25; 8:45 am]

BILLING CODE 6820-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE25-025, Rigorous Evaluation of Community- and Societal-Level Primary Prevention Approaches To Prevent Adverse Childhood Experiences (ACEs): Expanding the Best Available Evidence; Amended Notice of Closed Meeting

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

FOR FURTHER INFORMATION CONTACT: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S106-9, Atlanta, Georgia 30341. Telephone: (770) 488-1504; Email: AWilkes@cdc.gov.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE25-025, Rigorous Evaluation of Community- and Societal-Level Primary Prevention Approaches To Prevent Adverse Childhood Experiences (ACEs): Expanding the Best Available Evidence; February 25-26, 2025, 10 a.m.-5 p.m., EST, web conference, in the original **Federal Register** notice. The meeting notice was published in the **Federal Register** on November 27, 2024, 89 FR 93606 and 93607.

This meeting notice is being amended to change the meeting dates from a two-day meeting to a one-day meeting. The notice should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE25-025, Rigorous Evaluation of Community- and Societal-Level Primary Prevention Approaches To Prevent Adverse Childhood Experiences (ACEs): Expanding the Best Available Evidence.

Date: February 25, 2025.

Time: 10 a.m.-5 p.m., EST.

The meeting is closed to the public.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2025-00856 Filed 1-15-25; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10398 #87, #90, and #91]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the "generic" clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are "usually voluntary, low-burden, and uncontroversial collections," do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit 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 January 30, 2025.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #_____) and the OMB control number (0938–1148). 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: CMS–10398 #_____/OMB control number: 0938–1148, 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/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pralisting>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at 410–786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection’s supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. *Title of Information Collection:* Managed Care Plan (MCP) Medical Loss Ratio (MLR) Reporting Template; *Type of Information Collection Request:* New collection of information request; *Use:* Medicaid managed care is the predominant delivery system for Medicaid beneficiaries to access health care services. State Medicaid agencies contract with managed care plans (MCPs) that accept a fixed, prospective monthly payment for each enrolled beneficiary (also referred to as risk-based managed care). Section 1903(m)(2) of the Social Security Act and 42 CFR 438.4 require that capitation rates be actuarially sound, meaning that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required

under the terms of the contract and for the operation of the MCP for the time period and the population covered under the terms of the contract. The medical loss ratio (MLR) is a key measure of MCP financial performance and indicates the share of premium revenue (capitation payments) that a plan spends on covered health services and activities to improve health care quality compared to the share of revenue to cover administrative expenses and profit/surplus. MLRs are used as a retrospective tool to assess financial performance of MCPs. Section 438.8 provides detail on MLR calculations and MCP reporting requirements.

Section 438.8(k) requires State contracts with MCPs to include a requirement to annually report to the state specific details of the plan’s MLR. The attached Medicaid managed care plan MLR reporting template provides States with a standard format for collecting the required details from their contracted MCPs. States are not required to have their MCPs use this template; it is provided in response to States’ requests for a streamlined, consistent way to collect the required information. CMS’ review process for managed care MLR represents an essential Federal oversight function to ensure that States and MCPs are compliant with applicable Federal laws and regulations.

Form Number: CMS–10398 #87 (OMB control number: 0938–1148); *Frequency:* Yearly; *Affected Public:* Private Sector and State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 47; *Total Annual Hours:* 2,350. (For policy questions regarding this collection contact: Amy Gentile at 410–786–3499.)

2. *Title of Information Collection:* CAA of 2024, Section 206 Planning Grant Reporting; *Type of Information Collection Request:* New collection of information request; *Use:* This collection relates to section 206(a) of the Consolidated Appropriations Act, 2024 (CAA of 2024), “State Planning Grants to Promote Continuity of Care for Medicaid and CHIP Beneficiaries Following Incarceration”. This four-year, discretionary grant program supports state Medicaid agencies and Children’s Health Insurance Programs (CHIP) to develop the operational capabilities to promote continuity of care for Medicaid-eligible individuals who have been incarcerated. To ensure maximum state flexibility and to reduce the reporting burden on states as much

as possible, states will submit semi-annual and final progress reports in their preferred format. CMS will not require states to use a standardized template or form, and CMS is not making an optional template or form available for states to use. *Form Number:* CMS–10398 #90 (OMB control number: 0938–1148); *Frequency:* Semi-annually and once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 30; *Total Annual Responses:* 300; *Total Annual Hours:* 1,200. (For policy questions regarding this collection contact: Jennifer Bowdoin at 410–786–8551.)

3. *Title of Information Collection:* State Plan Amendment (SPA) Template for Medicaid Clinic Benefit; *Type of Information Collection Request:* New information collection request; *Use:* On November 27, 2024, CMS published the Prospective Payment System and Ambulatory Surgical Center Payment System final rule (CMS–1809–FC, RIN 0938–AV35) which amended 42 CFR 440.90 to authorize Medicaid coverage for clinic services furnished outside the “four walls” of their clinic. The rule provided States with the authority to amend their state plans and add additional coverage outside of the clinic to the optional clinic benefit. We have developed and attached a new state plan template to simplify the SPA development, submission, and review/approval processes for states and CMS.

Completion of the template is mandatory for states that both cover the clinic services benefit and cover tribal clinics to allow clinic services to be provided outside of the clinic under the clinic services benefit but will be available as an option for all states who wish to use the template to amend their state plan clinic pages for general updates.

Form Number: CMS–10398 #91 (OMB control number: 0938–1148); *Frequency:* One-time and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,400. (For policy questions regarding this collection contact: Marlana Thieler at 410–786–6274.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–01022 Filed 1–15–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****[Docket No. FDA-2024-N-5976]****Use of Cannabis-Derived Products, Including Cannabidiol, in Veterinary Practice; Request for Information****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments from the public, particularly veterinarians, related to the use of cannabis-derived products (CDPs) in animals, with an emphasis on cannabidiol (CBD) products and general trends associated with those products, including information about: usage trends (*e.g.*, product selection, indications, etc.), quality standards, benefits of use, potential drug interactions, adverse events and safety problems, and toxicological concerns. This information will enhance the Center for Veterinary Medicine's (CVM's) knowledge of potential safety signals associated with these products, in addition to aiding our understanding of veterinarians' experiences related to the use of CDPs for their animal patients.

DATES: Either electronic or written comments on the request for information must be submitted by April 16, 2025.

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 April 16, 2025. 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-2024-N-5976 for "Use of Cannabis-Derived Products, including Cannabidiol, in Veterinary Practice; Request for Information." 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." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Katherine Breed, Center for Veterinary Medicine, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20852, 301-796-9361, Katherine.Breed@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The CDP marketplace has grown significantly in the past few years as the U.S. Government removed certain restrictions related to specific aspects of the Cannabis plant's use and distribution. The Agricultural Act of 2014 (also known as the 2014 Farm Bill (<https://www.congress.gov/bill/113th-congress/house-bill/2642>)) specifically defined "industrial hemp" as any part of the Cannabis sativa L. plant with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis, allowing its use in limited situations for research purposes only. The Agricultural Improvement Act of 2018 (also known as the 2018 Farm Bill (<https://www.congress.gov/bill/115th-congress/house-bill/2>)) further relaxed certain Federal restrictions on hemp, which resulted in allowing interstate commerce of hemp and removing hemp from the Controlled Substances Act statutory definition of marijuana, among other changes. The 2018 Farm Bill also explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds, including hemp, under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (see 7 U.S.C. 1639(c)).¹

¹ See 86 FR 5596, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd> (see Question 2).

CVM is particularly interested in input from practicing veterinarians, whose expertise and experience can help inform FDA regarding the use and effect of CDPs in animals. FDA is gathering information relating to the use of CDPs in animals, with an emphasis on CBD products and other hemp-derived products and general trends associated with those products. For purposes of this request for information, “cannabis” refers to plants that can be further defined as either “hemp” or “marijuana,” depending on their delta-9 THC concentration. The focus of this request for information is hemp-derived products, and we use the term “hemp” to refer to the plant species *Cannabis sativa* L. and any part of that plant, including the seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis. We are interested in information about the use of hemp-derived products (typically labeled as products containing CBD) and not marijuana-derived products.

Firms marketing CBD products for use in (non-human) animals often make claims regarding a wide variety of diseases or conditions. Some products are also purported to enhance general wellness and promote longevity. Products are marketed in many different formulations, such as tinctures/oils, treats/chews, pellets for large animals, capsules, and sometimes as food toppers or infused in foods such as peanut butter; topical products infused with CBD, such as balms and shampoos, are also available for pets. Products that are intended for use in the cure, mitigation, treatment, or prevention of diseases in animals are animal drugs.

Currently, no FDA-approved, conditionally approved, or indexed animal drugs contain CBD. However, with respect to human drugs, FDA has approved one cannabis-derived drug product: EPIDIOLEX (cannabidiol), and three synthetic cannabis-related drug products: MARINOL (dronabinol), SYNDROS (dronabinol), and CESAMET (nabilone). Under the Animal Medicinal Drug Use Clarification Act of 1994 and its implementing regulations at 21 CFR part 530, under certain conditions, veterinarians can lawfully prescribe approved human drugs for use in animals in an extralabel manner.

FDA has made the regulation of the CBD market a priority, including products marketed for animals. While there is some limited published information about use of CDPs in animals, significant data gaps exist surrounding many aspects of CBD and

other CDPs in animals, and further research is necessary to assess the safety and effectiveness of these products. FDA is seeking a better understanding of what veterinarians are experiencing related to CDPs in their patients, such as: general patterns of use (*i.e.*, animal species, brands, formulations, doses, indications for use), quality standards, benefits of use, potential drug interactions, adverse events and safety problems, and toxicological concerns.

II. Questions for Consideration

We are particularly interested in input on the following questions regarding veterinarians' experiences related to CDPs in their patients (*Note:* You may submit your comment anonymously if you do not wish to provide your name along with your response. CVM will fully consider all comments. (<https://www.regulations.gov/faq>)).

1. Are you a veterinarian licensed to practice veterinary medicine in the United States? If so, in which State(s) do you hold an active license? Please indicate how many years of experience, as a practicing veterinarian, you have. Please indicate the type of community (*i.e.*, urban, suburban, or rural) that best describes where you work.

2. Are you in clinical practice, meaning, do you have physical contact with client-owned animals? If so, what species does your practice see (*e.g.*, food-producing species such as cattle, poultry, etc., and/or nonfood-producing species such as dogs, cats, etc.)?

3. Have clients asked you about using products derived from cannabis in their animals? If so, please describe approximately how often (weekly, monthly, quarterly, annually) your clients ask and describe for which animal species and for what indications your clients are using (or are interested in using) cannabis-derived products.

4. When clients ask about products derived from cannabis, do they generally distinguish between products derived from hemp versus those derived from marijuana (*i.e.*, do they ask about hemp products, marijuana products, or do they not specify)? What brands (if known) and formulations or types of products do clients ask about (*e.g.*, tinctures, treats, capsules, topical products, etc.)?

5. Have you prescribed or dispensed EPIDIOLEX, MARINOL, SYNDROS, or CESAMET for use in any of your patients? If so, which drug(s) for what species, and what was the reason or indication for which you prescribed or dispensed these drugs for animal patients?

6. Do you use or recommend hemp-derived cannabis products for your

animal patients? If so, are you confident that the products you use or recommend are labeled accurately (*e.g.*, concentration, ingredients, etc.)? What factors influence your decision on which brand of hemp-derived cannabis product to use or recommend (*e.g.*, certificate of analysis, research, continuing education lectures, etc.)? What CBD:THC cannabinoid ratio in hemp-derived cannabis products do you use or recommend for your animal patients (if known)?

7. Describe your practices surrounding recommendations of hemp-derived cannabis products for your animal patients including: for what indications do you use or recommend hemp-derived cannabis products; for which species; and which dosage forms (*e.g.*, oral, topical, inhalation), dose, brand, and cannabinoid(s) do you prefer? What information sources do you use to make these treatment decisions (continuing education, specialist recommendations, industry recommendations, etc.)? Describe any benefits of use related to hemp-derived cannabis products in your patients.

8. Related to hemp-derived cannabis products only: Have clients reported to you, or have you observed, adverse effects following an animal being administered a hemp-derived cannabis product (*i.e.*, after a client intentionally administered a hemp-derived cannabis product, not accidental ingestion of adult recreational use products)? If so, please describe each event(s) including animal species, clinical signs and severity of the adverse event, product/dose/route of exposure (if known), whether veterinary intervention was needed, and whether the animal recovered, or the adverse event resulted in death. Did you report any adverse events to FDA?

9. Do you have questions or concerns about drug interactions between hemp-derived cannabis products and other medications? For purposes of this information request, we are interested in interactions with any product used for medical purposes, including FDA-approved drugs, United States Department of Agriculture-licensed biologics, and other products, such as veterinary nutraceuticals and veterinary phytotherapy (plant-derived) products. Are you concerned about, or have you seen potential drug interactions (*e.g.*, reduction in the effectiveness, safety margin, or both, of either the hemp-derived cannabis products or the other medications) between hemp-derived cannabis products and other medications?

10. If you do not use or recommend hemp-derived cannabis products for

your animal patients, what factors have influenced your decision (e.g., legal issues surrounding cannabis, safety concerns, effectiveness concerns, product quality concerns, not found a need, etc.)? If you do not use or recommend hemp-derived cannabis products for your animal patients for reasons other than effectiveness concerns, are there any indications and species for which you believe they could be effective and why?

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025-00945 Filed 1-15-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5933]

Proposal to Refuse to Approve a New Drug Application for TRADIPITANT; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) at the Food and Drug Administration (FDA or Agency) is proposing to refuse to approve a new drug application (NDA) submitted by Vanda Pharmaceuticals, Inc. (Vanda), for TRADIPITANT capsules, 85 milligrams (mg), in its present form. This notice summarizes the grounds for the Center Director's proposal and offers Vanda an opportunity to request a hearing on the matter.

DATES: Either electronic or written requests for a hearing must be submitted by February 18, 2025; submit data, information, and analyses in support of the hearing and any other comments by March 17, 2025.

ADDRESSES: You may submit hearing requests, documents in support of the hearing, and any other comments as follows. Please note that late, untimely filed requests and documents will not be considered. The <https://www.regulations.gov> electronic filing system will accept hearing requests until 11:59 p.m. Eastern Time at the end of February 18, 2025, and will accept documents in support of the hearing and any other comments until 11:59 p.m. Eastern Time at the end of March 17, 2025. Documents received by mail/hand delivery/courier (for written/paper submissions) will be considered timely

if they are received on or before these dates.

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-2024-N-5933 for "Proposal To Refuse To Approve a New Drug Application for TRADIPITANT; Opportunity for a Hearing." 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:

Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 202-768-5659, tereza.hess@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Proposal To Refuse To Approve NDA 218489

Vanda submitted NDA 218489 for TRADIPITANT capsules, 85 mg, on September 18, 2023, pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)). Vanda proposed that TRADIPITANT capsules be indicated for "the treatment of [symptoms of] or [nausea in] in gastroparesis."

To support a demonstration of substantial evidence of effectiveness, Vanda referred to two randomized, double-blind, placebo-controlled studies (Study 2301 and Study 3301, Group 1), and the following additional data submitted as confirmatory evidence: (1)

post hoc pooled analyses of Study 2301 and Study 3301, Group 1; (2) an open-label study (Study 3301, Group 2); (3) data from individual patient expanded access uses; and (4) two studies in a different condition (Study 2401 and Study 3401 in motion sickness). Further, Vanda proposed that Study 2301 alone and Study 3301 alone each meet the standard for substantial evidence of effectiveness. To support a demonstration of the safety of TRADIPITANT for the treatment of gastroparesis, Vanda referred to the clinical studies described above and to nonclinical studies, including in vitro studies using new alternative methods, that have been completed.

On September 18, 2024, the Office of Immunology and Inflammation (OII) in CDER issued a complete response letter to Vanda under § 314.110(a) (21 CFR 314.110(a)) stating that NDA 218489 could not be approved in its present form because the application does not provide substantial evidence of effectiveness for TRADIPITANT and does not demonstrate that the drug is safe for the proposed conditions of use. The complete response letter described the specific deficiencies that led to this determination and, where possible, recommended ways that Vanda might remedy these deficiencies. Those deficiencies are summarized below.

1. The following deficiencies in Study 3301, Group 1, and Study 2301 preclude a finding of substantial evidence of effectiveness:

a. The results of Study 3301, Group 1 (a phase 3 study) did not demonstrate a statistically significant difference between TRADIPITANT and placebo for the primary endpoint of the change from baseline to Week 12 in biweekly average nausea severity, nor did they demonstrate a nominally significant difference on nausea severity for any of the 2-week intervals assessed. In addition, there were no nominally significant differences between TRADIPITANT and placebo for the multiplicity-controlled secondary endpoints that assessed individual signs and symptoms of gastroparesis, nor for other clinically relevant endpoints such as nausea-free days. The estimated difference between TRADIPITANT and placebo for these endpoints was generally close to zero, except for the nausea-free days endpoint, which numerically favored placebo at Week 12.

b. The post hoc analyses of the results of Study 3301, Group 1 did not demonstrate a consistent benefit in reduction of nausea nor do they overcome the lack of efficacy observed on the multiple prespecified endpoints

in Study 3301, Group 1. These post hoc analyses were neither controlled for multiplicity nor prespecified in the statistical analysis plan (SAP). The lack of both control for multiplicity and prespecification for the post hoc analyses greatly increases the chance of erroneously concluding a drug has an effect on an outcome when no effect exists, which is especially problematic in the context of a trial that did not demonstrate statistical significance on the primary endpoint and multiplicity-controlled secondary endpoints, such as Study 3301, Group 1.

c. Although the results of Study 2301 (a phase 2 study) demonstrated a statistically significant difference in the primary endpoint of change from baseline to Day 28 (Week 4) in the weekly average of individual daily nausea severity scores, the results were not persuasive because there were methodological shortcomings with the analysis that could bias results (*e.g.*, use of methods not in accordance with those described (or specified) in the SAP) and statistical analyses that addressed these concerns were not robust with respect to missing data assumptions. In addition, although several of the secondary endpoints were reported as having nominally statistically significant results at Day 28 (Week 4), these analyses were not controlled for multiplicity. The secondary efficacy endpoints also had the same methodological shortcomings as the primary efficacy endpoint. Furthermore, these results from Study 2301 were not supported by Study 3301, Group 1 as the latter did not achieve statistical significance on primary and secondary endpoints that were similar to those assessed in Study 2301, including at Week 4.

2. The data submitted as confirmatory evidence are not sufficient to constitute confirmatory evidence of either Study 3301, Group 1 or Study 2301. The post hoc pooled analyses of Study 3301, Group 1 and Study 2301 do not provide independent substantiation of the results of Study 2301; rather, the results of the post hoc analyses are driven by Study 2301. Additionally, the data and analysis provided from open-label sources (*i.e.*, Study 3301 Group 2, and individual patient expanded access use) are limited in their ability to support conclusions related to symptomatic improvement. Further, studies from the ongoing motion sickness program are not appropriate sources of additional efficacy data to provide confirmatory evidence for gastroparesis.

3. The application does not establish that data from either Study 3301, Group 1 or Study 2301 demonstrate substantial

evidence of effectiveness on its own. As noted above, Study 3301, Group 1 did not achieve statistical significance on primary and secondary endpoints that were similar to those assessed in Study 2301, including at Week 4. Study 2301 does not provide substantial evidence of effectiveness as a single adequate and well-controlled trial due to the methodological shortcomings and limitations of the results of the trial.

4. The clinical safety data submitted with the application are inadequate to characterize the safety of TRADIPITANT for treating patients with gastroparesis. The clinical safety database included controlled clinical trial data that were limited to 12 weeks in duration. Additional longer-term safety data are needed, in part, to inform the safe use of the drug because gastroparesis is a chronic condition that necessitates ongoing daily use or recurrent intermittent treatment over months to years in most patients.

5. The nonclinical safety data submitted with the application are inadequate to characterize the safety of TRADIPITANT for treating patients with gastroparesis. The provided in vitro studies along with the provided animal studies did not adequately characterize the long-term safety of TRADIPITANT to inform risk to humans.

These deficiencies preclude a finding that the application provides substantial evidence of effectiveness for TRADIPITANT, and that the application demonstrates that TRADIPITANT is safe, for the proposed conditions of use. The complete response letter stated that to address the deficiencies, OII recommends that Vanda leverage existing data to inform the design of two new adequate and well-controlled trials in adults with idiopathic or diabetic gastroparesis. OII also recommended that Vanda conduct a chronic repeat-dose toxicity study in a nonrodent species, which would support the clinical trials longer than 12 weeks in duration.

The complete response letter stated that Vanda is required either to resubmit the application, fully addressing all deficiencies listed in the letter, or take other actions available under § 314.110 (*i.e.*, withdraw the application or request an opportunity for a hearing).

Following the complete response letter, in a letter dated November 25, 2024, Vanda indicated that it wished to receive approval of its application or a notice of opportunity for a hearing. For the reasons described above, CDER cannot approve the application in its current form; thus, we are providing Vanda with this notice of opportunity for a hearing.

II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in the September 18, 2024, complete response letter, notice is given to Vanda and all other interested persons that the Center Director proposes that FDA issue an order refusing to approve NDA 218489 under section 505(c) of the FD&C Act, on the grounds that the application fails to meet the criteria for approval under section 505(d) of the FD&C Act because there is a lack of substantial evidence that the drug is effective, and the drug has not been shown to be safe, for the proposed conditions of use, including for the proposed indication of “the treatment of [symptoms of] or [nausea in] in gastroparesis” (sections 505(d)(4) and 505(d)(5) of the FD&C Act).¹

Vanda may request a hearing before the Commissioner of Food and Drugs (the Commissioner) on the Center Director’s proposal to refuse to approve NDA 218489. Pursuant to § 314.200(c)(1) (21 CFR 314.200(c)(1)), if Vanda decides to seek a hearing, it must file: (1) a written notice of participation and request for a hearing on or before 30 days after the notice is published in the **Federal Register** and (2) the studies, data, information, and analyses relied upon to justify a hearing, as specified in § 314.200, on or before 60 days after the date the notice is published in the **Federal Register**.

As stated in § 314.200(g), a request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing to resolve. We note in this regard that because CDER proposes to refuse to approve NDA 218489 based on the multiple deficiencies summarized above, any hearing request from Vanda should address all those deficiencies. Failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve NDA 218489.

¹ Section 505(d) of the FD&C Act provides that FDA shall refuse to approve an application if, among other reasons, “upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions” or “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof[.]” Sections 505(d)(4) and 505(d)(5) of the FD&C Act.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest. See § 314.200(g)(6). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16. See 21 CFR 314.201.

Paper submissions under this notice of opportunity for a hearing should be filed in one copy, except for those submitted as “Confidential Submissions” (see “Written/Paper Submissions” and “Instructions” in **ADDRESSES**). Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at <https://www.regulations.gov>. This notice is issued under section 505(c)(1)(B) of the FD&C Act and §§ 314.110(b)(3) and 314.200.

Dated: January 13, 2025.

Patrizia Cavazzoni,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2025–01027 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187]

Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” The draft guidance document provides blood establishments that collect blood and blood components with FDA’s revised recommendations to reduce the risk of transfusion-transmitted malaria (TTM). The guidance recommends selectively testing blood donations from donors at risk for malaria using an FDA-licensed donor screening nucleic acid test (NAT) for *Plasmodium species* (*spp.*), the causative agents of malaria. The draft guidance, when finalized, is intended to supersede the document entitled

“Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria,” dated December 2022.

DATES: Submit either electronic or written comments on the draft guidance by March 17, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2000–D–0187 for “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov>

or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” This guidance document provides blood establishments that collect blood and blood components with FDA’s revised recommendations to reduce the risk of TTM. Specifically, the guidance recommends selectively testing blood donations from donors at risk for malaria using an FDA-licensed donor screening NAT for *Plasmodium species* (*spp.*), the causative agents of malaria.

The recommendations contained in this draft guidance apply to the collection of Whole Blood and blood components, except Source Plasma. We do not require blood establishments to screen Source Plasma donors for malaria risk factors because Source Plasma undergoes further manufacturing steps to effectively remove or inactivate pathogens such as *Plasmodia spp.* (see 21 CFR 630.15(b)(8)). Licensed plasma derivatives manufactured from Source Plasma have not transmitted malaria.

The draft guidance, when finalized, is intended to supersede the document entitled “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria,” dated December 2022.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338;

and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01028 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NCATS RDCRC Grant Application Review.

Date: February 3–5, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Suite 1E504, Bethesda, MD 20892, (301) 435–0810, lourdes.ponce@nih.gov.

Name of Committee: National Center for Advancing Translational Sciences Special

Emphasis Panel; RDCRN Research Consortia B.

Date: February 5–7, 2025.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Suite 1E504, Bethesda, MD 20892, (301) 451-2405, henriquv@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 10, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00980 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Suicide Prevention in Crisis Response and LMIC Across the Lifespan.

Date: February 14, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of

Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, 301-500-5829, email: serena.chu@nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Precision Mental Health: Develop Tools to Inform Treatment Selection in Depression.

Date: February 18, 2025.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, (240) 796-6785, email: regina.dolan-sewell@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 10, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00857 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 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 contract proposals 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 and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; PLCO U01 SEP Review Meeting.

Date: February 12, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Shakeel Ahmad, Ph.D., Branch Chief, Research Technology and Contract Review, Branch Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850, 240-276-6442, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP-7: SBIR Contract Review Meeting (Review of SBIR Topics 431 and 439).

Date: February 20, 2025.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W254, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Susan Lynn Spence, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Rockville, Maryland 20850, 240-620-0819, susan.spence@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-9: NCI Clinical and Translational Cancer Research.

Date: February 27, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W542, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Biman Chandra Paria, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W542, Rockville, Maryland 20850, 240-858-3814, pariab@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award (R50) Clinician Scientist.

Date: March 11–12, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W526, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Viktoriya Sidorenko, Ph.D., Scientific Review Officer, Program and Review Extramural Staff Training Office, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W526, Rockville, Maryland 20850, 240-276-5073, viktoriya.sidorenko@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SEP: The Confluence of Cancer Stigma and HIV Stigma in HIV-positive Individuals (R01 and R21).

Date: March 20, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850.

Meeting Format: Virtual Meeting.

Contact Person: Ryan Gleason, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240-276-7329, ryan.gleason@nih.gov.

(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: January 10, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00977 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, TEP 2B: SBIR Review Meeting, February 25, 2025, 11 a.m. to 3 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W534, Rockville, Maryland, 20850 which was published in the **Federal Register** on December 26, 2024, FR Doc 2024-30711, 89 FR 105062.

This notice is being amended to change the virtual meeting date from February 25, 2025, 11 a.m. to 3 p.m. to March 13, 2025, 11 a.m. to 3 p.m. The meeting times, format, and location will stay the same. The meeting is closed to the public.

Dated: January 10, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00979 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with title 41 of the U.S. Code of Federal Regulations, section 102-3.65(a), notice is hereby given that the charter for the National Toxicology Program Special Emphasis Panel was renewed for an additional two-year period on January 7, 2025.

It is determined that the National Toxicology Program Special Emphasis Panel, is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or harriscl@mail.nih.gov.

Dated: January 13, 2025.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-01053 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, TEP 2A: SBIR Review Meeting, February 24, 2025, 11 a.m. to 3 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W534, Rockville, Maryland 20850 which was published in the **Federal Register** on December 26, 2024, FR Doc 2024-30711, 89 FR 105062.

This notice is being amended to change the virtual meeting date from February 24, 2025, 11 a.m. to 3 p.m. to March 10, 2025, 11 a.m. to 3 p.m. The meeting times, format, and location will stay the same. The meeting is closed to the public.

Dated: January 10, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00978 Filed 1-15-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2025-0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at <https://msc.fema.gov>.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed

since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being

already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the

floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Arizona:					
Gila (FEMA Docket No.: B-2476).	City of Globe (23-09-1282P).	The Honorable Al Gameros, Mayor, City of Globe, 150 North Pine Street, Globe, AZ 85501.	City Hall, 150 North Pine Street, Globe, AZ 85501.	Dec. 12, 2024	040029
Gila (FEMA Docket No.: B-2476).	Unincorporated areas of Gila County (23-09-1282P).	Steve Christensen, Chair, Gila County, Board of Supervisors, 1400 East Ash Street, Globe, AZ 85501.	Gila County, Assessor's Office, 1400 East Ash Street, Globe, AZ 85501.	Dec. 12, 2024	040028
Maricopa (FEMA Docket No.: B-2476).	City of Buckeye (24-09-0106P).	The Honorable Eric Orsborn, Mayor, City of Buckeye, 530 East Monroe Avenue, Buckeye, AZ 85326.	Engineering Department, 530 East Monroe Avenue, Buckeye, AZ 85326.	Nov. 22, 2024	040039
Maricopa (FEMA Docket No.: B-2474).	City of Goodyear (23-09-0729P).	The Honorable Joe Pizzillo, Mayor, City of Goodyear, 1900 North Civic Square, Goodyear, AZ 85395.	Engineering and Development Services, 14455 West Van Buren Street, Suite D101, Goodyear, AZ 85338.	Nov. 29, 2024	040046
Maricopa (FEMA Docket No.: B-2474).	City of Peoria (23-09-1280P).	The Honorable Jason Beck, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	City Hall, 8401 West Monroe Street, Peoria, AZ 85345.	Nov. 29, 2024	040050
Maricopa (FEMA Docket No.: B-2476).	City of Scottsdale (23-09-1134P).	The Honorable David D. Ortega, Mayor, City of Scottsdale, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	Planning Records, 7447 East Indian School Road, Suite 100, Scottsdale, AZ 85251.	Nov. 22, 2024	045012
Maricopa (FEMA Docket No.: B-2476).	City of Scottsdale (23-09-1358P).	The Honorable David D. Ortega, Mayor, City of Scottsdale, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	Planning Records, 7447 East Indian School Road, Suite 100, Scottsdale, AZ 85251.	Nov. 22, 2024	045012
Maricopa (FEMA Docket No.: B-2474).	City of Surprise (24-09-0009P).	The Honorable, Skip Hall, Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85374.	Public Works Department, Engineering Department Services, 16000 North Civic Center Plaza, Surprise, AZ 85374.	Dec. 6, 2024	040053
Maricopa (FEMA Docket No.: B-2474).	Unincorporated areas of Maricopa County (22-09-1095P).	Jack Sellers, Chair, Maricopa County Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	Nov. 29, 2024	040037
Maricopa (FEMA Docket No.: B-2474).	Unincorporated areas of Maricopa County (23-09-1280P).	Jack Sellers, Chair, Maricopa County Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	Nov. 29, 2024	040037
Maricopa (FEMA Docket No.: B-2474).	Unincorporated areas of Maricopa County (24-09-0009P).	Jack Sellers, Chair, Maricopa County Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	Dec. 6, 2024	040037
Maricopa (FEMA Docket No.: B-2476).	Unincorporated areas of Maricopa County (24-09-0106P).	Jack Sellers, Chair, Maricopa County Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	Nov. 22, 2024	040037
Mohave (FEMA Docket No.: B-2476).	City of Bullhead City (24-09-0373P).	The Honorable Steve D'Amico, Mayor, City of Bullhead City, 2355 Trane Road, Bullhead City, AZ 86442.	Public Works Department, 2355 Trane Road, Bullhead City, AZ 86442.	Nov. 25, 2024	040125
Yavapai (FEMA Docket No.: B-2474).	City of Cottonwood (22-09-0848P).	The Honorable Tim Elinski, Mayor, City of Cottonwood, 827 North Main Street, Cottonwood, AZ 86326.	Public Works Department, 1490 West Mingus Avenue, Cottonwood, AZ 86326.	Nov. 29, 2024	040096
Yavapai (FEMA Docket No.: B-2474).	Town of Clarkdale (22-09-0848P).	The Honorable Robyn Prud'Homme-Bauer, Mayor, Town of Clarkdale, 39 North 9th Street, Clarkdale, AZ 86324.	Public Works Department, 890 Main Street, Clarkdale, AZ 86324.	Nov. 29, 2024	040095

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Yavapai (FEMA Docket No.: B-2474).	Unincorporated areas of Yavapai County (22-09-0848P).	Craig L. Brown, Chair, Yavapai County, Board of Supervisors, 10 South 6th Street, Cottonwood, AZ 86326.	Yavapai County Flood Control District, 1120 Commerce Drive, Prescott, AZ 86305.	Nov. 29, 2024	040093
California:					
Alameda (FEMA Docket No.: B-2476).	City of Alameda (23-09-1261P).	The Honorable Marilyn Ezzy Ashcraft, Mayor, City of Alameda, 2263 Santa Clara Avenue, Alameda, CA 94501.	Public Works Department, 950 West Mall Square, Suite 110, Alameda, CA 94501.	Nov. 20, 2024	060002
Riverside (FEMA Docket No.: B-2474).	City of Perris (24-09-0210P).	The Honorable Michael Vargas, Mayor, City of Perris, 101 North D Street, Perris, CA 92570.	Engineering Department, 24 South D Street, Suite 100, Perris, CA 92570.	Dec. 9, 2024	060258
Riverside (FEMA Docket No.: B-2474).	Unincorporated areas of Riverside County (24-09-0210P).	Chuck Washington, Chair, Riverside County Board of Supervisors, 4080 Lemon Street, 5th Floor, Riverside, CA 92501.	Riverside County, Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.	Dec. 9, 2024	060245
Connecticut: Fairfield (FEMA Docket No.: B-2476).	City of Danbury (23-01-0686P).	The Honorable Roberto Alves, Mayor, City of Danbury, 155 Deer Hill Avenue, Danbury, CT 06810.	City Hall, 155 Deer Hill Avenue, Danbury, CT 06810.	Nov. 20, 2024	090004
Florida:					
St. Johns (FEMA Docket No.: B-2476).	Unincorporated areas of St. Johns County (24-04-0172P).	Joy Andrews, St. Johns County Administrator, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County Permit Center, 4040 Lewis Speedway, St. Augustine, FL 32084.	Dec. 2, 2024	125147
Orange (FEMA Docket No.: B-2476).	City of Orlando (24-04-1166P).	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32801.	Permitting Services, 400 South Orange Avenue, 1st Floor, Orlando, FL 32801.	Dec. 3, 2024	120186
Walton (FEMA Docket No.: B-2476).	Unincorporated areas of Walton County (24-04-1098P).	Stan Sunday, Walton County Administrator, 76 North 6th Street, DeFuniak Springs, FL 32433.	Walton County Courthouse, 571 U.S. Highway 90 East, DeFuniak Springs, FL 32433.	Nov. 21, 2024	120317
Idaho: Lemhi (FEMA Docket No.: B-2474).	City of Salmon (23-10-0431P).	The Honorable Todd Nelson, Mayor, City of Salmon, 200 Main Street, Salmon, ID 83467.	City Hall, 200 Main Street, Salmon, ID 83467.	Dec. 13, 2024	160093
Indiana:					
Boone (FEMA Docket No.: B-2474).	Town of Zionsville (22-05-2053P).	The Honorable John Stehr, Mayor, Town of Zionsville, 1100 West Oak Street, Zionsville, IN 46077.	Planning Department, 1100 West Oak Street, Zionsville, IN 46077.	Nov. 27, 2024	180016
Hamilton (FEMA Docket No.: B-2474).	City of Carmel (22-05-2053P).	The Honorable Sue Finkam, Mayor, City of Carmel, 1 Civic Square, Carmel, IN 46032.	Department of Community Services, 1 Civic Square, Carmel, IN 46032.	Nov. 27, 2024	180081
Hamilton (FEMA Docket No.: B-2474).	City of Westfield (22-05-2053P).	The Honorable Scott Willis, Mayor, City of Westfield, 2728 East 171st Street, Westfield, IN 46074.	City Hall, 130 Penn Street, Westfield, IN 46074.	Nov. 27, 2024	180083
Hamilton (FEMA Docket No.: B-2474).	Unincorporated areas of Hamilton County (22-05-2053P).	Mark Heirbrandt, President, Hamilton County Board of Commissioners, 1 Hamilton County Square, Suite 157, Noblesville, IN 46060.	Hamilton County, Planning Commission, 1 Hamilton County Square, Noblesville, IN 46060.	Nov. 27, 2024	180080
Kansas: Johnson (FEMA Docket No.: B-2476).	City of Olathe (23-07-0892P).	The Honorable John Bacon, Mayor, City of Olathe, 100 East Santa Fe Street, Olathe, KS 66061.	Planning Office, 100 East Santa Fe Street, Olathe, KS 66061.	Nov. 27, 2024	200173
Minnesota: Le Sueur (FEMA Docket No.: B-2476).	Unincorporated areas of Le Sueur County (24-05-0739P).	Steven J. Rohlfing, Chair, Le Sueur County Board of Commissioners, 28020 Maple Lane, Madison Lake, MN 56063.	Le Sueur County Environmental Services Department, 515 South Maple Avenue, Le Center, MN 56057.	Nov. 29, 2024	270246
Missouri: St. Louis (FEMA Docket No.: B-2476).	City of University City (24-07-0245P).	The Honorable Terry Crow, Mayor, City of University City, 6801 Delmar Boulevard, University City, MO 63130.	City Hall, 6801 Delmar Boulevard, University City, MO 63130.	Nov. 29, 2024	290390
Nevada:					
Washoe (FEMA Docket No.: B-2474).	City of Reno (24-09-0149P).	The Honorable Hillary Schieve, Mayor, City of Reno, P.O. Box 1900, Reno, NV 89505.	City Hall, 1 East 1st Street, Reno, NV 89501.	Dec. 3, 2024	320020
Washoe (FEMA Docket No.: B-2474).	Unincorporated areas of Washoe County (24-09-0149P).	Alexis Hill, Chair, Washoe County, Board of Commissioners, 1001 East 9th Street Building A, Reno, NV 89512.	Washoe County Administration Building, Department of Public Works, 1001 East 9th Street, Reno, NV 89512.	Dec. 3, 2024	320019
Oregon:					
Washington (FEMA Docket No.: B-2476).	City of Beaverton (24-10-0181P).	The Honorable Lacey Beaty, Mayor, City of Beaverton, 12725 Southwest Millikan Way, Beaverton, OR 97005.	Community Development Department, 12725 Southwest Millikan Way, Beaverton, OR 97005.	Nov. 22, 2024	410240
Washington (FEMA Docket No.: B-2476).	Unincorporated areas of Washington County (24-10-0181P).	Kathryn Harrington, Commissioner, Washington County Board of Commissioners, 155 North 1st Avenue, Hillsboro, OR 97124.	Washington County Public Services Building, 155 North 1st Avenue, Suite 350, Hillsboro, OR 97124.	Nov. 22, 2024	410238
Washington: King (FEMA Docket No.: B-2476).	City of Seattle (22-10-0801P).	The Honorable Bruce Harrell, Mayor, City of Seattle, P.O. Box 94749, Seattle, WA 98124.	Department of Construction and Inspections, 700 5th Avenue, Suite 2000, Seattle, WA 98104.	Nov. 25, 2024	530089

[FR Doc. 2025-01025 Filed 1-15-25; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID FEMA-2025-0002; Internal Agency Docket No. FEMA-B-2500]

Proposed Flood Hazard Determinations**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.**ACTION:** Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before April 16, 2025.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://hazards.fema.gov/femaportal/prelimdownload> and the respective

Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA-B-2500, to Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the

revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/srp_overview.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location <https://hazards.fema.gov/femaportal/prelimdownload> and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Van Buren County, Michigan (All Jurisdictions)	
PROJECT: 23-05-0012S PRELIMINARY DATE: JANUARY 31, 2024	
Township of Decatur	Township Hall, 103 E Delaware Street, Decatur, MI 49045.
Township of Hamilton	Hamilton Township Hall, 52333 Territorial Road W, Decatur, MI 49045.
Township of Keeler	Keeler Township Hall, 64121 Territorial Road W, Hartford, MI 49057.
Township of Lawrence	Township Hall, 411 N Paw Paw Street, Lawrence, MI 49064.
Township of Paw Paw	Township Hall, 114 N Gremps Street, Paw Paw, MI 49079.
Township of Porter	Porter Township Hall, 88040 M-40 Highway, Lawton, MI 49065.
Township of Waverly	Waverly Township Hall, 42114 M-43 Highway, Paw Paw, MI 49079.
Village of Decatur	Village Hall, 114 N Phelps Street, Decatur, MI 49045.

[FR Doc. 2025-01026 Filed 1-15-25; 8:45 am]

BILLING CODE 9110-12-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency****[Docket ID FEMA-2025-0002; Internal
Agency Docket No. FEMA-B-2444]****Proposed Flood Hazard
Determinations; Correction****AGENCY:** Federal Emergency
Management Agency; Department of
Homeland Security.**ACTION:** Notice; correction.

SUMMARY: On July 15, 2024, FEMA published in the **Federal Register** a proposed flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table to be used in lieu of the erroneous information. The table provided here represents the proposed flood hazard determinations and communities affected for Nelson County, Kentucky and Incorporated Areas.

DATES: Comments are to be submitted on or before April 16, 2025.

ADDRESSES: The Preliminary Flood Insurance Rate Map (FIRM), and where applicable, the Flood Insurance Study (FIS) report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA-B-2444, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed in the table below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to

review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP may only be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://floodsrp.org/pdfs/srp_fact_sheet.pdf.

The communities affected by the flood hazard determinations are provided in the table below. Any request for reconsideration of the revised flood hazard determinations shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations will also be considered before the FIRM and FIS report are made final.

Correction

In the proposed flood hazard determination notice published at 89 FR 57426 in the July 15, 2024, issue of the **Federal Register**, FEMA published a table titled “Nelson County, Kentucky and Incorporated Areas”. This table contained inaccurate information on the eligible communities featured in the table. In this document, FEMA is publishing a table containing the accurate information. The information provided below should be used in lieu of that previously published.

(Catalog of Federal Domestic Assistance No. 97.022, “Flood Insurance.”)

Nicholas A. Shufro,

*Assistant Administrator (Acting) for Risk
Management, Federal Emergency
Management Agency, Department of
Homeland Security.*

Community	Community map repository address
Nelson County, Kentucky and Incorporated Areas Project: 22-04-0013S Preliminary Date: March 27, 2024	
City of Bloomfield	Nelson County Joint City-County Planning Commission, 129 Parkway Drive, Bardstown, KY 40004.
Unincorporated Areas of Nelson County	Nelson County Joint City-County Planning Commission, 129 Parkway Drive, Bardstown, KY 40004.

[FR Doc. 2025-01023 Filed 1-15-25; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****[Docket ID FEMA-2025-0002]****Final Flood Hazard Determinations**

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of May 6, 2025 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at <https://msc.fema.gov> by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in

newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
St. Mary's County, Maryland and Incorporated Areas Docket No.: FEMA-B-2345	
Town of Leonardtown	Town Hall, 22670 Washington Street, Leonardtown, MD 20650.
Unincorporated Areas of St. Mary's County	St. Mary's County Department of Land Use and Growth Management, 23150 Leonard Hall Drive, Leonardtown, MD 20650.
Logan County, North Dakota and Incorporated Areas Docket No.: FEMA-B-2356	
City of Napoleon	City Hall, 225 Lake Avenue W, Napoleon, ND 58561.
Unincorporated Areas of Logan County	Logan County Courthouse, 301 Broadway Street, Napoleon, ND 58561.
Davison County, South Dakota and Incorporated Areas Docket No.: FEMA-B-2396	
City of Mitchell	City Hall, 612 North Main Street, Mitchell, SD 57301.
City of Mount Vernon	Davison County Emergency Management, 200 East 4th Avenue, Mitchell, SD 57301.
Town of Ethan	Town Office, 201 West Main Street, Ethan, SD 57334.
Unincorporated Areas of Davison County	Davison County Emergency Management, 200 East 4th Avenue, Mitchell, SD 57301.
Lunenburg County, Virginia and Incorporated Areas Docket No.: FEMA-B-2392	
Unincorporated Areas of Lunenburg County	Lunenburg County Administration Office, 11413 Courthouse Road, Lunenburg, VA 23952.

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID: FEMA 2024–0037; OMB No. 1660–0011]

Agency Information Collection**Activities: Proposed Collection; Comment Request; Debt Collection Financial Statement**

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of extension and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information related to disaster program accounts and debts owed to FEMA by individuals.

DATES: Comments must be submitted on or before March 17, 2025.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at <https://www.regulations.gov> under Docket ID FEMA–2024–0037. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <https://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Andrew McCormick, Section Chief, Accounts Receivable, FEMA Finance Center, (540) 532–7501, drew.mccormick@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: Under the Debt Collection Act as amended (31 U.S.C. 3701, *et seq.*), the Federal Claims

Collection Standards (31 CFR parts 900 through 904), and the Department of Homeland Security (DHS) regulations (6 CFR part 11), the Administrator of the Federal Emergency Management Agency (FEMA) is: (1) required to attempt collection of all debts owed to the United States arising out of activities of FEMA; and (2) for debts not exceeding \$100,000, authorized to compromise such debts or terminate collection action completely where it appears that no person is liable for such debt or has the present or prospective financial ability to pay a significant sum or that the cost of collecting such debt is likely to exceed the amount of the recovery (31 U.S.C. 3711(a)(2)). This information collection expired on June 30, 2025. FEMA is requesting an extension, without change, of a previously approved information collection for which approval has expired.

Collection of Information

Title: Debt Collection Financial Statement.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0011.

FEMA Forms: Debt Collection Financial Statement, FEMA Form FF–600–FY–22–102 (formerly 127–0–1).

Abstract: FEMA Form FF–600–FY–22–102 (formerly 127–0–1) is used to collect information provided voluntarily by the debtor to evaluate the debtor's financial abilities to determine if they qualify for a payment plan and set repayment terms, or determine a compromise to write-off a debt in part or in full. Financial information obtained is essential to evaluate the debtor's ability for the payment of the debt in part or in full. Debt may be a recoupment of an ineligible disaster assistance payment or improper payment to an employee.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 140.

Estimated Number of Responses: 140.

Estimated Total Annual Burden

Hours: 105.

Estimated Total Annual Respondent

Cost: \$4,793.

Estimated Respondents' Operation

and Maintenance Costs: \$0.

Estimated Respondents' Capital and Start-Up Costs: \$0.

Estimated Total Annual Cost to the Federal Government: \$23,363.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption

above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Maile Rasco-Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2025–00999 Filed 1–15–25; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6512–N–01]

Allocations for Community Development Block Grant Disaster Recovery and Implementation of the CDBG–DR Consolidated Waivers and Alternative Requirements Notice (UN AAN)

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Allocation Announcement Notice announces \$12,070,701,000 of Community Development Block Grant—Disaster Recovery (CDBG–DR) funds made available by the Disaster Relief Supplemental Appropriations Act, 2025, for major disasters occurring in 2023 or 2024. This Allocation Announcement Notice identifies grant requirements for these funds, including requirements in HUD's CDBG–DR Universal Notice (“Universal Notice”) published in the **Federal Register**. The Universal Notice includes waivers and alternative requirements, relevant regulatory requirements, the grant award process, criteria for action plan approval, and eligible disaster recovery activities.

DATES: *Applicability Date:* January 21, 2025.

FOR FURTHER INFORMATION CONTACT: Tennille Smith Parker, Director, Office of Disaster Recovery, Department of Housing and Urban Development, 451 7th Street SW, Room 7282, Washington, DC 20410, telephone number 202–708–3587 (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>. Facsimile inquiries may be sent to Ms. Parker at 202–708–0033 (this is not a toll-free number). Email inquiries may be sent to disaster_recovery@hud.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Allocations
- II. Use of Funds
- III. Overview of Grant Process
- IV. Applicable Rules, Statutes, Waivers, and Alternative Requirements
- V. Duration of Funding
- VI. Assistance Listing Numbers (formerly known as the CFDA Number)
- VII. Finding of No Significant Impact
- Appendix A: Allocation Methodology

I. Allocations

The Disaster Relief Supplemental Appropriations Act, 2025 (Pub. L. 118–158) (“the 2025 Appropriations Act”), approved on December 21, 2024, makes available \$12,039,000,000 in new CDBG–DR funds. The 2025 Appropriations Act also provides that HUD allocate any unobligated no-year balances remaining from Public Laws 108–324, 109–148, 109–234, 110–252, 110–329, 111–212, 112–55, and 113–2 (the “Prior Appropriations Acts”) for the same purposes as these new funds. The sum of all unobligated balances from these Prior Appropriations Acts is

\$31,701,000. This brings the total funding available for 2023 or 2024 disasters to \$12,070,701,000.

These CDBG–DR funds are for necessary expenses for activities authorized under title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*) (HCDA) related to disaster relief, long-term recovery, restoration of infrastructure and housing, economic revitalization, and mitigation in the “most impacted and distressed” (MID) areas resulting from a qualifying major disaster that occurred in 2023 or 2024. The 2025 Appropriations Act provides that \$78,850,000 of these amounts will be made available for these specific purposes: \$45,000,000 for salaries and expenses of the Office of Community Planning and Development, \$1,850,000 for HUD’s disaster recovery portal, \$7,000,000 for the Office of Inspector General, and \$25,000,000 for capacity building and technical assistance, leaving the remaining \$11,991,851,000 available for allocations to CDBG–DR grantees.

Of the \$11,991,851,000 made available, this notice announces \$11,889,437,000 in CDBG–DR allocations for disasters occurring in 2023 or 2024. HUD will allocate the remaining \$102,414,000 of available funds under a separate Allocation Announcement Notice that provides plus-up funding for disasters that occurred in January 2023 for which HUD previously allocated funding in a **Federal Register** notice published on November 27, 2023 at 88 FR 82982.

The 2025 Appropriations Act requires HUD to include with any final allocation for the total estimate of unmet need an additional 15 percent of that estimate for additional mitigation activities that reduce risk in the MID areas (see table 1). The 2025 Appropriations Act provides that grants shall be awarded directly to a State, unit

of general local government, or Indian Tribe at the discretion of the Secretary.

Pursuant to the 2025 Appropriations Act, HUD has identified MID areas based on the best available data for all eligible affected areas. A detailed explanation of HUD’s allocation methodology is provided in appendix A of this notice. To comply with requirements that all funds are expended in MID areas, Little Rock, AR; Broward County, FL; Ft. Lauderdale, FL; Hillsborough County, FL; Lee County, FL; Manatee County, FL; Orange County, FL; Pasco County, FL; Pinellas County, FL; St. Petersburg, FL; Sarasota County, FL; Volusia County, FL; Guam; Maui County, HI; Chicago, IL; Cicero, IL; Cook County, IL; St. Clair County, IL; Detroit, MI; Wayne County, MI; Asheville, NC; Harris County, TX; Houston, TX; and Spokane County, WA must use 100 percent of the total funds allocated to address unmet disaster needs and mitigation activities that benefit the HUD-identified MID areas identified in the last column in table 2.

All other grantees must use at least 80 percent of their allocations to address unmet disaster needs or mitigation activities that benefit the HUD-identified MID areas, as identified in the last column of table 2. These grantees may use the remaining 20 percent of their allocation to address unmet disaster needs or mitigation activities in those areas that the grantee determines are “most impacted and distressed” within an area that received a Presidential major disaster declaration (*i.e.*, grantee-identified MID areas) identified by the Federal Emergency Management Agency (FEMA) disaster numbers listed in column two of table 1. However, these grantees are not precluded from spending 100 percent of their allocation to benefit the HUD-identified MID areas if they choose to do so. Detailed requirements related to MID areas are provided in section III.D.2 of the Universal Notice.

TABLE 1—ALLOCATIONS FOR UNMET NEEDS AND MITIGATION ACTIVITIES UNDER PUBLIC LAW 118–158 FOR DISASTERS OCCURRING IN 2023 AND 2024

Year	FEMA Disaster No.	State	Grantee	Allocations for unmet needs under this notice from Public Law 118–158	CDBG–DR mitigation set-aside for amounts under this notice from Public Law 118–158	Total allocated under this notice from Public Law 118–158
2023 & 2024	4730; 4836	AK	State of Alaska	\$16,240,000	\$2,436,000	\$18,676,000
2023	4698; 4788	AR	State of Arkansas	51,346,000	7,702,000	59,048,000
2024	4698	AR	Little Rock, AR	18,170,000	2,725,000	20,895,000
2023 & 2024	4699; 4707; 4758	CA	State of California	362,258,000	54,339,000	416,597,000
2024 & 2024	4734; 4794; 4806; 4828; 4834	FL	State of Florida	804,690,000	120,704,000	925,394,000
2023	4709	FL	Broward County	25,410,000	3,812,000	29,222,000
2023	4709	FL	Ft Lauderdale, FL	76,566,000	11,485,000	88,051,000
2024	4828; 4834	FL	Hillsborough County	616,803,000	92,521,000	709,324,000
2024	4828; 4834	FL	Lee County	87,550,000	13,133,000	100,683,000

TABLE 1—ALLOCATIONS FOR UNMET NEEDS AND MITIGATION ACTIVITIES UNDER PUBLIC LAW 118–158 FOR DISASTERS OCCURRING IN 2023 AND 2024—Continued

Year	FEMA Disaster No.	State	Grantee	Allocations for unmet needs under this notice from Public Law 118–158	CDBG–DR mitigation set-aside for amounts under this notice from Public Law 118–158	Total allocated under this notice from Public Law 118–158
2024	4806; 4828; 4834	FL	Manatee County	219,749,000	32,962,000	252,711,000
2024	4834	FL	Orange County	29,006,000	4,351,000	33,357,000
2023 & 2024	4734; 4828; 4834	FL	Pasco County	509,308,000	76,396,000	585,704,000
2023 & 2024	4734; 4828; 4834	FL	Pinellas County	707,637,000	106,146,000	813,783,000
2023 & 2024	4734; 4828	FL	St. Petersburg, FL	139,030,000	20,854,000	159,884,000
2024	4806; 4828; 4834	FL	Sarasota County	182,690,000	27,404,000	210,094,000
2024	4834	FL	Volusia County	116,100,000	17,415,000	133,515,000
2023 & 2024	4738; 4821; 4830	GA	State of Georgia	231,066,000	34,660,000	265,726,000
2023	4715	GU	Guam	435,500,000	65,325,000	500,825,000
2023	4724	HI	Maui County	1,425,549,000	213,832,000	1,639,381,000
2024	4796	IA	State of Iowa	117,119,000	17,568,000	134,687,000
2023 & 2024	4728; 4749; 4819	IL	Chicago, IL	370,963,000	55,645,000	426,608,000
2023 & 2024	4728; 4749; 4819	IL	Cicero, IL	83,482,000	12,522,000	96,004,000
2023 & 2024	4728; 4749; 4819	IL	Cook County	212,315,000	31,847,000	244,162,000
2024	4819	IL	St. Clair County	77,855,000	11,678,000	89,533,000
2023	4704	IN	State of Indiana	6,663,000	1,000,000	7,663,000
2024	4817	LA	State of Louisiana	102,562,000	15,384,000	117,946,000
2024	4780	MA	State of Massachusetts	6,917,000	1,037,000	7,954,000
2024	4757	MI	State of Michigan	37,887,000	5,683,000	43,570,000
2024	4757	MI	Detroit, MI	301,621,000	45,243,000	346,864,000
2024	4757	MI	Wayne County	61,202,000	9,180,000	70,382,000
2023 & 2024	4697; 4727; 4790	MS	State of Mississippi	117,350,000	17,603,000	134,953,000
2024	4827	NC	State of North Carolina	1,241,843,000	186,277,000	1,428,120,000
2024	4827	NC	Ashville, NC	195,661,000	29,349,000	225,010,000
2024	4795; 4843	NM	State of New Mexico	119,285,000	17,893,000	137,178,000
2024	4777	OH	State of Ohio	12,275,000	1,841,000	14,116,000
2023 & 2024	4706; 4776	OK	State of Oklahoma	34,265,000	5,140,000	39,405,000
2024	4815	PA	State of Pennsylvania	12,713,000	1,907,000	14,620,000
2024	4829	SC	State of South Carolina	130,743,000	19,611,000	150,354,000
2024	4807	SD	State of South Dakota	13,370,000	2,005,000	15,375,000
2023 & 2024	4751; 4832	TN	State of Tennessee	74,555,000	11,183,000	85,738,000
2024	4781; 4798	TX	State of Texas	483,206,000	72,481,000	555,687,000
2024	4781; 4798	TX	Harris County	58,544,000	8,782,000	67,326,000
2024	4781; 4798	TX	Houston, TX	273,604,000	41,041,000	314,645,000
2024	4831	VA	State of Virginia	40,583,000	6,087,000	46,670,000
2023	4720	VT	State of Vermont	58,996,000	8,849,000	67,845,000
2024	4759	WA	Spokane County	38,393,000	5,759,000	44,152,000
Totals				10,338,640,000	1,550,797,000	11,889,437,000

TABLE 2—MOST IMPACTED AND DISTRESSED AREAS FOR DISASTERS OCCURRING IN 2023 AND 2024

Grantee	Minimum amount from Public Law 118–158 that must be expended in the HUD-identified “most impacted and distressed areas” in column 3	“Most impacted and distressed areas”
State of Alaska	\$14,940,800	Juneau (Borough) (ZIP code 99801); Lower Yukon Regional Education (ZIP code 99554).
State of Arkansas	47,238,400	Benton (County) (ZIP code 72756); Cross (County); Pulaski County).
Little Rock, AR	20,895,000	Little Rock.
State of California	333,277,600	Hoopa Valley Indian Reservation (ZIP code 95546); Merced (County); Monterey (County); San Benito (County) (ZIP code 95023); San Diego (County); San Joaquin (County) (ZIP code 95220); San Luis Obispo (County); Santa Cruz (County); Santa Cruz (County); Tulare (County); Tuolumne (County) (ZIP code 95370); Ventura (County).
State of Florida	740,315,200	Charlotte (County); Charlotte (County); Citrus (County); Collier (County) (ZIP code 34112); Columbia (County) (ZIP code 32055); DeSoto (County) (ZIP code 34266); Dixie (County); Duval (County) (ZIP code 32209); Hamilton (County) (ZIP codes 32052, 32053); Hernando (County) (ZIP code 34607); Highlands (County) (ZIP code 33870); Indian River (County) (ZIP code 32960); Lafayette (County) (ZIP code 32066); Lake (County); Leon (County); Levy (County) (ZIP codes 32625, 34498); Madison (County) (ZIP code 32340); Polk (County); Seminole (County) (ZIP code 32771); St. Lucie (County); Sumter (County) (ZIP codes 33597, 34785); Suwannee (County) (ZIP code 32060, 32064); Taylor (County).
Broward County, FL	29,222,000	Broward County.
Ft. Lauderdale, FL	88,051,000	Ft. Lauderdale.
Hillsborough County, FL	709,324,000	Hillsborough County.
Lee County, FL	100,683,000	Lee County.
Manatee County, FL	252,711,000	Manatee County.
Orange County, FL	33,357,000	Orange County.
Pasco County, FL	585,704,000	Pasco County.
Pinellas County, FL	813,783,000	Pinellas County.
St. Petersburg, FL	159,884,000	St. Petersburg.
Sarasota County, FL	210,094,000	Sarasota County.

TABLE 2—MOST IMPACTED AND DISTRESSED AREAS FOR DISASTERS OCCURRING IN 2023 AND 2024—Continued

Grantee	Minimum amount from Public Law 118–158 that must be expended in the HUD-identified “most impacted and distressed areas” in column 3	“Most impacted and distressed areas”
Volusia County, FL	133,515,000	Volusia County.
State of Georgia	212,580,800	Appling (County) (ZIP code 31513); Atkinson (County) (ZIP code 31642); Bacon (County) (ZIP code 31510); Berrien (County) (ZIP code 31639); Bryan (County) (ZIP code 31324); Burke (County); Candler (County) (ZIP code 30439); Clinch (County) (ZIP code 31634); Coffee (County); Columbia (County); Emanuel (County) (ZIP code 30401); Jeff Davis (County) (ZIP code 31539); Lanier (County) (ZIP code 31635); Laurens (County) (ZIP code 31021); Lowndes (County); Lowndes (County) (ZIP code 31601); McDuffie (County) (ZIP code 30824); Richmond (County); Spalding (County) (ZIP code 30223); Toombs (County) (ZIP codes 30436, 30474); Treutlen (County) (ZIP code 30457); Wheeler (County) (ZIP code 30428).
Guam	500,825,000	Guam (County-equivalent).
Maui County	1,639,381,000	Maui (County).
State of Iowa	107,749,600	Cherokee (County) (ZIP code 51012); Clay (County); Sioux (County); Woodbury (County) (ZIP code 51109).
Chicago, IL	426,608,000	Chicago.
Cicero, IL	96,004,000	Cicero.
Cook County	244,162,000	Cook County.
St. Clair County	89,533,000	St. Clair County.
State of Indiana	6,130,400	Sullivan (County) (ZIP code 47882).
State of Louisiana	94,356,800	Ascension (Parish) (ZIP code 70346); Assumption (Parish) (ZIP codes 70341, 70390); Jefferson (Parish); Lafourche (Parish); St. John the Baptist (Parish) (ZIP codes 70068, 70084); St. Mary (Parish); Terrebonne (Parish).
State of Massachusetts	6,363,200	Worcester (County) (ZIP code 01453).
State of Michigan	34,856,000	Macomb (County); Monroe (County) (ZIP code 48166); Oakland (County).
Detroit, MI	346,864,000	Detroit.
Wayne County	70,382,000	Wayne County.
State of Mississippi	107,962,400	Hinds (County); Humphreys (County) (ZIP code 39038); Humphreys (County) (ZIP code 39166); Jackson (County) (ZIP code 39563); Monroe (County) (ZIP code 38821); Scott (County); Sharkey (County).
State of North Carolina	1,142,496,000	Ashe (County); Avery (County); Buncombe (County); Burke (County); Caldwell (County) (ZIP code 28645); Cleveland (County) (ZIP code 28150); Haywood (County); Henderson (County); Madison (County) (ZIP code 28753); McDowell (County); Mecklenburg (County) (ZIP code 28214); Mitchell (County); Polk (County) (ZIP code 28782); Rutherford (County); Transylvania (County); Watauga (County); Yancey (County).
Ashville, NC	225,010,000	Ashville.
State of New Mexico	109,742,400	Chaves (County); Lincoln (County).
State of Ohio	11,292,800	Logan (County).
State of Oklahoma	31,524,000	Carter (County) (ZIP code 73401); McClain (County) (ZIP code 73010); Murray (County) (ZIP code 73086); Osage (County) (ZIP code 74002).
State of Pennsylvania	11,696,000	Tioga (County) (ZIP code 16950).
State of South Carolina	120,283,200	Aiken (County); Anderson (County); Greenville (County); Greenwood (County) (ZIP code 29646); Laurens (County) (ZIP code 29325); Spartanburg (County).
State of South Dakota	12,300,000	Union (County) (ZIP codes 57038, 57049).
State of Tennessee	68,590,400	Carter (County) (ZIP code 37643); Cocke (County); Greene (County) (ZIP code 37743); Johnson (County) (ZIP code 37683); Montgomery (County) (ZIP code 37042); Unicoi (County) (ZIP code 37650); Washington (County) (ZIP codes 37650, 37659).
State of Texas	444,549,600	Anderson (County) (ZIP code 75801); Bell (County) (ZIP codes 76501, 76502); Brazoria (County); Cooke (County) (ZIP code 76272); Dallas (County); Fort Bend (County); Galveston (County); Guadalupe (County) (ZIP code 78666); Hardin (County) (ZIP code 77656); Henderson (County); Hockley (County); Jasper (County) (ZIP code 75951); Jasper (County) (ZIP codes 75951, 75956); Kaufman (County) (ZIP code 75142); Liberty (County); Liberty (County) (ZIP code 77327); Matagorda (County); Montgomery (County); Montgomery (County); Polk (County) (ZIP code 77351); San Jacinto (County); San Jacinto (County) (ZIP codes 77331, 77371); Smith (County); Trinity (County) (ZIP code 75862); Tyler (County) (ZIP code 75979); Walker (County); Wharton (County) (ZIP codes 77437, 77488).
Harris County	67,326,000	Harris County.
Houston, TX	314,645,000	Houston.
State of Virginia	37,336,000	Giles (County) (ZIP code 24124); Washington (County) (ZIP code 24236).
State of Vermont	54,276,000	Lamoille (County) (ZIP code 05656); Washington (County).
Spokane County	44,152,000	Spokane County.

II. Use of Funds

Funds for disasters occurring in 2023 or 2024 announced in this notice are subject to the requirements of the Universal Notice, published on January 8, 2025, in the **Federal Register** at 90 FR 1754, including sections I through V and appendices A through C.

III. Action Plan Submission Process

As provided in section I.C.3. of the Universal Notice, published at 90 FR 1754, this Allocation Announcement Notice provides a process for Action Plan submittal. Within 90 days of the

applicability date of this notice, grantees are required to submit their Action Plan to HUD for review and approval. For all allocations announced in this Allocation Announcement Notice, HUD is requiring paper submission of the Action Plan. Grantees shall submit their Action Plan to their assigned Community Planning and Development (CPD) Specialist or other designated HUD CPD staff member, with a copy provided to disaster_recovery@hud.gov. HUD encourages grantees to use the Action Plan template available on the Universal Notice website at [https://](https://www.hud.gov/program_offices/comm_planning/cdbg-dr/universal_notice_grantees)

www.hud.gov/program_offices/comm_planning/cdbg-dr/universal_notice_grantees.

IV. Applicable Rules, Statutes, Waivers, and Alternative Requirements

The 2025 Appropriations Act authorizes the Secretary to waive or specify alternative requirements for any provision of any statute or regulation that the Secretary administers in connection with the obligation by the Secretary, or use by the recipient, of these funds, except for requirements related to fair housing.

nondiscrimination, labor standards, and the environment. The Universal Notice describes rules, statutes, waivers, and alternative requirements that apply to allocations governed by this notice. For each waiver and alternative requirement in the Universal Notice the Secretary has determined that good cause exists, and the waiver or alternative requirement is not inconsistent with the overall purpose of title I of the HCDA. The waivers and alternative requirements provide flexibility in program design and implementation to support full and swift recovery following eligible disasters, while ensuring that statutory requirements are met.

Grantees may request additional waivers and alternative requirements from the Department as needed to address specific needs related to their recovery and mitigation activities. Grantees should work with the appropriate HUD CPD staff member to request any additional waivers or alternative requirements from HUD headquarters. The waivers and alternative requirements described below apply to all grantees under this notice. Under the requirements of the 2025 Appropriations Act, waivers and alternative requirements are effective five days after they are published in the **Federal Register** or on the website of the Department.

V. Duration of Funding

The Appropriations Act makes these funds available for obligation by HUD until expended. HUD waives the provisions at 24 CFR 570.494 and 24 CFR 570.902 regarding timely distribution and expenditure of funds and establishes an alternative requirement providing that each grantee must expend 100 percent of its allocation within six years of the date HUD signs the grant agreement. HUD may extend the time period in this alternative requirement and associated grant period of performance administratively, if good cause for such an extension exists at that time, as requested by the grantee, and approved by HUD. When the period of performance has ended, HUD will close out the grant and any remaining funds not expended by the grantee on appropriate programmatic purposes will be recaptured by HUD.

VI. Assistance Listing Numbers (Formerly Known as the CFDA Number)

The Assistance Listing Numbers (formerly known as the Catalog of Federal Domestic Assistance numbers) for the disaster recovery grants under

this notice are as follows: 14.218; 14.228.

VII. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available online on HUD's CDBG-DR website at https://www.hud.gov/program_offices/comm_planning/cdbg-dr. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202-708-3055 (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>.

Adrianne R. Todman,

Deputy Secretary Performing the Duties of the Secretary of HUD.

Appendix A

Allocation of CDBG-DR Funds to Most Impacted and Distressed Areas Due to Presidentially Declared Disasters Occurring in 2023 and 2024

Background

The Disaster Relief Supplemental Appropriations Act, 2025 (approved on 12/21/2024) appropriated \$12.039 billion for CDBG-Disaster Recovery funds (CDBG-DR) for disasters “that occurred in 2023 or 2024.” The law instructs HUD that the funds are “for the same purposes and under the same terms and conditions as funds appropriated under such heading in title VIII of the Disaster Relief Supplemental Appropriations Act, 2022 (division B of Pub. L. 117–43).”

The key statutory text related to the allocation in Public Law 117–43:

“ . . . for necessary expenses for activities authorized under title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*) related to disaster relief, long-term recovery, restoration of infrastructure and housing, economic revitalization, and mitigation, in the most impacted and distressed areas resulting from a major disaster . . . *Provided*, That amounts made available under this heading in this Act shall be awarded directly to the State, unit of general local government, or Indian tribe (as such term is defined in section 102 of the Housing and Community Development Act of 1974 (42 U.S.C. 5302)) at the discretion of the Secretary: *Provided further*, That the Secretary shall allocate, using the best available data, an amount equal to the total

estimate for unmet needs for qualifying disasters under this heading in this Act: *Provided further*, That any final allocation for the total estimate for unmet need made available under the preceding proviso shall include an additional amount of 15 percent of such estimate for additional mitigation.”

This methodology applies to allocations for disasters occurring on or after January 1, 2023 and had been declared major disasters as of November 1, 2024. It reflects approximately \$11.992 billion under the Disaster Relief Supplemental Appropriations Act, 2025 after factoring in additional repurposed amounts and funds for capacity building and HUD administrative costs. The key statutory text from the Disaster Relief Supplemental Appropriations Act, 2025 is:

“For an additional amount for “Community Development Fund,” \$12,039,000,000, to remain available until expended, for the same purposes and under the same terms and conditions as funds appropriated under such heading in title VIII of the Disaster Relief Supplemental Appropriations Act, 2022 (Pub. L. 117–43), . . . *Provided*, That the Secretary of Housing and Urban Development shall allocate all funds provided under this heading in this Act for the total estimate for unmet needs including additional mitigation for qualifying disasters and publish such allocations in the **Federal Register** no later than January 15, 2025: . . . *Provided further*, That unobligated balances remaining as of the date of enactment of this Act included under Treasury Appropriation Fund Symbol 86 X 0162 from Public Laws 108–324, 109–148, 109–234, 110–252, 110–329, 111–212, 112–55, and 113–2 shall also be available for the purposes authorized under this heading in this Act (except that the amount for each set-aside provided herein shall not be exceeded), notwithstanding the purposes for which such amounts were appropriated: *Provided further*, That of the amounts made available under this heading in this Act, \$45,000,000 shall be transferred to “Department of Housing and Urban Development—Management and Administration—Program Offices” for salaries and expenses of the Office of Community Planning and Development for necessary costs, including information technology costs, of administering and overseeing the obligation and expenditure of amounts made available for activities authorized under title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*) related to disaster relief, long-term recovery, restoration of infrastructure and housing, economic revitalization, and mitigation in the most impacted and distressed areas resulting from a major disaster in this, prior, or future Acts (“this, prior, 4 or future disaster Acts”): *Provided further*, That of the amounts made available under this heading in this Act, \$1,850,000 shall be transferred to “Department of Housing and Urban Development—Information Technology Fund” for the disaster recovery data portal: *Provided further*, That of the amounts made available under this heading in this Act, \$7,000,000 shall be transferred to “Department of Housing and Urban Development—Office of Inspector General”

for necessary costs of overseeing and auditing amounts made available in this, prior, or future disaster Acts: Provided further, That of the amounts made available under this heading in this Act, \$25,000,000 shall be made available for capacity building and technical assistance, including assistance on contracting and procurement processes, to support recipients of allocations from this, prior, or future disaster Acts.”

Most Impacted and Distressed Areas

As with prior CDBG–DR appropriations, HUD is not required to allocate funds for all major disasters occurring in the statutory timeframes. HUD is directed to use the funds “in the most impacted and distressed areas.” HUD has implemented this directive by limiting CDBG–DR formula allocations to grantees with major disasters that meet these standards:

(1) Individual and Households Program (IHP) designation. HUD has limited allocations to those disasters where the Federal Emergency Management Agency (FEMA) had determined the damage was sufficient to declare the disaster as eligible to receive IHP funding.

(2) Concentrated damage. HUD has limited its estimate of serious unmet housing need to counties and zip codes with high levels of damage, collectively referred to as “most impacted areas.” For this allocation, HUD is defining most impacted areas as either most impacted counties—counties exceeding \$10 million in serious unmet housing needs—and most impacted Zip Codes—Zip Codes with \$2 million or more of serious unmet housing needs. The calculation of serious unmet housing needs is described below.

For disasters that meet the most impacted threshold described above, the unmet need allocations are based on the following factors summed together:

(1) Repair estimates for seriously damaged owner-occupied units without insurance (with some exceptions) in most impacted areas after FEMA and Small Business Administration (SBA) repair grants or loans

(2) Repair estimates for seriously damaged rental units occupied by very low-income renters in most impacted areas;

(3) Repair and content loss estimates for small businesses with serious damage denied by SBA; and

(4) The estimated local cost share for Public Assistance Category C to G projects.

Methods for Estimating Serious Unmet Needs for Housing

The data HUD uses to calculate unmet needs for 2023 and 2024 qualifying disasters come from the FEMA IHP data on housing-unit damage as of November 20, 2024 and reflect disasters occurring in 2023 and declared on or before November 1, 2024.

The core data on housing damage for both the unmet housing needs calculation and the concentrated damage are based on home inspection data for FEMA’s IHP and SBA’s disaster loan program. HUD calculates “unmet housing needs” as the number of housing units with unmet needs times the

estimated cost to repair those units less repair funds estimated to be provided by FEMA, SBA, and insurance.

Each of the FEMA IHP inspected owner units are categorized by HUD into one of five categories:

- Minor-Low: Less than \$3,000 of FEMA inspected real property damage.
- Minor-High: \$3,000 to \$7,999 of FEMA inspected real property damage
- Major-Low: \$8,000 to \$14,999 of FEMA inspected real property damage and/or 1 to 3.9 feet of flooding on the first floor;
- Major-High: \$15,000 to \$28,800 of FEMA inspected real property damage and/or 4 to 5.9 feet of flooding on the first floor.
- Severe: Greater than \$28,800 of FEMA inspected real property damage or determined destroyed and/or 6 or more feet of flooding on the first floor.

When owner-occupied properties also have a personal property inspection or only have a personal property inspection, HUD reviews the personal property damage amounts such that if the personal property damage places the home into a higher need category over the real property assessment, the personal property amount is used. The personal property-based need categories for owner-occupied units are defined as follows:

- Minor-Low: Less than \$2,500 of FEMA inspected personal property damage.
- Minor-High: \$2,500 to \$3,499 of FEMA inspected personal property damage.
- Major-Low: \$3,500 to \$4,999 of FEMA inspected personal property damage or 1 to 3.9 feet of flooding on the first floor.
- Major-High: \$5,000 to \$9,000 of FEMA inspected personal property damage or 4 to 5.9 feet of flooding on the first floor.
- Severe: Greater than \$9,000 of FEMA inspected personal property damage or determined destroyed and/or 6 or more feet of flooding on the first floor.

To meet the statutory requirement of “most impacted” in this legislative language, homes are determined to have a high level of damage if they have damage of “major-low” or higher. That is, they have a FEMA inspected real property damage of \$8,000 or above, personal property damage \$3,500 or above, or flooding 1 foot or above on the first floor.

Furthermore, a homeowner with flooding outside the 1 percent risk flood hazard area is determined to have unmet needs if they reported damage and no flood insurance to cover that damage. For homeowners inside the 1 percent risk flood hazard area, homeowners without flood insurance with flood damage below the greater of national median or 120 percent of Area Median Income are determined to have unmet needs. For non-flood damage, homeowners without hazard insurance with incomes below the greater of national median or 120 percent of Area Median Income are included as having unmet needs. The unmet need categories for these types of homeowners are defined as above for real and personal property damage.

FEMA IHP does not inspect rental units for real property damage so personal property damage is used as a proxy for unit damage.

Each of the FEMA-inspected renter units are categorized by HUD into one of five categories:

- Minor-Low: Less than \$1,000 of FEMA inspected personal property damage.
- Minor-High: \$1,000 to \$1,999 of FEMA inspected personal property damage or determination of “Moderate” damage by the FEMA inspector.
- Major-Low: \$2,000 to \$3,499 of FEMA inspected personal property damage or 1 to 3.9 feet of flooding on the first floor or determination of “Major” damage by the FEMA inspector.
- Major-High: \$3,500 to \$7,500 of FEMA inspected personal property damage or 4 to 5.9 feet of flooding on the first floor.
- Severe: Greater than \$7,500 of FEMA inspected personal property damage or determined destroyed and/or 6 or more feet of flooding on the first floor or determination of “Destroyed” by the FEMA inspector.

To meet the statutory requirement of “most impacted” for rental properties, homes are determined to have a high level of damage if they have damage of “major-low” or higher. That is, they have a FEMA personal property damage assessment of \$2,000 or greater or flooding 1 foot or above on the first floor.

Furthermore, landlords are presumed to have adequate insurance coverage unless the unit is occupied by a renter with income less than the greater of the Federal poverty level or 50 percent of the area median income. Units occupied by a tenant with income less than the greater of the poverty level or 50 percent of the area median income are used to calculate likely unmet needs for affordable rental housing.

The average cost to fully repair a home for a specific disaster to code within each of the damage categories noted above is calculated using the median real property damage repair costs determined by the SBA for its disaster loan program based on a match comparing FEMA and SBA inspections by each of the FEMA damage categories described above.

If there is a match of 20 or more SBA inspections to FEMA inspections for any damage category, the median damage estimate for the SBA properties is used less the estimated average FEMA IHP repair grant and average SBA disaster loan grant weighted on take-up rates, which are generally high for IHP and low and for SBA. Except that no matched multiplier can be less than the 25th percentile for all IHP eligible disasters combined in eligible disaster years at the time of the allocation calculation or more than the 75th percentile for all IHP eligible disasters combined with data available as of the allocation.

If there is a match of fewer than 20 SBA inspections to FEMA inspections within individual damage categories for an individual disaster, these multipliers are used which are based on the 2020/2021 disaster years:

Disaster type	Multipliers by disaster type		
	Major-low	Major-high	Severe
Dam/Levee Break	\$33,007	\$47,078	\$47,078
Earthquake	27,141	33,714	134,503
Fire	22,971	82,582	134,503
Flood	47,074	57,856	64,513
Hurricane	36,800	45,952	45,952
Severe Ice Storm	33,528	33,714	36,592
Severe Storm(s)	22,971	37,299	37,299
Tornado	52,961	82,582	134,503

A separate multiplier is applied to mobile homes for all disaster types. The mobile home multipliers are \$77,058 for major-low, \$98,463 for major-high, and \$134,834 for severe.

Methods for Estimating Serious Unmet Economic Revitalization Needs

Based on SBA disaster loans to businesses using data for 2023 and 2024 disasters from as of November 19, 2024, HUD calculates the median real estate and content loss by the following damage categories for each disaster:

- Category 1: real estate + content loss = below \$12,000
- Category 2: real estate + content loss = \$12,000–\$29,999
- Category 3: real estate + content loss = \$30,000–\$64,999
- Category 4: real estate + content loss = \$65,000–\$149,999
- Category 5: real estate + content loss = \$150,000 and above

For properties with real estate and content loss of \$30,000 or more, HUD calculates the estimated amount of unmet needs for small businesses by multiplying the median damage estimates for the categories above by the number of small businesses denied an SBA loan, including those denied a loan prior to inspection due to inadequate credit or income (or a decision had not been made), under the assumption that damage among those denied at pre-inspection have the same distribution of damage as those denied after inspection.

Because many of the larger disasters of 2023 and 2024 occurred recently and business need data remain incomplete for many disasters, no disaster in 2023 or 2024 receives for business unmet need less than 10 percent of their unmet housing need.

Methods for Estimating Unmet Infrastructure Needs

To calculate 2024 unmet needs for infrastructure projects, HUD received FEMA cost estimates on November 20, 2024 of the expected local cost share to repair the permanent public infrastructure (Categories C to G) to their pre-storm condition.

Because many of the larger disasters of 2023 and 2024 occurred recently and infrastructure need data remain incomplete for many disasters, no disaster in 2023 or 2024 receives for infrastructure unmet need of less than 10 percent of their unmet housing need.

Disaster Level Allocation Calculation

Once eligible entities are identified using the above criteria, the allocation to individual grantees represents their proportional share of the estimated unmet needs. For the formula allocation, HUD calculates total unmet recovery needs for eligible disasters as the aggregate of:

- Serious unmet housing needs in most impacted and distressed areas;
- Serious unmet business needs; and
- Unmet infrastructure need.

Mitigation is calculated as 15 percent of the unmet need calculation. Both unmet needs and mitigation grant amounts are rounded to the nearest \$1,000.

The unmet needs and mitigation are slightly greater than the amount to be allocated, so the amount allocated reflects the unmet needs and mitigation less a 1.2488 percent pro-rata reduction.

Grantee Level Allocations

As noted above, the basic formula for allocating these funds is to calculate for each disaster meeting a minimum “most impacted and distressed” damage threshold a formula that uses an estimate of unmet needs for housing, economic revitalization, and infrastructure plus 15 percent more for mitigation. Because in CY 2023 and CY 2024 some States and counties were impacted by multiple disasters, some States and counties are proposed to receive a single award for multiple disasters.

Where there are most impacted CDBG entitlement cities and/or CDBG entitlement urban counties, direct allocations were calculated to meet the dual goals of (i) funding locally and (ii) supporting efficient and effective program implementation.

Note that when an urban county is identified, the funds allocated are for the entirety of the county, not just participating jurisdiction in the regular CDBG program. The exception is when an entitlement city is also receiving a direct CDBG–DR award, in which case that is subtracted out of the county calculation.

[FR Doc. 2025–00943 Filed 1–15–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[256A2100DD/AAKC001030/
A0A501010.999900]

Mission Valley Power Project, Montana—Power Rate Adjustment

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) has adjusted its electric power rates for the Mission Valley Power Project (MVP).

DATES: The 2025 rate adjustment will be effective March 1, 2025. The 2026 rate adjustment will be effective March 1, 2026.

FOR FURTHER INFORMATION CONTACT: For details about MVP, please contact Shane R. Hendrickson, Superintendent, Bureau of Indian Affairs, P.O. Box 40, Pablo, Montana 59855, (406) 675–2700, Ext 1301. 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.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rate Adjustment was published in the **Federal Register** on November 14, 2024 (89 FR 90032) to propose adjustments to the electric power rates at MVP. The public and interested parties were provided an opportunity to submit written comments during the 30-day period that ended December 16, 2024.

Did BIA defer or change any proposed rate increases?

Yes. BIA will not implement the proposed 2024 rates due to procedural delays. The final 2025 and 2026 rates will be implemented as proposed.

Did BIA receive any comments on the proposed electric power rate adjustments?

No. BIA did not receive any comments on the proposed electric power rate adjustments.

Does this notice affect me?

This notice affects you if we provide you electric service. MVP is a federally-owned power utility, operated and maintained by the Confederated Salish and Kootenai Tribes through a contract pursuant to the Indian Self-Determination and Education Assistance Act of 1975, Public Law 93–638, 25 U.S.C. 5301 *et seq.* (formerly codified at 25 U.S.C. 450 *et seq.*). MVP provides service to customers located within the Flathead Indian Reservation and to areas in Flathead, Lake,

Missoula, and Sanders counties in Montana. MVP provides power for residential, governmental, irrigation, commercial, and industrial uses.

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior by 5 U.S.C. 301; 25 U.S.C. 13; 25 U.S.C. 385c; Act of March 7, 1928 (45 Stat. 212–213), as amended; Act of May 25, 1948, Public Law 554 (62 Stat. 269–273), as amended; Act of August 31, 1951 (65 Stat. 248); Act of December 23,

1981, section 112 (95 Stat. 1404). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under part 209, chapter 8.1A, of the Department of the Interior's Departmental Manual.

What electric power rates are adjusted by this notice?

The rate table below contains the present and final 2025 and 2026 electric power rates for MVP. An asterisk immediately following the rate category notes where the rate categories are adjusted from the present rate.

Rate category	Present rate (\$)	Final 2025 rate (\$)	Final 2026 rate (\$)
Residential (See Note #1)			
Basic Charge per month *	\$17.50	\$23.50	\$27.00
Basic Charge (Pre-Pay Meters) *	21.00	28.20	32.40
Basic Charge (Net Meters) *	20.00	28.50	32.00
Energy Charge:			
Each kilowatt-hour between 0–1,000 *	0.0812	0.0880	0.0901
Each kilowatt-hour between 1,001–2,000 *	0.0908	0.0983	0.1007
Each kilowatt-hour over 2,000 *	0.1126	0.1219	0.1249
Demand charge per kilowatt *	0.25	0.60	0.80
Small General Service (maximum monthly demand of 25 kilowatts or less) (See Note #1)			
Basic Charge per month *	17.50	23.50	27.00
Basic Charge (Pre-Pay Meters) *	21.00	28.20	32.40
Basic Charge (Net Meters) *	20.00	28.50	32.00
Energy charge per kilowatt-hour *	0.1034	0.1113	0.1136
Demand charge per kilowatt *	0.30	0.75	1.00
General Service (monthly demand of 26–1,000 kilowatts) (See Note #1)			
Basic charge per month:			
Single Phase *	32.50	43.50	50.00
Single Phase (Net Meters) *	37.50	48.50	55.00
Three Phase *	53.25	71.25	81.92
Three Phase (Net Meters) *	61.50	79.50	90.17
Energy Charge per kilowatt-hour *	0.0753	0.0797	0.0797
Demand Charge per kilowatt *	4.50	5.25	5.75
New Large Single Load (monthly demand over one megawatt) (See Note #2)			
Basic Charge per month	45.00	45.00	45.00
Energy Charge:			
Each kilowatt-hour between 0–730,000	0.0753	0.0753	0.0753
Each kilowatt-hour over 730,000	0.06395	0.06395	0.06395
Demand charge ^:			
Per kilowatt up to 1,000	4.50	4.50	4.50
Per kilowatt over 1,000	4.10	4.10	4.10
Area Lights			
LED Light *	10.05	13.43	15.43
Unmetered Services (See Note #3)			
Basic Charge *	17.50	23.50	27.00
Street Lighting (Metered)			
Basic Charge *	10.00	13.43	15.43
Energy Charge *	0.1034	0.1113	0.1136
Street Lighting (Unmetered)			
LED Light *	7.20	9.10	9.55

Rate category	Present rate (\$)	Final 2025 rate (\$)	Final 2026 rate (\$)
Irrigation (See Note #4)			
Basic charge per month *	5.00	15.00	20.00
Energy charge per kilowatt hour *	0.0712	0.0720	0.0746
Demand Charge per kilowatt * ^	3.00	5.25	5.75

* Notes rate categories adjusted.

^ We may apply a power factor penalty to Irrigation, General Service—Three Phase, and New Large Single Load customers.

Note #1. Residential and Small General Service customers may opt into the “Pre-Pay Meters” or “Net Meters” programs. General Service customers may opt into the “Net Meters” program. For the Pre-Pay Meters program, customers must pre-pay a minimum of \$50.00 fee at time of account setup. Any prepayment is credited to the account and applied to the customer’s future usage and demand charges. Pre-Pay customers are required to keep a positive balance in their account, or the meter will shut off automatically. Net Metering allows customer-owned renewable generation to interconnect with MVP’s distribution system.

Note #2. Customers with monthly demand of over three megawatts will be subject to other rates, as determined by MVP on a case-by case basis, and may be required to make a deposit of two months of estimated service.

Note #3. Unmetered Services refers to customers, using kilowatt hours without a meter, that do not fall under one of MVP’s other rate categories. Includes traffic lights, billboards, and telephone booths.

Note #4. Irrigation customers may receive a Bonneville Power Administration (BPA) discount for the months of May through September. BPA generally provides an irrigation discount to assist the agricultural sector in rural Northwest communities. After BPA provides MVP with the final irrigation discount rate, we will issue the discount as an annual credit on qualified irrigation customers’ bills.

Consultation and Coordination With Tribal Governments (Executive Order 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this notice under the Department’s consultation policy and under the criteria of Executive Order 13175 and have determined there to be substantial direct effects on federally recognized Tribes because the electric power utilities are located on or associated with Indian reservations. To fulfill its consultation responsibility to Tribes and Tribal organizations, BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of electric power delivery, electric power availability, and costs of administration, operation, maintenance, and rehabilitation of our utilities that concern them. This is accomplished at the individual power utility by utility, agency, and regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of our overall coordination and consultation process to provide notice to, and request comments from, these entities when we adjust electric power rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

The rate adjustments are not a significant energy action under the definition in Executive Order 13211. A statement of energy effects is not required.

Civil Justice Reform (Executive Order 12988)

This notice complies with the requirements of Executive Order 12988. Specifically, in issuing this notice, the Department has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct as required by section 3 of Executive Order 12988.

Regulatory Planning and Review (Executive Order 12866)

These rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866, as amended by Executive Order 14094.

Regulatory Flexibility Act

These rate adjustments are not a rule for the purposes of the Regulatory Flexibility Act because they establish “a rule of particular applicability relating to rates.” 5 U.S.C. 601(2).

Takings (Executive Order 12630)

These rate adjustments do not effect a taking of private property or otherwise have “takings” implications under Executive Order 12630. The rate adjustments do not deprive the public, State, or local governments of rights or property.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, these rate adjustments do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because they will not affect the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various

levels of government. A federalism summary impact statement is not required.

National Environmental Policy Act

The Department has determined that these rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rate adjustments are of an administrative, financial, legal, technical, or procedural nature (for further information see 43 CFR 46.210(i)). We have also determined that the rate adjustments would not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act of 1995

These rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0021 and expires March 31, 2026.

Unfunded Mandates Reform Act of 1995

These rate adjustments do not impose an unfunded mandate on State, local, or Tribal governments in the aggregate, or on the private sector, of more than \$130 million per year. They do not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, the Department is not required to prepare a statement containing the information

required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2025–01043 Filed 1–15–25; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[MO4500181945]

National Environmental Policy Act Implementing Procedures for the Bureau of Land Management (516 DM 11)

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: This notice announces a revision to the National Environmental Policy Act (NEPA) implementing procedures for the Bureau of Land Management (BLM) at Chapter 11 of part 516 of the Department of the Interior's Departmental Manual (516 DM 11). The revision adds a new categorical exclusion (CX) for geothermal resource confirmation activities on Federal geothermal resource leases.

DATES: The CX is effective January 16, 2025.

ADDRESSES: The new CX can be found at the web address for the BLM's revised NEPA procedures: <http://www.doi.gov/elips/> at Series 31, DM part 516, Chapter 11. The Substantiation Report for the CX is available at the BLM's ePlanning site: <https://eplanning.blm.gov/eplanning-ui/project/2034686/510>.

FOR FURTHER INFORMATION CONTACT:

Heather Bernier, Division Chief, Decision Support, Planning, and NEPA, at (303) 239–3635, or hbernier@blm.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:

I. Background

The United States (U.S.) Department of the Interior (Department) published the proposed CX for geothermal resource confirmation on October 22, 2024, for a 30-day public comment period. Refer to the **Federal Register** notice (89 FR 84380) for more information regarding the background and rationale for the CX. This notice

notifies the public of the BLM's establishment of the Geothermal Resource Confirmation CX and includes the BLM's responses to comments from the public on the proposed CX. The BLM has made clarifying edits to the CX text in response to comments as explained in this notice. These edits do not change the scope of the CX as proposed.

The Department proposed the CX for use by the BLM to support approval of an operations plan for lessees to drill and test wells to confirm the existence and capacity of a geothermal resource. Therefore, this increased efficiency will serve to expedite renewable energy development on BLM managed lands.

NEPA, 42 U.S.C. 4321 *et seq.*, requires Federal agencies to consider the environmental effects of their proposed actions in their decision-making processes and inform and engage the public in that process. Section 101(a) of NEPA sets forth a national policy to use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which humans and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans. 42 U.S.C. 4331(a). Section 102 of NEPA directs agencies to interpret and administer Federal policies, regulations, and laws consistent with NEPA's policies. 42 U.S.C. 4332.

NEPA also created the Council on Environmental Quality (CEQ), which has issued regulations implementing NEPA, 40 CFR parts 1500 through 1508 (CEQ regulations). CEQ also has issued numerous guidance documents to facilitate agency implementation of NEPA. See CEQ, CEQ Guidance Documents, <https://ceq.doe.gov/guidance/guidance.html>.

To comply with NEPA, agencies determine the appropriate level of review of any major Federal action—an environmental impact statement (EIS), environmental assessment (EA), or a categorical exclusion (CX). 40 CFR 1501.3. If a proposed action is likely to have significant environmental effects, the agency must prepare an EIS and document its decision in a record of decision. 40 CFR 1501.3(c)(3), part 1502, 1505.2. If the proposed action is not likely to have significant environmental effects or if the significance of the effects is unknown, the agency may instead prepare an EA, which is a concise public document used to support agency decision making on a proposed agency action. 40 CFR

1501.3(c)(2), 1501.5, 1508.1(j). After completing the analysis in the EA, the agency may conclude that the action will have no significant effects and document that conclusion in a finding of no significant impact, or conclude that the action is likely to have significant effects and therefore requires preparation of an EIS. 40 CFR 1501.6(a), 1508.1(j).

Under NEPA and the CEQ regulations, a Federal agency establishes CXs—categories of actions that the agency has determined normally do not have a significant effect on the human environment, individually or in the aggregate—in its agency NEPA procedures. 42 U.S.C. 4336(e)(1); 40 CFR 1501.4(a), 1507.3(c)(8), 1508.1(e). If an agency determines that a CX covers a proposed action, it then evaluates the proposed action for extraordinary circumstances, which are factors or circumstances that indicate a normally categorically excluded action may have a significant effect. 40 CFR 1501.4(b), 1508.1(o). If any extraordinary circumstances exist, the agency nevertheless may apply the CX if it conducts an analysis and determines that the proposed action does not in fact have the potential to result in significant effects notwithstanding an extraordinary circumstance, or the agency modifies the action to avoid the potential to result in significant effects. 40 CFR 1501.4(b)(1). In these cases, the agency must document such determination. *Id.* If the agency cannot categorically exclude the proposed action, it will prepare an EA or EIS, as appropriate, before issuing any decision to authorize the action. 40 CFR 1501.4(b)(2).

The CEQ regulations require Federal agencies to develop procedures to implement NEPA and the CEQ regulations, facilitate efficient decision making, and ensure that the agencies make decisions in accordance with the policies and requirements of NEPA. 40 CFR 1507.3. As part of their procedures, agencies must establish CXs and identify extraordinary circumstances. 40 CFR 1507.3(c)(8). When establishing new or revising existing CXs in agency NEPA procedures, agencies must substantiate the proposed new or revised CXs with sufficient information to conclude that each category of actions does not have a significant effect, individually or in the aggregate, on the human environment, and provide this substantiation in a written record that is made publicly available as part of the notice and comment process for developing or revising proposed agency procedures. See 40 CFR 1507.3(b), (c)(8). In developing NEPA procedures, agencies must consult with CEQ and

provide an opportunity for public review. 40 CFR 1507.3(b)(1)–(2). Before publishing final procedures, agencies must receive a determination from CEQ that the procedures conform with NEPA and the CEQ regulations. *See* 40 CFR 1507.3(b)(2).

II. Proposed Categorical Exclusion

The text of the proposed CX, as provided in the October 22, 2024, **Federal Register** notice, was as follows:

Approval of an operations plan for geothermal resource confirmation wells (e.g., core drilling, temperature gradient wells, and/or resource wells), including, but not limited to, construction of temporary routes for access, reclamation of all surface disturbance, and direct testing (e.g., flow tests) to confirm the existence of a geothermal resource, to improve injection support, or to demonstrate communication between wells that:

- Does not include resource utilization;
- Does not exceed 20 acres of total (contiguous or noncontiguous) surface disturbance;
- Includes reclamation of temporary routes when their intended purpose(s) has been fulfilled, unless through a separate review and decision-making process the BLM incorporates and appropriately designates a route as part of its transportation system. Unless a temporary route is specifically intended to accommodate public use, use of the temporary route is limited to project specific geothermal resource confirmation purposes;
- Requires temporary routes to be constructed and used to allow for the reclamation, by artificial or natural means, of the temporary route and areas where the vegetative cover was disturbed by the construction or use of the route, and requires such treatment to be designed to reestablish vegetative cover as soon as possible, but at least within 10 years after approved reclamation commences; and
- Includes design elements to protect resources and resource uses consistent with the applicable Resource Management Plan, laws, regulations, and lease terms.

III. Comments on the Proposed CX

The BLM received 27 comment letters during the 30-day public comment period on the proposed CX. Comments were submitted by State and local governments and agencies, interest groups, non-profit organizations, and private citizens. The BLM received comments both in support of and in opposition to the proposed CX. Some comments were beyond the scope of the

BLM's proposed CX, such as a recommendation for the BLM headquarters to allocate more funding for new employees and another to require consultation on the forthcoming Infrastructure Impact Tool being developed by the United States Geological Survey, which is still in development and not led by the BLM.

The BLM considered all comments to date and responds in this notice to all 24 substantive issues raised in the public comments. The BLM has noted in the responses to comments when it changed the text of the CX in response to a comment. The BLM appreciates the interest and participation of all respondents. The BLM, where appropriate, grouped together similar or related comments, and responds to the comments as follows:

Comment 1: At least 18 commenters expressed support for establishing the CX, stating that it would substantially reduce permitting timelines for geothermal energy authorizations and advance the responsible development of clean and reliable energy on public lands while keeping in place strong commitments to environmental stewardship. In addition, commenters noted that the availability of the CX for the BLM's use could help the BLM to expedite approval of new geothermal projects and promote the realization of their associated economic benefits while allowing the BLM's staff to focus on other proposals that may have a significant environmental effect.

Response 1: The BLM agrees with these comments and will continue to conduct the appropriate level of NEPA review for proposed Federal actions, including, where appropriate, application of available CXs, and public engagement, as necessary. The BLM will continue to appropriately consider potential adverse effects of proposed activities through the NEPA process.

Comment 2—Transparency and public input: At least nine commenters requested that the BLM coordinate with the public and appropriate agencies when relying on the CX to authorize geothermal energy projects.

Response 2: The CEQ and Department's NEPA implementing regulations do not require public notice for an agency to use a CX. As provided in CEQ regulations and guidance, establishing, revising, and appropriately using CXs is consistent with NEPA. CXs are not exemptions or waivers from NEPA. Rather, they are a type of NEPA review intended to accomplish the purposes of NEPA efficiently and effectively. The establishment of a CX is a public process through which the agency must demonstrate that the

category of actions does not normally have significant effects on the human environment, individually or in the aggregate (40 CFR 1501.4). Having made such a demonstration, subject to public review and comment, the agency may then apply the CX to complete the NEPA environmental review process for proposals that fall within the scope of the CX, unless any extraordinary circumstances exist that make application of the CX inappropriate. The BLM will continue to cooperate and collaborate with Tribal, State, local, and Federal agencies as appropriate in managing the public lands. Although public engagement is not required as part of the process for applying a CX, the BLM may elect to involve the public (e.g., through notification or public scoping), where appropriate, in an action for which the BLM intends to rely on a CX for approval, based on various considerations, including the level of public interest (40 CFR 1501.9(c)(3)). Each use of this CX will be documented on the BLM NEPA register website (<https://eplanning.blm.gov/eplanning-ui/home>) and made available to the public.

Comment 3—Potential groundwater depletion: At least three commenters expressed concern that use of the CX could lead to groundwater depletion.

Response 3: Geothermal resource confirmation includes drilling wells to confirm the existence of a geothermal resource and evaluate its commercial viability and to determine the extent of the resource by demonstrating communication between wells but does not include commercial utilization of the geothermal resource. Such drilling and flow testing of geothermal resources during the resource confirmation phase of development does not result in a consumptive use of groundwater. Groundwater extracted during geothermal resource confirmation activities is reinjected back into the geothermal resource. Groundwater consumption that may occur during any subsequent production or utilization phase would not be covered by the CX and would be subject to a separate authorization decision, based on a subsequent, independent NEPA review.

Comment 4—Adequate level of NEPA analysis: At least two commenters asserted that NEPA analysis through an environmental assessment or environmental impact statement is necessary for approval of geothermal resource confirmation drilling projects.

Response 4: As documented in the accompanying Substantiation Report, the category of geothermal resource confirmation actions covered by this CX does not normally have significant

effects on the human environment, individually or in the aggregate. The BLM reviewed 26 environmental assessments related to geothermal resource confirmation, as well as 20 oil and gas drilling projects, each of which supported a finding of no significant impact (FONSI). The BLM further confirmed that no unanticipated effects occurred because of project implementation for any of the studied projects. These 26 geothermal projects represent all of the geothermal resource confirmation projects that have been approved by the BLM over the last 21 years and were suitable for analysis in the Substantiation Report (*i.e.*, those completed and where full documentation was available, including assessment of any unanticipated effects after project completion). In addition, for any proposed action that the BLM intends to approve in reliance on the CX, the BLM would evaluate effects to resources through the Department's extraordinary circumstances review process (43 CFR 46.205 and 46.215). This review would be documented and included in the information posted on the BLM's NEPA register. If the Responsible Official cannot rely on the CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c), before issuing any decision to authorize the proposed action.

Comment 5—Potential air quality effects: At least one commenter expressed concern for potential effects to air quality that might result from operation of geothermal power plants.

Response 5: Effects to air quality resulting from geothermal resource confirmation projects, which includes drilling wells to confirm the existence of a geothermal resource and evaluate its commercial viability, are normally minor and temporary, as documented in the accompanying substantiation report. The scope of the CX does not include the construction or operation of power plants, and thus potential effects to air quality associated with any proposed geothermal power plant are beyond the scope of the CX. If a utilization plan is proposed, the potential effects of that plan (*e.g.*, air quality effects) would be evaluated during the NEPA review associated with a proposed utilization project for geothermal development (*e.g.*, operation of geothermal power plants).

Comment 6—Potential water quality effects: At least one commenter expressed concern that geothermal systems may affect water quality

through discharge of heavy metals and dissolved solids.

Response 6: Geothermal resource confirmation operations do not normally include the use of toxic heavy metals. With regard to dissolved solids, drilling muds composed of inert naturally occurring clays, such as bentonite and barite, are used, but these do not impact water quality. If a particular project would involve an atypical use of materials with potential to adversely affect water quality, the BLM would consider that fact as part of its consideration of extraordinary circumstances. Potential effects to water quality associated with any proposed geothermal power plant are beyond the scope of the CX, which does not include the construction or operation of a geothermal power plant. If a utilization plan is proposed, the potential for those effects would be reviewed during a future NEPA review associated with a proposed utilization project for geothermal development.

Comment 7—Potential land subsidence: At least two commenters expressed concern that fluid withdrawals associated with geothermal development can cause land subsidence.

Response 7: Typically, the resource confirmation phase does not result in consumptive use of groundwater. The possibility of land subsidence that may be associated with the operation of any proposed geothermal power plant due to any fluid withdrawals is beyond the scope of the CX, as it is not included in the resource confirmation phase. If a utilization plan is proposed, the potential for those effects would be reviewed during the NEPA review associated with a proposed utilization project for geothermal development.

Comment 8—Potential biological and cultural resources effects: At least six commenters expressed concern that geothermal exploration can affect vegetation and wildlife (including special status species like Greater sage-grouse), biodiversity, surface water, cultural resources, and groundwater; and at least one commenter recommended that the BLM incorporate protections for species into the CX text.

Response 8: The BLM's geothermal operations plan review process includes several layers of protection, which ensure that resource confirmation projects will not significantly impact site-specific biological and cultural resources, regardless of the level of NEPA review. Therefore, these resources do not need to be addressed specifically in the text of the CX.

First, regardless of the level of analysis the BLM conducts for NEPA

compliance, actions that are proposed to take place on BLM-managed lands, including geothermal resource confirmation activities, must be reviewed for conformance with the applicable BLM Resource Management Plan (RMP) as part of the BLM's compliance with the Federal Land Policy and Management Act and its implementing regulations (43 CFR 1610.5–3). Any geothermal resource confirmation activities would be subject to applicable RMP terms and conditions and any applicable lease stipulations, which include requirements to ensure protection of sensitive resources.

Second, any geothermal resource confirmation activities must also comply with any lease stipulations. Such activities would be evaluated in the NEPA review conducted at the leasing stage. Leases may contain site-specific lease stipulations related to resource protection (*e.g.*, seasonal restrictions for species and habitat protection, thermal features, water resources, vegetation) that become part of the enforceable lease terms. In addition, the BLM assembles an interdisciplinary team to facilitate coordination among agencies where appropriate. The BLM ensures that design elements are included in geothermal drilling permit (GDP) approvals to ensure conformance with the applicable RMP, lease terms, and other relevant requirements. For example, it is typical for the BLM to address the timeframe of the activity and relevant drilling requirements as well as reclamation activities within a Conditions of Approval (COA) of the GDP (*e.g.*, plugging, abandonment and reclamation activities must be completed within 3 years of project completion). BLM professionals review each proposed action for potential resource conflicts and incorporate appropriate design elements into an approval.

Third, the BLM must comply with the requirements of the Endangered Species Act regarding effects on any threatened or endangered species, as an obligation independent of compliance with NEPA.

Finally, before relying on the CX to approve any proposed action, the BLM must consider extraordinary circumstances (43 CFR 46.215), which include consideration of effects on public health and safety; natural resources and unique geographic characteristics such as historic or cultural resources; park, recreation, or refuge lands; wilderness areas; wild or scenic rivers; national natural landmarks; sole or principal drinking water aquifers; prime farmlands; wetlands; floodplains; national

monuments; migratory birds; and other ecologically significant or critical areas; unresolved conflicts concerning alternative uses of available resources; unique or unknown environmental risks; precedent for future decision making; historic properties; listed or proposed species or critical habitat; low income or minority populations; access by Indian religious practitioners to, and for ceremonial use of, Indian sacred sites and the physical integrity of those sites; and contribution to the introduction, continued existence, or spread of invasive plants or non-native invasive species. This review would be documented and included in the information posted on the BLM's NEPA register. If the Responsible Official cannot rely on the CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c).

Comment 9—Potential noise effects: At least one commenter expressed concern that geothermal exploration can cause noise.

Response 9: As documented in the Substantiation Report, the BLM reviewed 26 environmental assessments related to geothermal resource confirmation that supported FONSIs, as well as 20 similar oil and gas drilling project EAs. These environmental assessments analyzed noise effects associated with geothermal resource confirmation. The EAs concluded that noise effects were temporary in nature and could result from increased traffic on local roads. Ultimately, such effects are expected to be minimal, short-term, and addressed through the implementation of design elements.

Comment 10—Potential seismic effects: At least four commenters expressed concern that geothermal development could contribute to seismic effects.

Response 10: When geothermal projects are submitted for approval, the BLM evaluates the volume of fluid to be injected and estimates potential for seismicity. Following a standard protocol, potential seismicity above a certain level would trigger requirements for reducing the injection rate or making other adjustments (<https://www.energy.gov/eere/geothermal/articles/protocol-addressing-induced-seismicity-associated-enhanced-geothermal>).

This level is lowered when sensitive resources are nearby. This is standard practice regardless of the level of NEPA review conducted. In addition, for any proposed action that the BLM intends to approve in reliance on the CX, the BLM

evaluates effects to resources through the Department's extraordinary circumstances review process set forth at 43 CFR 46.205 and 215. This review is documented and included in the information posted on the BLM's NEPA register. If the Responsible Official cannot rely on the CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official prepares an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c).

Comment 11—Water usage: At least one commenter expressed concern that geothermal power plants require a large amount of water for cooling, which could create conflicts over water use.

Response 11: Geothermal resource confirmation activities do not use water for cooling. The scope of the CX does not include the construction or operation of power plants. If a utilization plan is proposed, the potential for the possibility of conflicts over water use that may be associated with any proposed geothermal power plant would be reviewed during the NEPA review associated with a proposed utilization project for geothermal development.

Comment 12—Produced hazardous waste: At least one commenter expressed concern that geothermal exploration can produce hazardous waste that requires safe disposal.

Response 12: Geothermal resource confirmation activities do not normally produce hazardous waste because geothermal resource confirmation activities largely consist of drilling wells—using water and mud to drill, then placing steel casing and cement to construct a well bore. The mud is generally naturally occurring inert clay, such as bentonite or barite. If a particular project would involve an atypical use of materials with potential to adversely affect water quality, the BLM would consider that fact as part of its consideration of extraordinary circumstances.

Comment 13—Cumulative Effects: At least five commenters expressed concern that projects approved using the CX would not account for analysis of cumulative effects and connected or closely related actions. At least one commenter suggested that all environmental reviews for geothermal exploration projects should include analysis of cumulative effects and connected actions of potential geothermal projects in one NEPA document. Additionally, at least one commenter expressed concern that the proposed CX was unclear about whether a proponent would be required to abandon a well and proceed to

reclamation if the BLM was simultaneously conducting a NEPA review for a utilization development proposal.

Response 13: Before authorizing a project in reliance on a CX, the BLM must complete an extraordinary circumstances review that includes evaluation of whether its proposed action has the potential to have “a direct relationship to other actions with individually insignificant but cumulatively significant environmental effects.” 43 CFR 46.215(f). Therefore, unless the Responsible Official affirmatively determines that the proposed action does not have such a potential, the BLM cannot rely on this CX. Geothermal exploration, resource confirmation, and utilization are distinct actions that are not dependent on each other. None of these three phases automatically triggers any other phase of geothermal development, and the BLM retains authority to impose conditions or deny permits at each phase. If the project proponent does not find a suitable geothermal resource, then the project proponent would not proceed to the next phase and site reclamation would commence; however, if a proponent does find suitable geothermal resource and proceeds to the next phase, separate authorization for that next phase, supported by a NEPA review, is required. The BLM does not envision requiring a project proponent to proceed to reclamation while processing an application for approval of a utilization (production) plan.

Comment 14—BLM objectivity: One commenter expressed concern with the objectivity of the BLM in developing the proposed CX and suggested that establishment of the CX was a “giveaway” to energy industries.

Response 14: The Federal Land Policy and Management Act of 1976, as amended, requires the BLM to manage the public lands for multiple use and sustained yield unless otherwise provided by law. Not all lands need to be managed for the same uses; “multiple use” is defined as including, among other values, “a combination of balanced and diverse resource uses that takes into account the long-term needs of future generations for renewable and non-renewable resources” (43 U.S.C. 1702(c)). In accordance with the CEQ regulations (40 CFR 1500.5(a)), the BLM is proposing this CX to improve efficiency in processing applications for geothermal resource confirmation that normally have no significant effects. The BLM evaluated the potential for a geothermal resource confirmation CX independently without external influence, in accordance with existing

laws and regulations. The BLM reviewed 26 environmental assessments related to geothermal resource confirmation projects as well as 20 environmental assessments for oil and gas drilling projects that supported FONSI, and subsequently confirmed that no unanticipated effects occurred because of project implementation. The Substantiation Report was available to the public during the 30-day comment period following **Federal Register** publication of the proposed CX. In addition, BLM consulted with CEQ on the development of this CX, as required by 40 CFR 1507.3(b).

Comment 15—Site-specific mitigation measures: At least one commenter expressed concern that, although geothermal resource confirmation projects approved through the proposed CX would be subject to mandatory design features, the CX approval process would not consider or include site-specific mitigation measures typically developed during the NEPA process through an EA.

Response 15: Design elements include the requirements or limitations that are outlined in applicable RMPs, geothermal lease terms, and other relevant requirements (applicable Federal and State laws, regulations, and policy) to avoid or minimize environmental consequences and optimize efficient implementation to meet resource objectives in the location where the geothermal resource confirmation project would occur, if approved. As such, the BLM ensures that applicants are aware of these design elements and applicants can change their intended projects as first proposed to incorporate any design elements, or the BLM can include the elements in the permit approval through a COA. The range of potential effects and common protective measures are familiar to the BLM and to operators. Regardless of the level of analysis that the BLM conducts for NEPA compliance, all geothermal development decisions and activities must be consistent with the applicable RMPs and lease stipulations placed on the parcel. Activities that are not in conformance with the BLM RMP decisions and lease stipulations are prohibited and will not be authorized, regardless of whether the BLM complies with NEPA through an EIS, EA, or a CX (see response to comment 8). Therefore, the CX relies on the limits in the applicable RMP and lease terms to ensure that the actions approved in reliance on the CX would include appropriate design elements and not have significant effects. In addition, for any proposed action that the BLM intends to approve in reliance on the

CX, the BLM would evaluate potential effects to resources through the Department's extraordinary circumstances review process set forth at 43 CFR 46.205 and 215. This review would be documented and included in the information posted on BLM's NEPA register website. If the Responsible Official cannot rely on the CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c).

Comment 16—Suggested revisions to allowable acreage: At least 2 commenters suggested reducing the 20 acres of allowable surface disturbance proposed in the CX, while at least 1 other commenter suggested that the BLM expand the acreage amount of allowable surface disturbance.

Response 16: To support the development of the CX, in its Substantiation Report (Addresses section), the BLM examined the range of surface disturbance in 26 geothermal projects analyzed in EAs that all supported FONSI, and that were completed between 2005 and 2019, to identify potential effects resulting from the kinds of activities normally included in geothermal resource confirmation operations plans, as outlined in the Department's regulations at 43 CFR part 3200, subpart 3260. As discussed in the Substantiation Report, the EAs and associated FONSI were reviewed to determine the scope of environmental effects anticipated to result from the proposed actions. The size and scale of geothermal resource confirmation projects reviewed in those documents were the basis of the surface disturbance limitations chosen for the CX, and as such the BLM declines to modify the allowable acreage.

Comment 17—Total surface disturbance: At least one commenter recommended that the CX should include all types of routes, including drive and crush (routes that are made when vehicles drive over and crush any vegetation rather than by excavation or laying of any road surface) as part of the 20-acre disturbance limit.

Response 17: The BLM concurs and notes that all routes, including drive and crush, will be considered as part of the 20-acre disturbance limitation within the CX, which is standard practice for any BLM proposed action.

Comment 18—Potential effects from different kinds of geothermal resource confirmation projects: At least one commenter expressed concern that the proposed CX failed to account for different kinds of geothermal resource

confirmation projects with differing construction requirements that may result in effects to resources not contemplated by the proposed CX. Additionally, the commenter expressed concern that the CX fails to distinguish between or prioritize those projects that are most likely to minimize environmental effects.

Response 18: In its Substantiation Report, the BLM contemplated different well pad, well diameter, and access road requirements for confirming a resource. For example, as described within the Substantiation Report, within the 26 projects analyzed in the EAs reviewed, resource well pad size ranged from 2.5 to 4.1 acres, depending on the well diameter size, as well as the number of wells proposed per pad. The 20 acres of disturbance provides flexibility for these various resource confirmation project requirements. The commenter did not identify any specific kind of geothermal resource confirmation project that the BLM did not adequately consider in developing this CX. The BLM's prioritization of different geothermal projects is outside the scope of establishment of a CX.

Comment 19—Geothermal drill permits: At least one commenter expressed concern that the proposed CX was limited to approval of an operations plan, noting that geothermal resource confirmation projects require approval of a GDP and sundry notice in addition to approval of an operations plan.

Response 19: The BLM concurs with the commenter and has updated the text of the CX to make clear that it would apply to approval of both operations plans and associated GDPs. The analysis in the Substantiation Report includes the approval of GDPs. Therefore, the inclusion of GDPs in the CX clarifies the text while not changing the scope of the CX.

Comment 20—Potentially limiting multiple-use: At least one commenter expressed concern that geothermal projects eliminate all other public uses of multiple-use land, including wildlife habitat and public recreation.

Response 20: The Federal Land Policy and Management Act of 1976, as amended, requires the BLM to manage the public lands according to the principles of multiple use and sustained yield, and to manage the lands under land use plans (*i.e.*, RMPs) developed consistent with these principles. The BLM's RMPs and site-specific lease stipulations serve to protect resources on public lands, including wildlife habitat areas. FLPMA's definition of "multiple use" contemplates "the use of some land for less than all the resources." 43 U.S.C. 1702(c).

Comment 21—Previously disturbed lands: At least one commenter recommends the use of previously disturbed lands, BLM lands identified for disposal, and other less environmentally sensitive land for geothermal energy projects.

Response 21: The BLM considers the appropriateness of using previously disturbed lands, lands identified for disposal, and other less environmentally sensitive land in relation to proposed actions, consistent with the applicable RMP, regardless of the level of NEPA compliance conducted.

Comment 22—Extraordinary circumstances review: At least one commenter expressed concern that the discretionary nature of extraordinary circumstances review could lead to variation in how the criteria are evaluated.

Response 22: For any proposed action that the BLM intends to approve in reliance on the CX, the BLM must evaluate effects to resources through the Department's extraordinary circumstances review process set forth at 43 CFR 46.205 and 46.215. This review would be documented and included in the information posted on the BLM's NEPA register. If the Responsible Official cannot rely on the CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c). The Responsible Official relies upon the knowledge and experience of the BLM professionals when determining if extraordinary circumstances are present.

Comment 23—Resource management plan protections: At least one commenter expressed concern that prior geothermal leasing EAs and older RMPs do not sufficiently analyze or provide protections for resources against effects caused by geothermal resource confirmation projects. Another commenter suggested updating the 2008 Programmatic Environmental Impact Statement for Geothermal Leasing in the Western United States.

Response 23: Although some RMPs date back to the 1980s, the 2008 Programmatic Environmental Impact Statement for Geothermal Leasing amended 114 RMPs that were signed prior to 2008, in the 12 western states of Alaska, Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming, by adding design elements appropriate for exploration and development of geothermal resources. Additionally, responsible officials have the option of conducting additional

NEPA analysis if the existing analysis supporting the lease and the RMP is not sufficient. Suggestions or proposals regarding updating the 2008 Programmatic Environmental Impact Statement for Geothermal Leasing in the Western United States or revising or amending BLM land use plans are outside the scope of the establishment of the new CX in this notice.

Comment 24—Unanticipated effects: At least one commenter expressed concerns that unanticipated effects occurred from three past geothermal projects.

Response 24: The BLM is unaware of any unanticipated effects that occurred as a result of any resource confirmation projects, and the commenter did not identify geothermal resource confirmation projects that resulted in unanticipated effects. Nor did the commenter identify these potential unanticipated effects.

IV. Additional Clarifying Changes

While considering the comments and recommendations the BLM received during the public comment period on the proposed CX revisions, the BLM incorporated several changes to the CX text proposed in October 2024. These changes and the rationale for them are described below.

In response to a comment recommendation, the BLM added “and associated Geothermal Drilling Permits” after “operations plan” in the CX text to make it clear that the CX includes issuance of Geothermal Drilling Permits associated with an approved operations plan for geothermal resource confirmation (as required in 43 CFR 3261.11). The BLM also added the word “a” before “geothermal resource confirmation” for readability. The BLM replaced the word “wells” with “project” after “geothermal resource confirmation” because the CX supports the entire project and not just individual wells. The BLM removed the following from the CX text “wells (e.g., core drilling, temperature gradient wells, and/or resource wells), including, but not limited to, construction of temporary routes for access, reclamation of all surface disturbance, and direct testing (e.g., flow tests) to confirm the existence of a geothermal resource, to improve injection support, or to demonstrate communication between wells” because these examples of geothermal resource confirmation operations are not needed to define the scope of the CX. At the same time, the BLM added “pursuant to 43 CFR part 3200, subpart 3260” for clarification. These edits do not change the scope of the CX as proposed.

The BLM changed the format from a bulleted list to an alphabetized list. The BLM added a new third provision (c), “Requires reclamation of all surface disturbances when their intended purpose has been fulfilled,” to clarify that that all surface disturbance is reclaimed as soon as its intended purpose has been fulfilled. The proposed CX had focused on reclamation of temporary routes and did not explicitly address other reclamation.

In the third (c) and fourth provisions (d), the BLM replaced “Includes” with “Requires” making it clear that reclamation is a requirement for approval of an operations plan. Additionally, the BLM created a new fifth provision (e) from the second sentence of the third provision (c), which is now in the fourth provision (d), by rewording it to be consistent with the other provisions; therefore, the text proposed as “unless a temporary route is specifically intended to accommodate public use; use of the temporary route is limited to project-specific geothermal resource confirmation purposes;” is changed to “Does not make a temporary route available for public use unless a temporary route is specifically intended to accommodate public use;”.

The new sixth provision (f), after the word “used”, the BLM changed the word “to” to “so as to” for readability. Additionally, in the new sixth provision (f), “of the temporary route and areas where the vegetative” has been changed to “of vegetative cover on the temporary route” to simplify the language. Finally, in the new sixth provision (f), BLM changed the words, “at least” to “at most” to show that the 10-year requirement is the maximum time allowed for reclamation.

V. Categorical Exclusion Justification

The BLM finds that the category of actions described in the CX (below) does not normally have a significant effect on the human environment, individually or in aggregate. This finding is based on the analysis of the BLM's proposal to establish the CX in the BLM's Substantiation Report and supporting record documents. The Substantiation Report explains that, because the restrictions on the proposed Geothermal Resource Confirmation CX limit surface disturbance and access road construction, and the required design elements incorporated into the operations plan and GDP approvals are effective to address environmental effects, the BLM concludes that the category of actions included in this CX does not normally result in significant environmental effects, individually or in

the aggregate. The Substantiation Report summarizes the review of 26 geothermal resource confirmation EAs that supported FONSIs, as well as 20 similar oil and gas drilling project EAs, to demonstrate the finding that actions under the revised CX would not normally result in significant effects to the human environment. The Substantiation Report includes evaluation of the BLM NEPA analyses and available scientific research on the effects of routine actions included in the new CX over time and over different geographic areas, and following consideration of comments from the public.

The Department and the BLM consulted with CEQ on the proposed and final CX. CEQ issued a letter stating that it has reviewed the CX and found it to be in conformity with NEPA and the CEQ NEPA regulations. Therefore, the Department adds the final CX to the BLM's NEPA procedures at Department Manual at 516 DM 11.9. When applying this CX, Responsible Officials within the BLM will evaluate proposed actions covered by the CX to determine whether any extraordinary circumstances are present in accordance with the requirements in the Department's NEPA implementing procedures at 43 CFR 46.205 and 46.215. This review would be documented and included in the information posted on the BLM's NEPA register. If the Responsible Official cannot rely on this CX to support a decision to authorize geothermal resource confirmation activities due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS before doing so, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c). When applying this CX, the BLM will document its reliance and publish the documentation on the BLM NEPA register website.

VI. Amended Text for the Departmental Manual

BLM's NEPA procedures in 516 DM 11 is modified as follows:

Part 516: National Environmental Policy Act of 1969

Chapter 11: Managing the NEPA Process—Bureau of Land Management

11.9 Actions Eligible for a Categorical Exclusion (CX)

B. Oil, Gas, and Geothermal Energy

(7) *Approval of an operations plan and associated Geothermal Drilling Permits for a geothermal resource confirmation project, pursuant to 43 CFR part 3200, subpart 3260; which:*

- a. Does not include resource utilization;*
- b. Does not exceed 20 acres of total (contiguous or noncontiguous) surface disturbance;*

c. Requires reclamation of all surface disturbances when their intended purpose has been fulfilled;

d. Requires reclamation of temporary routes when their intended purpose(s) has been fulfilled, unless through a separate review and decision-making process the BLM incorporates and appropriately designates the route as part of its transportation system;

e. Does not make a temporary route available for public use unless the temporary route is specifically intended to accommodate public use;

f. Requires temporary routes to be constructed and used so as to allow for the reclamation, by artificial or natural means, of vegetative cover on the temporary route and areas where the vegetative cover was disturbed by the construction or use of the route, and requires such treatment to be designed to reestablish vegetative cover as soon as possible, but at most within 10 years after approved reclamation commences; and,

g. Includes design elements to protect resources and resource uses consistent with the applicable Resource Management Plan, laws, regulations, and lease terms.

Authorities: NEPA, the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*); E.O. 11514, March 5, 1970, as amended by E.O. 11991, May 24, 1977; and CEQ regulations (40 CFR 1507.3).

Stephen G. Tryon,

Director, Office of Environmental Policy and Compliance.

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

[MO 4500183156]

Notice of Adoption of Categorical Exclusions under Section 109 of the National Environmental Policy Act

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior (Department) is notifying the public and documenting the adoption of 11 Department of Energy (DOE) and 6 National Telecommunications Information Administration (NTIA) categorical exclusions (CXs) for use by the Bureau of Land Management (BLM) and the Bureau of Indian Affairs (BIA), under section 109 of the National Environmental Policy Act (NEPA). In accordance with section 109, this notice identifies the types of actions for which the BLM and BIA will rely on the CXs, the considerations that the BLM and BIA will use in determining the applicability of the CXs, and the consultation between the agencies on the use of the CXs, including

application of extraordinary circumstances.

DATES: The adoption is effective January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

BLM: Amelia Savage, Senior Planning and Environmental Analyst, Division of Support, Planning and NEPA, alsavage@blm.gov, telephone (480) 307–8665. BIA: Chester McGhee, Branch Chief, Environmental Services, chester.mcgee@bia.gov, telephone (615) 289–3390.

SUPPLEMENTARY INFORMATION:

Background

Program Background

1. Realty

The BLM and BIA realty programs process applications for rights-of-way or other land use authorizations that facilitate commercial, non-commercial, recreational, and conservation activities including communication sites, transmission lines, fiber optic infrastructure, and renewable energy.

2. Recreation

The BLM's recreation program supports and delivers a wide variety of recreational experiences including, but not limited to, camping, hunting, fishing, hiking, horseback riding, off-highway vehicle driving, mountain biking, bird watching, and various winter sports. The program manages over 4,000 recreation sites and associated facilities, in addition to over 400 fee sites. An estimated 82 million visitors enjoy outdoor recreation on BLM-managed public lands every year. The recreation program also supports the bureau's travel and transportation management program, which includes trails, roads, primitive roads, and associated parking lots and trail heads.

3. Resource Protection

The BLM's and BIA's Wildlife and Cultural Heritage Programs manage wildlife habitat to help ensure self-sustaining, abundant, and diverse populations of wildlife on public and Tribal lands and preserve public and Tribal lands and their resources that are important to the public and to American Indian and Alaska Native communities to ensure that current and future generations retain the ability to connect to their natural and cultural heritage.

4. Minerals

The BLM manages Federal mineral resources pursuant to the Mineral Leasing Act of 1920 (MLA), 30 U.S.C. 181 *et seq.*, and other legal authorities.

BIA is authorized to approve leases for exploration, extraction of, or removal

of certain minerals on Indian Lands under the Indian Mineral Leasing Act of 1938 (IMLA); the Act of March 3, 1909; the Indian Mineral Development Act of 1982 (IMDA); and other Tribe-specific statutes. BIA regulations implementing the IMLA, the 1909 Act, and the IMDA are found at 25 CFR parts 211, 212, and 225, respectively.

National Environmental Policy Act and Categorical Exclusions

NEPA as amended at, 42 U.S.C. 4321–4347, requires all Federal agencies to consider the environmental impact of their proposed actions before deciding whether and how to proceed. 42 U.S.C. 4321, 4332. NEPA aims to ensure agencies consider the environmental effects of their proposed actions in their decision-making processes and inform and involve the public in those processes. 42 U.S.C. 4331. The NEPA created the Council on Environmental Quality (CEQ), which promulgated NEPA implementing regulations, 40 CFR parts 1500 through 1508 (CEQ NEPA regulations).

Under NEPA and the CEQ's NEPA implementing regulations, a Federal agency can establish CXs—categories of actions that normally do not have a significant effect on the human environment, individually or in the aggregate, and therefore do not require preparation of an environmental assessment (EA) or an environmental impact statement (EIS)—in their agency NEPA procedures. 42 U.S.C. 4336(e)(1); 40 CFR 1501.4, 1507.3, 1508.1(e). If an agency determines that a CX covers a proposed action, it then evaluates the proposed action for extraordinary circumstances in which a normally excluded action may have a significant effect. 40 CFR 1501.4(b). If no extraordinary circumstances are present, the agency may apply the CX to the proposed action without preparing an EA or EIS. 42 U.S.C. 4336(a)(2), 40 CFR 1501.4.

Section 109 of NEPA, enacted as part of the Fiscal Responsibility Act of 2023, allows a Federal agency to “adopt” or another agency’s CX for a category of proposed agency actions. 42 U.S.C. 4336(c). To rely on another agency’s CXs under Section 109, the adopting agency must identify the relevant CX listed in another agency’s (“establishing agency”) NEPA procedures that cover the adopting agency’s category of proposed actions or related actions; consult with the establishing agency to ensure that the proposed adoption of the CX for a category of actions is appropriate; identify to the public the CX that the adopting agency plans to use for its proposed actions; and

document adoption of the CX. 42 U.S.C. 4336c. The BLM and BIA have prepared this notice to describe how they have met applicable statutory requirements for the adoption of 17 CXs and to notify the public of these adoptions. Eleven of these CXs were established by DOE: 10 CFR part 1021, subpart D, appendix B, paragraphs B1.11, B1.13, B1.19, B1.20, B4.6, B4.7, B4.13, B4.14, B5.12, B5.16, and B5.23. Six of these CXs were established by NTIA: 89 FR 22688, April 2, 2024, Categorical Exclusions, Operational, C–2, C–4, C–5, C–6, C–7, and C–8.

The Department’s NEPA procedures, codified at 43 CFR part 46, address compliance with NEPA. The Department’s protocol for application of CXs is at 43 CFR 46.205. The Department’s CXs available to all bureaus within the Department are listed in 43 CFR 46.210. Additional Department-wide NEPA policy is found in the Department’s Departmental Manual (DM), in chapters 1 through 4 of part 516. Supplementary NEPA procedures for the Department’s bureaus are published in additional chapters in part 516 of the DM. Chapter 10 and 11 of the 516 DM covers the BIA’s and the BLM’s NEPA procedures, respectively. The BLM CXs are listed in 516 DM 11.9 and BIA’s CXs are listed in 516 DM 10.5.

Categorical Exclusions That Are Adopted

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B1.11, regarding installation of fencing, for adoption. Examples of actions for which BLM and BIA programs would rely on the CX include, but are not limited to, installation of fences to mark the boundary of facilities such as visitor centers, recreation sites, or communication sites; along highways to guide wildlife to safe passages to facilitate migration; and to protect resources.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B1.13, regarding pathways, short access roads, and rail lines, for adoption. Examples of actions for which the BLM’s and BIA’s recreation and realty programs would rely on the CX include, but are not limited to, construction of walkways and trails, bicycle paths, small outdoor fitness areas, and short access roads and rail lines.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B1.19, regarding microwave, meteorological, and radio towers, for adoption. Examples of actions for which the

BLM’s and BIA’s realty programs would rely on the CX include, but are not limited to, modification, operation, and removal of existing communications facilities and associated infrastructure. BIA would rely on this CX for associated approvals for siting or construction of a new communication facility, but the BLM would not rely on this CX to site or construct a new communication facility. BIA would rely on this CX to approve Wind Energy Evaluation Leases. Additionally, the BLM and BIA may rely on this CX to authorize new land uses that support adjacent communications facilities. The reference to B(4)(iv) in this CX is for DOE’s “Integral Elements”.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B1.20, regarding protection of cultural resources, fish and wildlife habitat, for adoption. Examples of actions for which the BLM’s and BIA’s cultural heritage, wildlife, fisheries, and other programs would rely on the CX include, but are not limited to, small habitat restoration projects, fencing for resource protection, and installation of fish passage structures.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B4.6, regarding additions and modifications to transmission facilities, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, transmission line reconductoring to upgrade facilities, replacing damaged insulators, installing fire monitoring equipment, and paving of roads to access transmission lines in previously disturbed or developed facility areas.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B4.7, regarding adding fiber optic cables, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, installing fiber optic lines within existing rights-of-ways, or previously disturbed utility corridors, and associated vaults and pulling and tensioning sites outside of rights-of-way in nearby previously disturbed or developed areas.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B4.13, regarding upgrading and rebuilding existing powerlines, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, upgrading or rebuilding existing powerlines, replacing poles to different material, and placing emergency control and fault

notification equipment on poles within existing powerline right-of-way or within otherwise previously disturbed or developed lands. Additionally, powerlines would be upgraded or rebuilt within the existing right-of-way boundary and could extend into a small (as discussed at 10 CFR 1021.410(g)(2)) area beyond such lands as needed to comply with applicable electrical standards. The BLM and BIA would incorporate appropriate design and construction standards, control technologies, and best management practices into the authorizations.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B4.14, regarding construction and operation of electrochemical-battery or flywheel energy storage systems, for adoption. Examples of actions for which BLM and BIA would rely on this CX include, but are not limited to, construction, operation, upgrading, retrofitting, and decommissioning of electrochemical-battery or flywheel energy storage systems within a previously disturbed or developed area or within a small area contiguous to a previously disturbed or developed area consistent with the text of the CX, such as for installation of back up battery systems for wind and solar energy generation and at communication facilities.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B5.12, regarding workover of existing wells, for adoption. Examples of actions for which the BLM and BIA would rely on the CX include, but are not limited to, projects involving the reuse of existing well facilities for in situ recovery of locatable and non-energy leasable minerals such as lithium or similar mineral bearing brines, sedimentary aquifer hosted uranium deposits, or subsurface non-energy leasable resources, and conversion of existing wells to aid in carbon sequestration consistent with the CX text.

The CX refers to DOE best practices and protocols, which refer to conditions that DOE places on the conduct of work. These conditions are specific to the type and location of the project. "Best management practices" are not specified in the CXs because they change over time and vary by location and technology. The BLM and BIA would use their respective best management practices and industry standards when using CXs that mention "best practices and protocols."

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B5.16, regarding solar photovoltaic systems, for

adoption. Examples of actions for which the BLM and BIA would rely on the CX include, but are not limited to, installation of solar photovoltaic systems on or adjacent to existing facilities (*i.e.*, recreation sites, fire annex buildings, and other BLM and BIA owned facilities). Additionally, BIA would rely on this CX for construction of solar photovoltaic systems on previously disturbed or developed lands.

The BLM and BIA have identified the DOE CX, found at 10 CFR part 1021, subpart D, appendix B, paragraph B5.23, regarding electric vehicle charging stations, for adoption. Examples of actions for which the BLM and BIA would rely on the CX include, but are not limited to, installation of electric vehicle charging stations at BLM and BIA facilities, rest stops, or on Indian lands.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-2, regarding outdoor research activities, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, the examples listed in the CX text, as well as geotechnical surveys to properly site facilities and structures.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-4, regarding new construction or improvement of non-tower structures, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, addition of equipment and structures (such as emergency power facilities) to support existing communication facilities and new construction of facilities that support communication systems, within a previously disturbed area that cause no more than 1 acre of disturbance.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-5, regarding existing microwave or radio communication facilities, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, installing, operating, maintaining, retrofitting, upgrading, repairing, removing, and/or replacing infrastructure (examples listed in CX text) within an existing communication facility.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-6, regarding new construction or improvement of temporary buildings or experimental equipment, for adoption. Examples of actions for which the BLM

and BIA would rely on this CX include, but are not limited to, new construction or improvement of temporary buildings or experimental equipment such as installation of small instrument panels and other small facilities outside the existing communication facility, installation of buildings that will aid in carbon sequestration, and seismic testing stations on previously disturbed ground consistent with the CX text.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-7, regarding new construction of self-supporting wireless communication towers, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, support for approval of the installation of communication towers to aid in placement of wind turbines and installation of self-supporting towers within an existing communication site, consistent with the CX text.

The BLM and BIA have identified the NTIA CX, found at 89 FR 22688, Categorical Exclusions, Operational, C-8, regarding aerial or buried utility communication and security systems, for adoption. Examples of actions for which the BLM and BIA would rely on this CX include, but are not limited to, support for approval of installation, reconstruction, replacement and operation of water, sewer, electrical, other utilities, and fiber optic cables that are within existing rights-of-ways, easements, grants of license, distribution systems, facilities, or similar arrangements, such as previously disturbed areas.

Consultation With DOE and NTIA and Determination of Appropriateness

The BLM and BIA consulted with DOE and NTIA on the appropriateness of the adoption of these CXs for the BLM's and BIA's use in September and October 2024. The consultations included a review of DOE's and NTIA's experience developing and applying these CXs, as well as the types of actions for which the BLM and BIA plan to utilize the CXs. The BLM and BIA actions are similar in type and scope to the actions that DOE and NTIA conduct and therefore the effects of the BLM's and BIA's actions are expected to be similar to the effects of DOE and NTIA actions, which are not significant, assuming compliance with all applicable conditions and absent the existence of extraordinary circumstances. DOE regulations at 10 CFR 1021 subpart D, appendix B also identify "conditions that are integral elements of the classes of actions in

appendix B” that apply to the CXs that BLM and BIA are adopting. As described below, the BLM and BIA will ensure that proposed actions comply with these “DOE Integral Elements” when relying on CXs adopted from DOE. The Department has determined that adoption of the CXs for the BLM’s and BIA’s use as described in this notice is appropriate.

DOE Integral Elements

When the BLM and BIA intend to rely on a CX adopted from DOE as described in this notice, the Responsible Official will evaluate the proposed action against the DOE’s Integral Elements, which are additional conditions for reliance on each CX. The Responsible Official will only rely on a CX adopted from DOE as identified in this notice if the proposed action complies with the DOE Integral Elements. The DOE Integral Elements are described in 10 CFR 1021 subpart D, appendix B. The BLM and BIA will use their respective environment, safety, and health protocols when using these CXs.

Consideration of Extraordinary Circumstances

In consultation with DOE and NTIA, the BLM and BIA evaluated the extraordinary circumstances to be considered when applying these CXs. When applying these CXs, Responsible Officials (43 CFR 46.30) within the BLM and BIA will evaluate proposed actions covered by the CXs to determine whether any extraordinary circumstances, listed at 43 CFR 46.215, are present that would preclude reliance on the CX. The Department’s extraordinary circumstances include, in part, consideration of impacts on public health and safety; natural resources and unique geographic characteristics such as historic or cultural resources; park, recreation, or refuge lands; wilderness areas; wild or scenic rivers; national natural landmarks, sole or principal drinking water aquifers; prime farmlands; wetlands; floodplains; national monuments; migratory birds; and other ecologically significant or critical areas; unresolved conflicts concerning alternative uses of available resources; unique or unknown environmental risks; precedent for future decision-making; historic properties; listed species or critical habitat; low income or minority populations; access by Indian religious practitioners to, and for ceremonial use of, Indian sacred sites and the physical integrity of those sites; and contribution to the introduction, continued existence, or spread of invasive weeds or non-native invasive species.

The Department’s list of extraordinary circumstances addresses those of the DOE found at 10 CFR 1021.410(b)(2) and those of the NTIA found at 89 FR 22688; therefore, BLM and BIA Responsible Officials intending to rely on these CXs will review whether the proposed action has the potential to result in significant effects as described in the Department’s extraordinary circumstances. If the Responsible Official cannot rely on a CX to support a decision on a particular proposed action due to extraordinary circumstances, the Responsible Official will prepare an EA or EIS, consistent with 40 CFR 1501.4(b)(2) and 43 CFR 46.205(c).

Notice to the Public and Documentation of Adoption

This notice identifies to the public that the BLM and BIA are adopting 11 DOE CXs and 6 NTIA CXs for the BLM’s and BIA’s use. The notice identifies the types of actions to which the BLM and BIA would apply these CXs. The documentation of the adoptions is available at <https://www.blm.gov/programs/planning-and-nepa/what-informs-our-plans/nepa> for the BLM, <https://www.bia.gov/service/nepa-compliance> for BIA and at <https://www.doi.gov/oepe/nepa/categorical-exclusions>. The BIA and the BLM will add the adopted CXs to their respective NEPA DM Chapters, 516 DM 10 and 11.

Authorities

National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Stephen G. Tryon,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 2025–01057 Filed 1–15–25; 8:45 am]

BILLING CODE 4331–27–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251]

Notice of Availability of the Record of Decision for the Jove Solar Project, La Paz County, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) announces the availability of the Record of Decision for the Jove Solar Project, located in La Paz County, Arizona. The

Record of Decision signed on January 3, 2025, constitutes the decision of the BLM, as approved by the Department of the Interior.

DATES: The Department of the Interior approved the BLM’s Record of Decision on January 3, 2025.

ADDRESSES: The Record of Decision, Final Environmental Impact Statement, and other documents pertinent to the Jove Solar Project are available for review on the BLM ePlanning project website at: <https://eplanning.blm.gov/eplanning-ui/project/2017881/510>. Printed copies of the Record of Decision are available at the BLM Yuma Field Office, 7341 East 30th Street, Yuma, Arizona 85365.

FOR FURTHER INFORMATION CONTACT:

Derek Eysenbach, Project Manager, at deysenbach@blm.gov, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona 85004, or by phone at (602) 417–9505. 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 for contacting Mr. Eysenbach. 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 Department of the Interior has approved the BLM’s decision to issue a right-of-way grant for an initial term of 30 years for construction, operation, maintenance, and decommissioning of a utility-scale solar photovoltaic facility, called the Jove Solar Project. The Project encompasses 3,495 acres of public lands administered by the BLM Yuma Field Office and 38 acres administered by La Paz County, located in southeastern La Paz County, Arizona, south of Interstate 10 midway between Phoenix and the California border, approximately 22 miles east-southeast of the community of Brenda and the I–10/Highway 60 junction, and 30 miles west of the community of Tonopah. The Jove Solar Project consists of up to 1.2 million solar photovoltaic modules and associated infrastructure, new and improved roads, and powerlines for collection and transmission of electricity to the Cielo Azul Switchyard adjacent to the Ten West Link 500-kilovolt transmission line and will have a generation capacity of 600 megawatts or more.

The decision to authorize this energy generation project on public lands is consistent with FLPMA and the BLM’s right-of-way regulations ((43 U.S.C.

1761) (<https://www.govinfo.gov/link/uscode/43/1761>); ((43 CFR part 2800) (<https://www.ecfr.gov/current/title-43/part-2800>)). Approval of this right-of-way grant constitutes the final decision of the Department of the Interior and is not subject to appeal under Departmental regulations at 43 CFR part 4 (<https://www.ecfr.gov/current/title-43/part-4>).

(Authority: 43 U.S.C. 1761 and 43 CFR part 2800)

Raymond Suazo,

State Director.

[FR Doc. 2025-01042 Filed 1-15-25; 8:45 am]

BILLING CODE 4331-12-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

DEPARTMENT OF AGRICULTURE

Forest Service

[PO4820000251]

Records of Decision and Approved Resource Management Plan for Bears Ears National Monument and Approval of the Amendment to the Manti-La Sal National Forest Land and Resource Management Plan in Utah

AGENCY: Bureau of Land Management, Interior; Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM), and U.S. Department of Agriculture, Forest Service (USDA Forest Service) (jointly “the Agencies”) announce the availability of the Records of Decision (ROD) for the Approved Resource Management Plan (RMP) for BLM-administered portions of the Bears Ears National Monument (BENM) and a ROD for the Approval of the Amendment to the 1986 Manti-La Sal National Forest Land and Resource Management Plan (LRMP) that adopts the Approved RMP for USDA Forest Service-administered portions of BENM located in southeastern Utah. The Department of the Interior Principal Deputy Assistant Secretary for Land and Minerals Management signed the BLM ROD, which constitutes the final decision of the BLM and makes the Approved RMP effective immediately on BLM-administered lands. The Manti-La Sal National Forest Supervisor signed the USDA Forest Service ROD approving an amendment to the LRMP to adopt the Approved RMP. The amendment to the LRMP will become effective 30 days

after the publication of this notice in the **Federal Register**.

ADDRESSES: The RODs and Approved RMP are available online at <https://eplanning.blm.gov/eplanning-ui/project/2020347/510>. Printed copies of the BLM ROD/Approved RMP are available for public inspection at the BLM Monticello Field Office, 365 North Main, Monticello, Utah 84535, and BLM Utah Public Room, 440 West 200 South, Ste. 500, Salt Lake City, UT 84101 or can be provided upon request by contacting BLM Project Manager Jill Stephenson at jstephenson@blm.gov or 435-259-2141. The USDA Forest Service ROD/Approved RMP are available for public inspection at the Manti-La Sal National Forest Monticello Ranger District, 397 North Main Street, Monticello, Utah 84535 or can be provided upon request by contacting Michael Engelhart at michael.engelhart@usda.gov.

A copy of the Protest Resolution Report is available at: <https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports>.

FOR FURTHER INFORMATION CONTACT: Jill Stephenson, Project Manager, telephone 435-259-2100; address Bureau of Land Management Canyon Country District 82 E Dogwood, Moab, Utah 84532; email jstephenson@blm.gov regarding the BLM ROD. Michael Engelhart, District Ranger, telephone 435-636-3341; address Manti-La Sal National Forest Monticello District PO Box 820, Monticello, UT 84535; email michael.engelhart@usda.gov, regarding the USDA Forest Service ROD. 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 for contacting Ms. Stephenson. 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 planning area encompasses approximately 1.36 million acres of Federal land administered by the BLM and USDA Forest Service in San Juan County, Utah. Presidential Proclamation 10285 directs the Agencies to “prepare and maintain a new management plan for the entire monument” for the specific purposes of “protecting and restoring the objects identified [in Proclamation 10285] and in Proclamation 9558.” The RMP’s purpose is to provide a management framework, including goals, objectives,

and management direction to guide BENM management consistent with the protection of BENM objects and the management direction provided in Proclamation 10285. The USDA Forest Service amendment’s purpose is to incorporate the approved BENM RMP and update land management allocations of the BENM boundary area into the Manti-La Sal LRMP.

The Approved RMP is based on the Proposed RMP from the Final Environmental Impact Statement (EIS), with minor changes to management actions, goals, and best practices. All changes are described in each Agency’s ROD (section 1.2 in the BLM ROD and section 3 and 6 in the USDA Forest Service ROD). The Agencies were informed in the development of the Approved RMP by input from the public, including from the scoping and public comment periods on the EIS and from the protest period, cooperating agencies, State and local governments, including the Utah Division of Wildlife Resources, government-to-government consultation with Tribal Nations, the Monument Advisory Committee, the National Historic Preservation Act consultation, the Endangered Species Act consultation, and the Governor’s consistency review. The Approved RMP includes designation of the Aquifer Protection Area of Critical Environmental Concern, retains other existing Areas of Critical Environmental Concern, and closes portions of BENM to recreational shooting, among other management direction.

The BLM and USDA Forest Service provided the Proposed RMP/Final EIS to the public on October 4, 2024, for a 30-day protest period and received 40 protest letters. The USDA Forest Service adopted the BLM’s administrative review protest procedures, as provided by 36 CFR 219.59(a). The BLM and USDA Forest Service jointly signed a memorandum documenting the resolutions of all protests for both Agencies. The BLM Assistant Director for Resources and Planning resolved all protests. Responses to protest issues were compiled and documented in a Protest Resolution Report (see **ADDRESSES**). While no protests were granted, the Agencies made several edits to the Approved RMP text to improve clarity based on input received during the protest period.

The BLM provided the Proposed RMP/Final EIS to the Governor of Utah for a 60-day Governor’s consistency review on October 4, 2024. The Governor’s Office identified concerns and inconsistencies between the Proposed RMP/FEIS and the State and local plans, policies, and programs in a

letter received December 3, 2024. The BLM considered the concerns, and where not in conflict with the purposes, policies and programs of Federal laws and regulations applicable to public lands, accepted recommendations, which are described in sections 1.2 of the BLM ROD. As the changes were within the range of alternatives considered in the RMP/EIS, the BLM did not seek public comments on the recommendations that were accepted.

On January 8, 2025, the Governor appealed to the BLM Director the Acting State Director's decision not to accept or address all the State's recommendations, consistent with 43 CFR 1610.3–2. After careful review and consideration of the Governor's points, the Department of the Interior determined that the planning effort properly considered all applicable State and local plans, policies, and programs, and that no further changes are necessary to provide for a reasonable balance between the national interest and the State's interest. The BLM has published the reasons for the Department of the Interior's determination to reject the Governor's appeal and recommendations on its website (see **ADDRESSES**).

The Department of the Interior Principal Deputy Assistant Secretary for Land and Minerals Management signed the BLM ROD. The Manti-La Sal National Forest Supervisor signed the USDA Forest Service ROD.

(Authority: 36 CFR 219.13, 36 CFR 219.16, 36 CFR 219.17, 40 CFR 1501.9, 43 CFR 1610.2, and 43 CFR 1610.5–1)

Matthew A. Preston,
BLM Utah State Director, Acting.

Barbara Van Alstine,
Manti-La Sal National Forest Supervisor.
[FR Doc. 2025–00863 Filed 1–15–25; 8:45 am]

BILLING CODE 4331–25–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251]

Intent To Prepare an Environmental Impact Statement for the Oil and Gas Leasing Decisions in Seven States From February 2015 to December 2020

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: The Bureau of Land Management (BLM) intends to prepare an Environmental Impact Statement (EIS) for approximately 3,224 oil and gas leases sold in Colorado, Montana,

New Mexico, North Dakota, South Dakota, Utah, and Wyoming and issued pursuant to 74 individual lease sale decisions. The EIS will provide a comprehensive analysis of the potential environmental impacts from these leases, which have been remanded to BLM for further review, including the impacts of greenhouse gas emissions (to include the social cost of carbon) and other common impacts.

DATES: This notice initiates the public scoping process for the EIS. Comments on issues, impacts, and potential new alternatives to be analyzed, as well as on relevant information, studies, or analyses, may be submitted in writing until March 17, 2025. The BLM will announce on its website any additional venues for commenting during scoping.

ADDRESSES: You may submit comments by any of the following methods:

- Website: <https://eplanning.blm.gov/eplanning-ui/project/2036015/510>.
- Mail: BLM, Headquarters, Division of Fluid Minerals, Attention—Oil and Gas litigated leases EIS, 301 Dinosaur Trail, Santa Fe, New Mexico 87508.

FOR FURTHER INFORMATION CONTACT:

Janna Simonson, Project Lead, or John Ajak, Division Chief, via email at blm_hq_litigated_leases_EIS@blm.gov, or via telephone at 505–954–2000; or by mail at Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, NM 87508. You may also request to be added to the mailing list for the EIS. The 2022 supplemental EA may be found at the <https://eplanning.blm.gov/eplanning-ui/project/2022218/510>.

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 for contacting Ms. Headen. 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 BLM will review the environmental analyses for the leasing decisions that were challenged in the following lawsuits: *WildEarth Guardians v. BLM*, 19–cv–00505 (D.N.M.), 20–2146 (10th Cir.) (challenging leasing decisions in New Mexico); *WildEarth Guardians v. Bernhardt*, 16–cv–01724 (D.D.C.) (challenging leasing decisions in Colorado, Utah, and Wyoming); *WildEarth Guardians v. Bernhardt*, 20–cv–00056 (D.D.C.) (challenging leasing decisions in Colorado, Montana, New Mexico, North Dakota, South Dakota, Utah, and Wyoming); *WildEarth Guardians v. Bernhardt*, 21–cv–00175

(D.D.C.) (challenging leasing decisions in Colorado, New Mexico, Utah, and Wyoming); and *WildEarth Guardians v. Bernhardt*, 21–cv–00004 (D. Mont.) (challenging leasing decisions in Montana, North Dakota and South Dakota). Impacts to other resources were also raised in the subject complaints. The BLM may elect to include additional analysis in the EIS for resources and impacts beyond greenhouse gas emissions, climate change, and the social cost of greenhouse gases.

The area encompassed by the challenged oil and gas leases includes approximately 3.5 million acres within the States of Colorado, Montana, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. In September 2022, the BLM prepared and solicited public comments on the Supplemental Environmental Assessment Analysis for Greenhouse Gas Emissions Related to Oil and Gas Leasing in Seven States from February 2015 to December 2020. In consideration of new science and information related to greenhouse gas emissions, climate change, and the social cost of greenhouse gases (*e.g.*, the Department's adoption, on October 16, 2024, of new estimates of the social cost as the best available science), and the number of oil and gas leases under consideration across seven States, the BLM is electing to prepare an EIS, with associated opportunities for public comment. The number of leases and amount of acreage at issue may also warrant analysis of other common impacts, such as those to wildlife, water resources, and night skies.

The purpose of this public scoping process is to solicit information from the public related to these leases. Information received during this process will influence the development of the EIS and guide the scope of the environmental analysis.

The leasing decisions that will be analyzed in this EIS arise from BLM's responsibility under the Federal Land Policy and Management Act and the Mineral Leasing Act. The purpose and need for the EIS is to address issues raised in multiple civil lawsuits about the adequacy of the environmental analyses for the various decisions at issue and to ensure compliance with the National Environmental Policy Act, applicable Executive and Secretarial Orders, and Departmental policies regarding analysis of the impacts from greenhouse gas emissions and the social cost of greenhouse gases—including Executive Order 13990, Secretary's Order 3399, and new information provided in the 2023 BLM Specialist Report on Annual Greenhouse Gas

Emissions and Climate Trends. Potential new alternatives to be considered in the EIS include, but are not limited to, those that would affirm the issuance of these leases under the terms, conditions, and stipulations as originally issued, or not affirm their issuance under their original terms, conditions, and stipulations.

After the scoping comment period is closed, the BLM will review and consider the scoping comments received and will develop a Draft EIS, which BLM estimates will be completed approximately 6 to 8 months after the scoping period ends. At that time, the Draft EIS will be made available for public comment for at least 45 days. After the close of the Draft EIS comment period, the BLM will develop a Final EIS incorporating comments received on the Draft, which the BLM estimates will be completed approximately 6 months after the Draft EIS comment period ends. A record of decision selecting an alternative from the Final EIS would be issued no sooner than 30 days after notice of the availability of the Final EIS is published in the **Federal Register**.

(Authority: 30 U.S.C. 181 and 226; 43 U.S.C. 1701 *et seq.*; 42 U.S.C. 4332; and 43 CFR part 3100 (2024))

Steven Feldgus,

Principal Deputy Assistant Secretary, Land and Minerals Management.

[FR Doc. 2025-00854 Filed 1-15-25; 8:45 am]

BILLING CODE 4331-27-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251]

Call for Nominations for Bureau of Land Management Northern New Mexico Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of call for nominations.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management's (BLM) Northern New Mexico Resource Advisory Council (RAC) for terms scheduled to expire. This RAC provides advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within its geographic areas.

DATES: All nominations must be received no later than February 18, 2025.

ADDRESSES: Nominations and completed applications should be sent to the

individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Jamie Garcia, BLM Rio Puerco Field Office, 100 Sun Avenue NE, Suite 330, Albuquerque, NM 87109; email: jagarcia@blm.gov; phone: (505) 761-8787. 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: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM through the establishment of 10- to 15-member citizen-based advisory councils that are managed in accordance with the Federal Advisory Committee Act (FACA). As required by FACA, RAC membership must be balanced and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR part 1780 subpart 1784. The RACs include the following three membership categories:

Category One—Holders of Federal grazing permits or leases within the area for which the RAC is organized; represent interests associated with transportation or rights-of-way; represent developed outdoor recreation, off-highway vehicle users, or commercial recreation activities; represent the commercial timber industry; or represent energy and mineral development.

Category Two—Representatives of nationally or regionally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups.

Category Three—Hold state, county, or local elected office; are employed by a state agency responsible for the management of natural resources, land, or water; represent Indian tribes within or adjacent to the area for which the RAC is organized; are employed as academicians in natural resource management or the natural sciences; or represent the affected public at large.

Individuals may nominate themselves or others. Nominations received during the National Call for Nominations are being considered and individuals do not

need to reapply. Nominees must be residents of the State of New Mexico. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

- A completed RAC application, which can either be obtained through your local BLM office or online at: https://www.blm.gov/sites/default/files/docs/2022-05/BLM-Form-1120-19_RAC-Application.pdf
- Letters of reference from represented interests or organizations; and
- Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, the BLM will issue an online announcement providing additional information for submitting nominations.

(Authority: 43 CFR 1784.4-1)

Sabrina Flores,

Albuquerque District Manager.

[FR Doc. 2025-00950 Filed 1-15-25; 8:45 am]

BILLING CODE 4331-23-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500183710; AA-11821]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in certain lands to Cook Inlet Region, Inc., an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA), as amended. Ownership of the subsurface estate will be retained by the United States.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513-7504.

FOR FURTHER INFORMATION CONTACT:

Heidi C. Wanner, Supervisory Land Law Examiner, BLM Alaska State Office, 907-271-3153 or hwanner@blm.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: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Cook Inlet Region, Inc. The decision approves conveyance of the surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended. Ownership of the subsurface estate will be retained by the United States.

The lands are located within the Kenai National Wildlife Refuge within T. 9 N., R. 4 W., Seward Meridian, Alaska, containing 0.40 acres.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands approved for conveyance.

The BLM will also publish notice of the decision once a week for four consecutive weeks in the "Anchorage Daily News" newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until February 18, 2025 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Heidi C. Wanner,
Supervisory Land Law Examiner,
Adjudication Section.

[FR Doc. 2025-00949 Filed 1-15-25; 8:45 am]

BILLING CODE 4331-10-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[PO #4820000251]

Response to Utah Governor's Appeal of the BLM Utah State Director's Governor's Consistency Review Determination for the Grand Staircase-Escalante National Monument Proposed Resource Management Plan and Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of response.

SUMMARY: The Bureau of Land Management (BLM) is publishing this notice to explain why the Department of the Interior denied the Governor of Utah's recommendations regarding the Grand Staircase-Escalante National Monument (GSENM) Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement (EIS).

ADDRESSES: A copy of the GSENM Record of Decision (ROD) and Approved RMP is available on the BLM website at: <https://eplanning.blm.gov/eplanning-ui/project/2020343/510>.

FOR FURTHER INFORMATION CONTACT:

Heather Bernier, Division Chief for Decision Support, Planning, and National Environmental Policy Act; telephone 303-239-3635; address P.O. Box 151029, Lakewood, CO 80215; email hbernier@blm.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 for contacting Ms. Bernier. 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 August 30, 2024, the BLM released the Proposed RMP/Final EIS for the GSENM (89 FR 70662). In accordance with the regulations at 43 CFR 1610.3-2(e), the BLM submitted the Proposed RMP/Final EIS for the GSENM to the Governor of Utah for a 60-day Governor's Consistency Review for the Governor to review the Proposed RMP and identify any inconsistencies with State plans, policies, or programs. On October 29, 2024, the Governor of Utah submitted a response for the GSENM Proposed RMP and Final EIS to the Acting BLM Utah State Director. The Acting State Director reviewed and considered the Governor's response and sent a written response to

the Governor on November 22, 2024. As explained in the response, the Acting State Director accepted some of the Governor's recommendations but did not accept the others for the reasons detailed in this response.

On December 20, 2024, the Governor of Utah appealed the Acting State Director's decision to the BLM Director. The regulations at 43 CFR 1610.3-2(e) state that, in reviewing these appeals, "[t]he Director shall accept the (consistency) recommendations of the Governor(s) if he/she determines they provide for a reasonable balance between the state's interest and the national interest." On January 6, 2025, the Department of the Interior Principal Deputy Assistant Secretary, Land and Minerals Management, issued a response to the Governor detailing the reasons that the recommendations that the Acting State Director rejected did not meet this standard. Pursuant to 43 CFR 1610.3-2(e), the basis for the BLM's determination on the Governor's appeal is presented below. The BLM is publishing the appeal response verbatim.

"This letter addresses the State of Utah's appeal of the response provided by the BLM Utah Acting State Director regarding the consistency review of the Grand Staircase-Escalante National Monument (GSENM) Proposed Resource Management Plan and Final Environmental Impact Statement (EIS).

The applicable regulations at 43 CFR 1610.3-2(e) provide you with the opportunity to appeal to the BLM Director the Acting State Director's decision to not accept the recommendations you made in your consistency review letter. Exercising the delegable authority of the Department of the Interior's Assistant Secretary, Land and Minerals Management, I have chosen to assume the review and resolution of your appeal from the BLM Director. The regulations at 43 CFR 1610.3-2(e) guide review of the appeal, in which I must consider whether you have raised actual inconsistencies with State or local plans, policies, and or programs. If inconsistencies are raised, I consider whether your recommendations address the inconsistencies and provide for a reasonable balance between the national interest and the State of Utah's interest.

In your consistency review and your appeal, you allege 13 inconsistencies with State or local plans, policies, and programs. The alleged inconsistencies are as follows:

- "BLM's Failure to Disclose All Key Inconsistencies (The Failure to Accomplish the Prerequisite to the Governor's Consistency Review) . . .

The State reaffirms its request that the BLM provide a complete disclosure of all key inconsistencies it was aware of before the 60-day review period began.”

- “Coordination and Process Issues . . . The State reaffirms its position that the BLM violated its duty to coordinate with the State at appropriate stages of the planning process, as required by the State RMP.”

- “Monument Designation . . . The State reaffirms its position that the BLM violated its duty to respect the State’s interests . . . on all designations of over 5,000 acres.

- “Objects . . . The BLM’s approach of maximal protection in the absence of a finalized inventory of Monument objects is neither required by law nor consistent with the BLM’s legal obligations under FLPMA and the State RMP.

- “Rejection of Multiple Use and Sustained Yield . . . The State has consistently maintained that when the BLM does not need to diminish multiple-use activities to protect specific Monument objects, it must not . . . The State RMP makes clear that non-use (saving the land for conservation purposes) cannot trump multiple use principles, only use limitations required to protect specific Monument objects can.

- “Management Zones . . . The State asserts again that its RMP specifically prohibits the management area approach.

- “Management of WSAs [Wilderness Study Areas] and LWCs [Lands with Wilderness Characteristics] . . . the BLM must manage LWCs under the multiple-use and sustained yield framework unless such management conflicts with the proper care of Monument objects . . . Regarding WSAs, the BLM can meet its non-impairment obligations and remain consistent with the State RMP by designating these areas as OHV limited rather than fully closing them.”

- “Travel Management, Land Access, and R.S. 2477 Rights-of-Way . . . the BLM ignores that the regulations allow for land to be designated as allowing “limited” OHV use, which is exactly what the State RMP requires . . . the BLM’s response does not address the inconsistency the State raised regarding the prohibition of nonmotorized recreational trails, including paved and mechanized trails, in the Primitive Area . . . The State also appeals the BLM’s decision not to provide access to claimed R.S. 2477 routes within the GSENM . . . The State also appeals the BLM’s decision to close the V-Road.”

- “Livestock Grazing . . . The State appeals the BLM’s decision not to

accept the majority of its livestock grazing recommendations. Foremost among these concerns are protecting and accommodating livestock grazing and leaving lands available for grazing.”

- “Invasive Species Management . . . The State reaffirms its recommendation to ensure that the Proposed RMP supports the State’s goal of eradicating Russian olive and tamarisk by 2030 and facilitates their removal without unnecessary restrictions.”

- “VRM [Visual Resource Management] Classifications along the Highway 89 Utility Corridor . . . The State reaffirms its recommendation to classify the entire utility corridor as VRM Class IV. If the BLM rejects this recommendation, the State requests that the four-mile segment be managed as VRM Class III . . .”

- “Harvest of Forest Products . . . The State requests that the BLM modify the Proposed RMP to allow for small-scale commercial timber harvests (such as firewood sales) in appropriate areas and remove the prohibition on noncommercial harvests in LWCs where it is not detrimental to Monument objects as well as in all other areas where a site-specific decision to limit harvest has not been made.”

- “Camping and Recreation Restrictions . . . The State reaffirms its recommendation to remove the blanket permit requirement for all overnight camping in GSENM and to limit the requirement to areas where it is genuinely needed for management purposes, such as in high-traffic areas, to protect sensitive resources, or in areas where additional safety, education, or visitor use data is needed.”

Your appeal included specific recommendations to resolve each of these alleged inconsistencies, including that the BLM restart the planning process. The national interest for this planning effort is founded upon Proclamations 6920 and 10286, which make clear there is an obligation to protect GSENM’s vast and austere landscape and array of historic and scientific objects for future generations to both experience and learn from. For example, in Proclamation 10286, President Biden stated “it is in the public interest to ensure the preservation, restoration, and protection of the objects of historic or scientific interest on the Grand Staircase-Escalante lands, including the entire Monument landscape . . .” To protect that interest, the Federal policy for this planning effort is to protect and restore the Monument’s landscape and resources for all Americans throughout the nation. Considering this clear expression of national interest, and

upon review of your appeal, I find that the State’s recommendations do not present a reasonable balance between the national interest and the State’s interest for the reasons discussed below.

First, the State’s appeal alleges that the BLM has failed to identify inconsistencies with State and local planning and regulations; however, I concur with the Acting State Director’s finding that Appendix O in the Proposed RMP/Final EIS, which identifies key consistencies and differences between the Proposed RMP and State and county plans, is consistent with 43 CFR 1610.3–2(e). To the extent that the State has now identified additional alleged inconsistencies in writing through the consistency review and appeal process, the BLM has considered and responded through the Acting State Director’s November 22 reply and through this response to your appeal. Accordingly, I do not accept the State’s recommendation that the BLM provide the Governor with an additional 60 days for supplementary review.

Second, regarding coordination, as the Acting State Director noted in his reply, and as is outlined in the Proposed RMP/Final EIS, particularly Chapter 4, sections 4.1 and 4.3, the BLM engaged extensively with the State, counties, and local land managers throughout the RMP development process. The BLM coordinated with the State of Utah’s Public Lands Policy Coordinating Office as the primary contact and lead representative for all applicable state agencies. The BLM also consulted with the Utah Division of Wildlife Resources on the proposed recreational shooting closures in the Proposed RMP/Final EIS, as required by the John D. Dingell, Jr. Conservation, Management, and Recreation Act. In addition, Kane County, Garfield County, Kane County Water Conservancy District, Washington County Water Conservancy District, and various local municipalities participated as cooperating agencies throughout the development of the RMP. Moreover, the components of Alternative E (*i.e.*, the Proposed RMP) derive from the alternatives presented in the Draft EIS and are within the range of alternatives considered and analyzed in the Draft EIS and were informed by BLM’s engagement with State and local governments, as well as public input received during the public comment period. As such, the BLM complied with all applicable laws regarding coordination and consultation, including, but not limited to, the National Environmental Policy Act and Federal Land Policy and Management Act (FLPMA), throughout the planning

process. Therefore, I do not accept the State's recommendation that the BLM "re-open" the planning process or offer additional opportunities for public comment.

Third, regarding the designation of the Monument, I concur with the Acting State Director that the President's designation of the Monument is not subject to the consistency review process set forth in 43 CFR 1610.3–2. Furthermore, your allegations regarding the lack of coordination with the State regarding implementation of the Proclamation and planning for the Monument are unfounded. Your recommendations are therefore not accepted, as described in the preceding paragraph.

Fourth, with respect to the inventory of objects of historic and scientific interest protected by the designation of the Monument, I agree with the Acting State Director that the Proposed RMP provides reasonable and appropriate protections to both the objects identified in Proclamation 6920 and 10286, as well as the resources discussed in those proclamations that do not themselves qualify as Monument objects. FLPMA provides the BLM with broad discretion to manage public lands in a manner that will protect the quality of scientific, scenic, historical, ecological, environmental, air and atmospheric, water resource, and archaeological values. That is especially true where, as here, a Presidential proclamation issued in accordance with the Antiquities Act has dedicated public lands to specific, protection-oriented uses. Thus, while the BLM is under an obligation to manage GSENM in a manner that is consistent with the protection of the objects identified in Proclamations 6920 and 10286, the agency retains the discretion to manage the Monument in a manner that also protects the other resources located therein.

As the BLM explained in its July 29, 2022, Notice of Intent to prepare an RMP for the Monument, the planning effort was intended to, among other goals, protect and restore the entirety of the Monument's landscape, its biological resources, its varied geology and associated scenery, and its world-class outdoor recreation opportunities, in addition to protecting and restoring the Monument objects for which GSENM was designated. The Proposed RMP, which provides reasonable and appropriate protection to both GSENM's objects and resources, accomplishes those goals while allowing for a diverse array of uses in the Monument. The Proposed RMP does not, however, provide "maximum protection", as you allege, to GSENM's resources, as

evidenced, in part, by the fact that the Proposed RMP is not comprised of the most restrictive management direction analyzed in the EIS. As such, I disagree that the Proposed RMP is inconsistent with the State RMP's direction that "reasonable protection should not be translated to mean the maximum amount of protection possible." Because I find that the agency is providing reasonable and appropriate protection to resources within the Monument, while meeting our obligation under Proclamation 10286 to protect Monument objects, your recommendations are not accepted.

Fifth, you express concerns about the Proposed RMP's implementation of the principles of multiple use and sustained yield in the Monument. As described above, while the Proposed RMP provides appropriate protections for both monument objects and other resources, it also provides for other uses within the Monument, including livestock grazing, motorized recreation, and several other forms of use. Further, in managing the Monument, the BLM is obligated to comply with Section 302(a) of FLPMA, which requires the BLM to "manage the public lands under principles of multiple use and sustained yield . . . except that where a tract of such public land has been dedicated to specific uses according to any other provisions of law it shall be managed in accordance with such law." (43 U.S.C. 1732(a)). Thus, complying with the directives of the Proclamation is paramount, per section 302(a) of FLPMA. Overall, with respect to the nation's interest, as described above, I find that that agency has appropriately balanced protection and use with this plan.

Sixth, with regard to Management Zones, I acknowledge your reiteration and clarification that the management area approach is inconsistent with the State RMP. While I agree with the Acting State Director that the management areas are not considered by BLM to be "special designations," I understand from your appeal that the State considers these management areas as special designations with respect to the State RMP, and therefore finds them to be inconsistent with the State RMP. Regardless, the BLM believes that using management areas is the best way to protect and restore Monument objects, protect and maintain intact and resilient landscapes in GSENM, and protect and restore world-class outdoor recreation opportunities in the Monument. Management areas, which are essentially a way to organize various underlying management actions, allow the BLM to manage visitation and

allowable uses in a holistic manner that is readily understandable by the public. By comparison, adopting the State RMP's approach would not achieve Federal policy goals, as it would not provide the public with an easy way to understand the allowable uses within given areas of GSENM. When considering the balance between national and state interests, I find that the use of management areas, which have been largely in place as a successful tool since 2000, is the appropriate way to manage recreation in the Monument in a way that visitors will understand, and that provides the agency with the framework to minimize user conflict, provide diverse experiences, and protect Monument objects. Therefore, I do not accept the State's recommendation to remove management areas from the Proposed RMP, as the State's approach would not represent a reasonable balance between the national interest and the State interest.

Seventh, concerning management of WSAs and LWCs, while I understand that you find that the protection of the wilderness values of these areas is inconsistent with the State RMP, I have determined that the Proposed RMP's approach to managing WSAs and LWCs provides a reasonable balance between the national and the State's interest, whereas the State's approach does not. Wilderness character is a public land resource, and the management direction in the Proposed RMP that would require its protection in certain areas in GSENM is consistent with the policy of protecting the Monument's large, remote, rugged, and markedly impenetrable landscapes, as well as protecting and restoring the biological resources in the Monument that owe, in part, to its remoteness. Treating all areas of the Monument that contain wilderness character as the State recommends would fail to achieve this policy goal. Indeed, it would counteract it. Similarly, the closure of WSAs to off-road vehicle (OHV) use is often the best way to ensure that WSAs are managed in a manner so as not to impair their suitability for preservation as wilderness, as is required under section 603 of FLPMA. Closing WSAs to OHV use will also help achieve the goals stated above concerning the protection and restoration of GSENM's remote landscape and biological resources. By comparison, facilitating OHV use in the Monument's WSAs by designating them as OHV limited would jeopardize the BLM's ability to comply with section 603 and make it harder to achieve the policy goals of the Federal Government,

including those outlined in the Proclamations and FLPMA. Because the State's recommendations concerning LWC and WSAs are inconsistent with Federal policy, and potentially inconsistent with Federal law, I do not believe that the State's recommendations provide for a reasonable balance between the national interest and the State's interest. It is also worth re-stating the Acting State Director's observation that closing WSAs to BLM designation of OHV routes does not preclude the BLM from recognizing routes in these areas that are subsequently determined to be held by the State or counties pursuant to R.S. 2477.

Eighth, regarding travel management, land access, and R.S. 2477 rights-of-way, under 43 CFR 8342.1, the BLM must designate all public lands as either open, limited, or closed to OHVs based on the protection of the resources of the public lands, the promotion of the safety of all the users of the public lands, and the minimization of conflicts among various uses of the public lands. Under the Proposed RMP, the BLM applied OHV closures to areas within GSENM that (1) would minimize damage to soil, watersheds, vegetation, air and other resources; (2) would minimize harassment of wildlife or significant disruption of wildlife habitats; (3) would minimize conflicts between off-road vehicle use and other existing or proposed recreational uses of the same or neighboring public lands, and to ensure the compatibility of such uses with existing conditions in populated areas, taking into account noise and other factors; and, (4) would minimize potential adverse effects to primitive areas consistent with the intent of the area. As noted in the Acting State Director's response, maximizing motorized vehicle access in GSENM would be inconsistent with the BLM's regulatory obligations under 43 CFR 8342.1 to minimize resource impacts and user conflicts. Moreover, designating the entirety of GSENM as OHV limited—to the extent it would be consistent with 43 CFR 8342.1—would be inconsistent with the Federal policy of protecting and restoring GSENM's remote landscape, varied geology and associated scenery, and biological resources. That is especially true given that many of the areas of GSENM that the State recommends designating as OHV limited have not experienced authorized OHV use in more than two decades, despite the fact that the 2020 Grand Staircase, Kaiparowits, and Escalante Canyons Units and Kanab Field Office-Escalante Area Resource

Management Plans designated these areas as OHV limited. I therefore do not find the State's position, as described in the State RMP, to be a reasonable balance between the national and the State's interest. The Acting State Director also correctly summarized the agency's approach to managing claimed R.S. 2477 rights-of-way, including the V-Road. The BLM will update management accordingly if routes in these areas are subsequently determined to be held by the State or counties pursuant to R.S. 2477.

Your appeal also alleges that one of the State's recommendations regarding nonmotorized recreational trails in the primitive area from the Governor's letter was not addressed in the Acting State Director's response. While the Acting State Director's response did not directly address this recommendation, it was indirectly addressed as part of the response regarding motorized trails in the primitive area that explained that this area-based restriction is necessary to protect Monument objects while balancing specific user experiences. The Acting State Director's response further explained that this approach is consistent with the State's policies to ensure a broad range of uses, particularly for economic, cultural, and public safety purposes. For instance, this management approach allows for a self-discovery approach to recreation, including the opportunity to cross-county hike, rather than being limited to a specific trail or trails. In addition, construction of either new motorized or nonmotorized trails in the primitive area could result in increased surface disturbance in a broad swath of the Monument and inhibit the protection of the rugged and remote Monument landscape, as required by the Proclamation. There remain other opportunities in the Monument for more structured recreation experiences including nonmotorized trail-based, mechanized, and motorized experiences. Upon review of the recommendation through this appeal, for the reasons described above, I decline to accept the recommendation, as it does not provide for the reasonable balance between the national interest and the State's interests.

Ninth, with regards to livestock grazing management and range improvements, I find that, to the extent the Proposed RMP is inconsistent exist with the State's plans, programs or policies, those inconsistencies are necessary to comply with Federal law and policy. As explained below, the Proposed RMP appropriately balances the needs of livestock producers, wildlife populations, and the natural

environment, as required by FLPMA and Proclamation 10286.

Making certain allotments in the Monument unavailable to grazing is necessary to comply with the Federal law and the Proclamations and is consistent with the national interest. By prohibiting livestock grazing in these areas for the time being, the Proposed RMP helps to mitigate impacts to ecological and hydrological functions which, in turn, enhances BLM's ability to comply with the requirement imposed by section 302 of FLPMA and the Proclamations to provide proper care and management to Monument objects. This management approach is likewise necessary to achieving desired outcomes for the Monument, including the Federal policy of protecting and restoring the entirety of the Monument and its biological resources. By comparison, making these allotments available to livestock grazing and introducing the possibility that livestock would be reintroduced into these areas after being absent for more than 20 years would undermine the national interest in protecting GSENM's objects and resources for future generations. As a result, I do not accept the State's recommendation to make these allotments available to grazing, as this would be inconsistent with the national interest.

With respect to the four pastures that are limited to trailing until rangeland health standards are met, I find that the management approach you propose, and the management approach the agency is now taking (per the Acting State Director's November 22nd letter), are now sufficiently aligned to be deemed consistent. I also appreciate your offer of support to help perform future land health assessments.

Next, regarding the management direction involving modifications to existing structural range improvements and the construction of new range improvements, such actions are not prohibited under the Proposed RMP. Rather, the Proposed RMP requires that such construction and improvements be associated with documentation that the improvement or its modification would support the achievement of rangeland health standards (based on a land health assessment within the last 10 years) and that the action is consistent with the protection of GSENM objects. This is necessary to achieve the Federal policy of protecting and restoring the entirety of the GSENM landscape and its associated scenery, as well as its biological resources and processes. To ensure consistency with the Proclamations, the Proposed RMP requires that structural range

improvements and construction be tied to the protection of GSENM objects. Eliminating the requirement, as the State recommends, would be inconsistent with Federal policy, and therefore not represent a reasonable balance between the national interest and State interest.

Similarly, I concur with the Acting State Director's response that non-structural improvements primarily for an increase in forage would not be consistent with the protection of GSENM objects, nor would it be consistent with the Federal policy of restoring natural biological processes in the Monument. Furthermore, nothing in the proposed RMP prohibits a nonstructural range improvement from having a secondary benefit that increases forage, as long as it is consistent with other management in the plan.

Your appeal also notes that while the Acting State Director intends to make changes to the Approved RMP for data used to inform drought conditions, you remain concerned with drought management and AUM limits. I find the concerns regarding drought management do not contain an identified inconsistency with State or local policy, program or plan, and the AUM limitations are addressed under concerns about general grazing management. Further, the updated approach (per the Acting State Director's November 22nd letter) regarding AUM adjustments during drought conditions provide that adjustments would be based on the data that informs drought severity at the appropriate scale, including local rain gauges and field data collection of present forage condition. Given this refinement in the type of data that indicates the drought conditions, AUM reductions would be targeted and based on the best available data.

Finally, with respect to livestock grazing, your appeal also alleges that five of the State's recommendations from your letter were not addressed in the Acting State Director's response. After my review of the five recommendations, I have determined that the recommendations do not provide for the reasonable balance between the national interest and the State's interests, and I do not accept them for the reasons noted below.

Regarding grazing recommendation #7, to "allow two-sided flexibility in AUMs", the State's letter speaks to the potential for increasing AUMs depending on forage availability. The BLM's grazing regulations already provide for the consideration of temporary adjustments in AUMs. In

addition, as supported by resource conditions and monitoring, suspended AUMs may also be restored to active use without an additional land use plan-level decision. Therefore, flexibilities exist to address potential increases in AUMs through future plan implementation, and no inconsistency exists between the Proposed RMP and the State's RMP, and I am not accepting your recommendation.

Regarding grazing recommendation #9, to "incorporate best available science in decision-making," there are already present in law, regulation, and policy requirements to collect and use the best available information when making land use decisions and implementation decisions, including for livestock grazing. It is unnecessary to repeat the same requirement in an RMP, and accordingly, no inconsistency exists here between the Proposed RMP and the State's RMP, and I am not accepting your recommendation.

Regarding grazing recommendation #12, to "prioritize other options over reducing grazing" in areas where rangeland health deteriorates, the BLM considers all options that are consistent with the grazing regulations when considering changes to implementation-level grazing practices and does not elevate one option as a means to achieve healthy rangelands. As such, the proposed RMP does not prioritize or minimize a given approach if an area is not meeting rangeland health standards. Rather, it directs to "consider both a decrease in permitted use. . . and changes to grazing practices. . ." Such consideration would provide the BLM a comparison from which to make informed decisions when determining changes to improve rangeland health. Furthermore, in some cases, based on the facts, the BLM may find that changes to grazing use levels and practices are not necessary, and will rather implement restoration actions to improve rangeland health, consistent with several management actions in the plan. As such, I found that no inconsistency exists here between the Proposed RMP and the State's RMP, and I am not accepting your recommendation.

Regarding grazing recommendation #13, to focus on removing tamarisk and Russian olive plants before closing grazing pastures to protect riparian areas and address different aspects of riparian health, a change was made, as described in the Acting State Director's November 22 response, to provide for an adaptive management opportunity to remove the trailing-only restrictions in the four pastures when they meet rangeland health standards. The adaptive

management may include such restoration actions that you describe in your appeal letter. This adjustment strikes the balance between riparian health in the identified pastures and the use of public lands for livestock grazing. As such, I do not find that a substantive inconsistency exists between the Proposed RMP and the State RMP, and I am not accepting your recommendation.

Regarding grazing recommendation #14, to "employ and rely on stock-and-monitor to test rangeland effects," for areas available to livestock grazing, the Proposed RMP directs the BLM to conduct land health assessments and, if needed, causal factor determinations, to inform the processing and issuance of grazing permits to support the achievement of the BLM Utah Rangeland Health Standards and ensure consistency with the protection of Monument objects. While this language is similar in concept to the recommended "stock-and-monitor to test" approach, it more accurately aligns with the direction in BLM's grazing regulations. The grazing regulations also direct BLM to identify in the RMP which lands are available for livestock grazing and to set forth the constraints and general management practices needed to achieve the management objectives, including managing the Monument for healthy rangelands. As such, I do not find that a substantive inconsistency exists between the Proposed RMP and the State RMP, and I am not accepting your recommendation.

Tenth (noted as eleventh in the appeal letter), with regard to invasive species management, as noted in the Acting State Director's response, the BLM intends to eliminate inconsistency with the State's RMP by expanding allowable management of invasive plants, including Russian olive and tamarisk, where doing so is consistent with other management direction and the protection of Monument objects. While the BLM supports the State RMP's objective of removal of Russian olive and tamarisk plants from all riparian areas by 2030, the BLM's proposed management of invasive species is not inconsistent with the State's plans or policies simply because it does not mirror the exact language of the State's RMP. As a result, I do not accept the State's recommendations regarding invasive species.

Eleventh (noted as twelfth in the appeal letter), regarding the State's concerns about Visual Resource Management (VRM) along a four-mile segment of the Highway 89 utility corridor, I find that these concerns do

not raise an inconsistency with State or local plans, policies, and programs. As explained in the Acting State Director's response, management of this segment as VRM Class II is necessary for protecting the visual resources associated with the Cockscomb formation, an object identified for protection in Proclamation 10286, while still allowing access, maintenance, or development of utilities, consistent with Public Law 105–355 and consistent with the State RMP's intent to protect access to utilities, improve infrastructure, and conduct vegetation management activities near infrastructure. Because the State has not identified any inconsistencies related to the VRM classifications in the Proposed RMP, I do not accept the State's recommendation to make changes to those classifications.

Twelfth (noted as thirteenth in the appeal letter), the State's appeal alleges continued inconsistencies regarding commercial forestry and woodland harvest within the proposed RMP. I concur with the Acting State Director's finding that the limitations on commercial and noncommercial harvests within the Monument are necessary for the protection of various Monument objects identified in Proclamation 10286, including certain forest resources, as well as the overall GSENM landscape. Commercial timber harvest has not been authorized in the Monument for more than 20 years, and lifting this limitation could jeopardize various Monument objects and would be inconsistent with the Federal policy goal of protecting and restoring GSENM's landscape, scenic attributes, and biological resources. In addition, because commercial timber harvest is allowed on other Federal lands in southern Utah, the prohibition in the Proposed RMP would not constrain the general ability to harvest timber in the State. Accordingly, I find that the State's recommendation to allow commercial timber harvest in GSENM (even those that you describe as "small-scale, local commercial operations") does not provide for a reasonable balance between the national and the State's interest.

Regarding alleged inconsistency from the Proposed RMP's restriction of noncommercial harvest in lands managed for the protection of wilderness characteristics, this restriction provides for a reasonable balance between the national and the state interests, in that it allows for some noncommercial harvests in the Monument but does so in a way that protects other resource values and management objectives. The Proposed

RMP's restriction of noncommercial harvest throughout portions of the Monument, especially those portions managed for the protection of wilderness characteristics, is necessary to facilitate the protection and restoration of the Monument's biological, cultural, and scenic resources. By comparison, the State's recommendation to allow for noncommercial harvest in lands managed for the protection of wilderness characteristics would hinder the BLM's ability to protect and restore these resources and, therefore, would be inconsistent with Federal policy. Moreover, noncommercial harvest is allowed on other Federal lands in the vicinity, so the prohibition in the Proposed RMP would not prohibit all noncommercial harvest of timber resources in the area. Therefore, I also find that the State's recommendation to allow for noncommercial timber harvest in lands managed for the protection of wilderness characteristics does not provide for a reasonable balance between the national and the State's interest.

Thirteenth (noted as fourteenth in the appeal letter), concerning your appeal regarding permits for overnight camping, I agree with the Acting State Director that the requirement in the Proposed RMP that all overnight campers obtain free-use permits is not inconsistent with the State RMP's vision of promoting balanced, accessible, and sustainable outdoor recreation opportunities. Much like the State, the BLM supports making access to public lands easy and affordable for all visitors. The BLM is also required to protect Monument objects noted in the Monument proclamation, and to ensure the safety of public land users. The overnight camping permit requirement, which is intended to provide the BLM with the opportunity to share messaging with overnight users regarding safety and resource protection, to better track visitor use to support informed management, and to help better track or locate overdue parties, is consistent with both those goals. Notably, the permit requirement in the Proposed RMP does not limit the number of permits that will be issued, create a lottery to obtain a permit, or otherwise impose restrictions that will reduce the public's ability to camp in GSENM. In addition, the public would be able to obtain a permit either in person or online. Accordingly, the permit requirement in the RMP is consistent with promoting balanced, accessible, and sustainable outdoor recreation opportunities. Balanced, accessible, and

sustainable outdoor recreation opportunities do not necessarily mean an entirely unregulated experience. Because I disagree that a substantive inconsistency exists between the Proposed RMP and the State RMP regarding permits for overnight camping, I am not accepting your recommendations.

Finally, the BLM has prepared the GSENM Proposed RMP/Final EIS in accordance with all applicable Federal laws, regulations, and policies. The BLM carefully reviewed and considered applicable State, local, and other Federal agency plans, policies, and programs in the development of the GSENM RMP/Final EIS. The Proposed RMP is consistent, to the extent practicable, with these plans as required by FLPMA and the planning regulations at 43 CFR 1610.3–2(e). In conclusion, to the extent any inconsistencies exist, I find that the recommendations outlined in your appeal do not provide for a reasonable balance between the national interest and the State's interest for the reasons discussed herein. Accordingly, I do not accept the State's recommendations."

(Authority: 43 CFR 1610.3–2(e))

Nada Wolff Culver,
Principal Deputy Director.

[FR Doc. 2025–00951 Filed 1–15–25; 8:45 am]

BILLING CODE 4331–25–P

DEPARTMENT OF THE INTERIOR

National Park Service

**[NPS–WASO–NAGPRA–NPS0039328;
PPWOCRADN0–PCU00RP14.R50000]**

Notice of Intended Disposition: U.S. Department of Agriculture, Forest Service, Chugach National Forest, Anchorage, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of Agriculture, Forest Service, Chugach National Forest intends to carry out the disposition of unassociated funerary objects removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains in this notice may occur on or after February 18, 2025. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Jeff E. Schramm, Forest Supervisor, Chugach National Forest, Supervisor's Office, 161 E 1st Ave, Door 8, Anchorage, AK 99501, telephone (907) 743-9500, email jeff.schramm@usda.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 Chugach National Forest, and additional information on the human remains in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

The 10 unassociated funerary objects items consist of hide pieces, a flaked, flat piece of soft slate or shale, pieces of dried leather fragments (sewn or with sewing holes), and strips of split spruce (joined by a series of knots and twists, fragment of knotted spruce roots, carved wooden slat.

The 10 items were found in 1992 during a Bureau of Indian Affairs (BIA) on-site investigation on Squire Island, Chugach Census Area, Alaska at site SEW-832. SEW-00832 was recorded as an archaeological site which contains both a habitation area under a rock shelter and a burial cave. These artifacts were housed with the BIA until they were transferred to the Chugach National Forest Supervisor's Office on October 25, 2019.

Determinations

The Chugach National Forest has determined that:

- The 10 unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- The Native Village of Chenega (aka Chenega) and Native Village of Tatitlek have priority for disposition of the cultural items described in this notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization 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 they have priority for disposition.

Disposition of the human remains in this notice may occur on or after February 18, 2025. If competing claims for disposition are received, the Chugach National Forest must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. The Chugach National Forest is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01019 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039309; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: David A. Fredrickson Archaeological Collections Facility at Sonoma State University, Rohnert Park, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Sonoma State University has completed an inventory of associated funerary objects and has determined that there is a cultural affiliation between the associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Doshia Dodd, Sonoma State University, 1801 East Cotati Avenue, Rohnert Park, CA 94928, telephone (530) 514-8472, email Doshia.dodd@sonoma.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 Sonoma State University and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

In 2007, human remains from CA-MRN-254, CA-SON-159, CA-SON-293, CA-SON-455, and CA-SON-456 were listed in a Notice of Inventory Completion, published in the **Federal Register** on June 21, 2007 (72 FR 34275-34276) were repatriated to the Federated Indians of Graton Rancheria. Additionally, human remains from archaeological sites CA-MRN-484, CA-MRN-365, CA-MRN-502, CA-MRN-503, CA-SON-290, and CA-SON-1048 were listed in a Notice of Inventory Completion, published in the **Federal Register** on June 4, 2007 (72 FR 30823-30825) were repatriated to the Federated Indians of Graton Rancheria. This notice includes the remaining 38,617 associated funerary objects not included in the previous repatriations by Sonoma State University from the previously listed archaeological sites.

A lot of one associated funerary object is a projectile point taken from CA-MRN-372 in Bolinas, Marin County, California. The cultural item has been housed at Sonoma State University since 1985 under Accession number 84-01.

The lot of 10 associated funerary objects taken from archaeological site CA-MRN-357 in Marin County, California are projectile points. The cultural items were found during re-inventory of MRN-27 collection. The tag in box identifies the cultural items as associated with a burial from CA-MRN-357.

A lot estimated to contain up to 100 items taken from archaeological site CA-MRN-365 was donated to Sonoma State University in 1984 or 1985 by the Marin Museum of the American Indian. The collection was never given an

Accession number and has been housed at Sonoma State University since 2007.

A lot estimated to contain up to 100 items taken from archaeological site CA-MRN-254 was donated to Sonoma State University in 1971 by Jodie Sanchez. The collection was never given an Accession number and has been housed at Sonoma State University since 2007.

The lot of one associated funerary object taken from archaeological site CA-MRN-484 in Marin County, California is shell. The cultural item has been housed at Sonoma State University since 1978 under Accession number 78-03.

A lot estimated to contain up to 100 items, taken from archaeological site CA-MRN-502, was donated to Sonoma State University in 1992 by Steve Dietz, and has remained at Sonoma State University under Accession number 98-05.

A lot estimated to contain up to 100 items, taken from archaeological site CA-MRN-503, has remained at Sonoma State University under Accession number 98-05.

CA-SON-159 in Cotati, Sonoma County, California was excavated as part of a series archaeological field methods classes at Sonoma State University from 1972 to 1977. The four classes resulted in collections of cultural material housed under Accessions numbers 72-01, 74-03, 75-28, and 77-11 at Sonoma State University. The lot of 12,033 associated funerary objects from the four Accession numbers combined are flaked stone tools and debitage; ground stone tools; bone tools; shell and bone beads and ornaments; unmodified faunal bone; dietary shell; historic-period items; and quartz crystal.

CA-SON-293 in Bodega Head, Sonoma County, California was excavated in 1968 by Western Heritage Inc. and Dr. David A. Fredrickson. The collection has been accessioned at the Sonoma State University since 1968 under Accession number 68-01. The lot of 334 associated funerary objects are botanical remains; flaked stone tools and debitage; faunal bone tools; ground stone tools; historic-period items; modified faunal bone and shell; ornament; pipe; shell beads; unmodified faunal bone and shell.

CA-SON-455/H in Santa Rosa, Sonoma County, California was excavated in 1968 and 1969 under the direction of Dr. David A. Fredrickson. The collection has been accessioned at the Sonoma State University since 1968 under 68-03. The lot of 14,743 associated funerary objects are flaked stone tools and debitage; ground stone tools; bone tools; shell beads;

unmodified faunal bone; and historic-period items.

CA-SON-456 near Sebastopol, Sonoma County, California was excavated by students of Santa Rosa Junior College (SRJC) between 1969 and 1972. The collection was housed at SRJC until 1983 when it was transferred to Sonoma State University. The lot of 1,348 associated funerary objects are flaked stone tools and debitage; ground stone tools; shell and bone beads and other ornaments; bone tools; unmodified faunal bone; and historic-period items.

CA-SON-290 near Bodega, Sonoma County, California was excavated in 1977. The collection has remained at Sonoma State University since it was accessioned under 77-03. The lot of 121 associated funerary objects are a charmstone; flaked stone tools and debitage; groundstone; historic material; modified faunal bone; and unmodified shell.

CA-SON-1048 in Sebastopol, Sonoma County, California was investigated through two archaeological surveys and one excavation. The work resulted in collections of cultural material housed Sonoma State University under Accession numbers 77-03, 79-04, and 81-01. The lot of 9,626 associated funerary objects from all three Accession numbers combined are flaked stone tools and debitage; groundstone; historic-period material; modified faunal bone and shell; shell beads; unmodified faunal bone and shell.

Based on records concerning the associated funerary objects and the institution in which they are housed, there is no evidence of the associated funerary objects being treated with hazardous substances.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The Sonoma State University has determined that:

- The 38,617 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the associated funerary objects described in this notice and the Federated Indians of Graton Rancheria, California.

Requests for Repatriation

Written requests for repatriation of the associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the associated funerary objects described in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the Sonoma State University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the associated funerary objects are considered a single request and not competing requests. The Sonoma State University 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01003 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039324; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intended Repatriation: Longyear Museum of Anthropology, Colgate University, Hamilton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Longyear Museum of Anthropology (LMA) intends to repatriate certain cultural items that meet the definition of unassociated funerary objects that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after February 18, 2025.

ADDRESSES: Kelsey Olney-Wall, Repatriation Manager, University Museums, Colgate University, 13 Oak Drive, Hamilton, NY 13345, telephone (315) 228-7677, email kolneywall@colgate.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 LMA, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 26 cultural items have been requested for repatriation. The 26 unassociated funerary objects are 25 shell beads and one shell pendant. The 25 "discoidal clamshell wampum beads" and the abalone shell pendant were removed from Prehistoric Maidu Culture, Cremation burial, Bennett Mound, Sacramento County. The LMA acquired the 26 objects as a gift from John Hagen, of Hudson Falls, New York, in 1962. It is unknown how and when he acquired these items, although there is evidence they may have originated from the Gibbs Collection, Gilroy, California. There is no known presence of any potentially hazardous substances used to treat the cultural items.

Determinations

The LMA has determined that:

- The 26 unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and the Shingle Springs

Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **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 February 18, 2025. If competing requests for repatriation are received, the LMA 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 LMA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01015 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039318; PPWOCRADNO-PCU00RP14.R50000]

Notice of Intended Repatriation: University of California, Riverside, Riverside, 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, Riverside intends to repatriate certain cultural items that meet the definition of unassociated funerary objects or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after February 18, 2025.

ADDRESSES: Megan Murphy, University of California, Riverside, 900 University Avenue, Riverside, CA 92517-5900, telephone (951) 827-6349, email megan.murphy@ucr.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, Riverside, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 82 cultural items have been requested for repatriation. The five unassociated funerary objects are one lot of ceramic sherds, one lot of lithics, one lot of faunal remains, one lot of geological materials, and one pipe fragment. The 77 of objects of cultural patrimony are 16 lots of lithics, eight lots of metal, 11 lots of faunal, seven lots of botanical materials, two lots of mineralogical materials, one lot of unmodified shell, three lots of ceramics, four lots of glass, one lot of wood, six lots of geological materials, two lots of charcoal, one lot of textile fragments, one lot of rope, one lot of flotation samples, one lot of soil, one lot of plastic, four lots of shell beads, three lots of fire affected rock, two lots of grinding stones, one lot of modified shell, and one steatite ring.

In 1965, the University of California, Riverside Archaeological Research Unit (UCR-ARU) was contracted by the Southern California Gas Company to examine the region surrounding a pipeline along the lower Crowder Canyon area and Cajon Creek. The project, "The Sayles Complex, A Late Milling Stone Assemblage from Cajon Pass, and the Ecological Implications of its Scraper Planes", was led by Makoto Kowta and carried out by anthropology students from Pasadena City College and the University of California, Riverside. Archaeologists described the site as consisting of a prehistoric midden and historical-period culvert. A total of 1,294 artifacts, including 88 surface specimens, were recovered from the site. The artifacts recovered were several manos (both small and large), pendants, painted stones, milling stones, projectile points and blades, scrapers, bifacial choppers,

hammerstones, cores, and miscellaneous small, flaked objects, animal bone, floral material, mineralogical objects, and unmodified shell. Kowta described the site as being “one of the best Milling Stone Horizon sites” in San Bernardino County. All artifacts were cleaned, cataloged, and housed with the Department of Anthropology, University of California, Riverside as accession number 11.

In 1972 an archaeological excavation of CA-RIV-502 (Nibbled Rock Ridge site) in the Jurupa Hills (Riverside, County) was led by Thomas King of the University of California, Riverside Archaeological Research Unit (UCR-ARU). The excavations were undertaken during construction on Route 60 in Riverside County to convert the expressway to full freeway standards. The site was reported by King to have been a large “seed processing site” with a number of grinding “slicks” or metates. In King’s 1972 paper, “Nibbled Rock Ridge (CA-RIV-502): A prehistoric milling station in the Jurupa Mountains, Riverside County, California”, he notes that fifteen bedrock grinding slicks were recorded in the site area and estimated a total of 60 slicks existed in the surrounding area. According to King’s report burned bones and the “bulk of all cultural materials” were found on the east side of the ridge in a layer of “darkened soil”. A reported “hearth feature” was also found in the same layer with a rhyolite projectile point and a mano. Archaeologists have asserted that Serrano peoples have continuously occupied the San Bernardino Mountains and the Santa Ana River Watershed for up to 5,000–6,000 years BP. Ethnographer John Peabody Harrington recorded several Serrano place names throughout the Watershed during his interviews with Yuhaaviatam leader, Santos Manuel in 1918. Manuel told Harrington that the Santa Ana River is called hu’napat patr, meaning “bears water”.

In 1975, the University of California, Riverside Archaeological Research Unit (UCR-ARU) was contracted to conduct an archaeological evaluation of cultural resources within the Cucamonga Creek and Tributaries Project. The project, UCR-ARU #165, “Environmental Impact Evaluation: Bi-weekly Report of Cultural Resource Survey of Cucamonga, Demens, Deer, and Hillside Creek Channels, San Bernardino and Riverside Counties California”, was led by Patricia Martz and Nelson Leonard. The investigation included an on-foot survey of the project area and excavation of four test units in archaeological site CA-SBR-895. It was identified by Leonard who noted what

he believed was a cooking hearth. He believed that the site likely represents a temporary or seasonal camp near the Marrya’yam (Serrano) village of Cucamonga. Archaeologists recovered 14 cultural objects including lithic flakes, ground stones, and faunal remains. The site lies within the boundaries of what representatives of the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) have identified as being part of Serrano ancestral territory.

In 1976 Yucaipa Valley Water District contracted the University of California, Riverside Archaeological Research Unit (UCR-ARU) to evaluate archaeological site CA-SBR-1000 which was likely to be affected by a sewage project in the area. The site is believed to represent the Maara’yam (Serrano) village of Yukaipa’t and was first recorded by Gerald Smith of the San Bernardino County Museum (SBCM) in 1974. The site was excavated in multiple phases by UCR archaeology students under the supervision of UCR graduate students Patricia Martz and Eric Ritter, and Nelson Leonard, director of the UCR-ARU. During the first phase of excavation, in August and October of 1976, approximately 903 objects were removed from the site and housed at the San Bernardino County Museum. The second phase of excavations took place in October of 1976 with 2612 cultural objects being removed and stored at SBCM. The final phase of excavation took place in the spring of 1977 which resulted in the recovery of about 143 cultural objects that were subsequently stored at UCR. During this part of the excavation fragments of a human cranium were excavated from unit N-12, which was reportedly a few meters from an area where a burial was excavated in 1958. The human remains were repatriated by UCR to the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) in 2008, but the cultural materials were not included in the repatriation. In 2022, during NAGPRA consultation, tribal representatives of the Yuhaaviatam of San Manuel Nation identified the remaining items in the collection as being unassociated funerary objects. In 2024 the Morongo Band of Mission Indians also identified CA-SBR-1000 as an important village site to their tribal history.

In 1971 the University of California, Riverside Archaeological Research Unit was contacted by the Mojave River Museum Association requesting an emergency salvage excavation of archaeological site CA-SBR-554 (Jellyroll Cave). The members of the

association discovered vandalism and looting of the cave resulting in the damage to artifacts and the removal of baskets and other perishable objects. The cave is a small dry cave located in the Ord Mountains that was found by the UCR-ARU to contain well preserved perishable artifacts including a possible rodent snare, cordage and basketry fragments, and botanical materials such as seed and cacti. The roof of the cave appeared to be smoke-blackened and a midden deposit seemed to have formed at the floor of the valley about 5 meters below the mouth of the cave. Materials collected during the excavation were housed at UCR under accession number 48, but were never cataloged or analyzed. In 2022 tribal representatives from the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) reviewed the collection and identified it as being a Serrano cache or bundle. A considerable amount of tortoise shell was also found in the cave which tribal representatives noted might have been used in a ceremonial context.

In 1979 the University of California, Riverside Archaeological Research Unit (UCR-ARU) was contracted by the Southern California Edison Company to provide cultural resource impact analysis on various portions of transmission line corridors running through the Mojave Desert of California and Nevada. The work mostly consisted of foot survey and field sampling by archaeological surveyors from the UCR-ARU. The survey resulted in the location 61 archaeological sites and 146 isolates and artifacts collected from the surface were subsequently housed at the University of California, Riverside under accession number 70. In 2022, tribal representatives of the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) identified archaeological site CA-SBR-2131, on the Baker Transmission Line, to be a part of Serrano Ancestral territory. They identified a chalcedony biface removed from the site as being an object of cultural patrimony as it represents an important piece of Serrano history and culture.

The University of California, Riverside Archaeological Research Unit (UCR-ARU) conducted an archaeological assessment of a three-mile stretch of road leading from Dale Dry Lake to Amboy Road in 1986 at the request of Western America Ore Company, ahead of potential redevelopment. During the project, led by Adella Schroth of the UCR-ARU, a field survey was conducted with the collection of surface materials subsequently housed at UCR under

accession number 117. The survey uncovered one historic site and one prehistoric site. The geographic area is known to the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians and the Morongo Band of Mission Indians as Serrano ancestral territory. In 2022, representatives of the Yuhaaviatam of San Manuel Nation reviewed the collection and identified the items as being objects of cultural patrimony. The objects included metal, quartz, lithics, and faunal remains.

In 1989, at the request of the Southwestern Portland Cement Company (SPCC), the University of California, Riverside Archaeological Research Unit (UCR-ARU) conducted a cultural resources assessment of 1028 acres of land. The assessment, led by Joan Schneider and Brooke Arkush, consisted of a foot survey and test excavations. The project resulted in the identification of eleven prehistoric archaeological sites. Of these sites, archaeological materials were collected from nine sites and housed at UCR under accession numbers 153 and 180 through 186. These materials included lithics, glass, shell beads, faunal remains, botanical materials, fire affected rock, metal, charcoal, manos and metates, a steatite ring, and geological materials. The sites identified consisted of grinding slicks and bedrock mortars, boulders with cupules, hearths and roasting pits, and fire affected rock scatters. In 2022, during tribal consultation, representatives of the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) identified this project as falling within Serrano ancestral territory.

In 1990, the University of California, Riverside Archaeological Unit (UCRARU) conducted an archaeological assessment of 320 acres of land located southwest of the City of Barstow, in western San Bernardino County, California at the request of Tala-Lynwood, Inc., ahead of a development project. The project, UCRARU #1047, "Environmental Impact Evaluation: An Archaeological Assessment of 320 Acres of Land Located near Barstow in San Bernardino County, California", was led by Robert Yohe II and Brooke Arkush. During the assessment, an on-site survey was conducted with the collection of surface materials subsequently housed at UCR under accession number 163. The survey uncovered nine prehistoric sites and seven prehistoric isolates. The materials found within the area included lithic scatter, consisting of less than 30 flakes. In 2024, during tribal consultation, representatives of the

Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) and the Morongo Band of Mission Indians identified this project as falling within Serrano ancestral territory. Tribal representatives identified the lithic materials collected during the project as being objects of cultural patrimony.

In 1992, the University of California, Riverside Archaeological Research Unit (UCRARU) conducted an archaeological assessment on 20 acres of land designated Tentative Parcel 13964, located in the Baldy Mesa area of San Bernardino County, California at the request of Creative Boundaries, ahead of a proposed development project. The project, UCRARU #1185, "Cultural Resource Assessment: Tentative Parcel 13964 Located near Baldy Mesa in San Bernardino County, California", was led by Bruce Love and Michael Hogan. The project area is located to the east of Oro Grande Wash, north of the Cajon Summit area of the San Gabriel Mountains. During the assessment, an on-foot survey was conducted with the collection of surface materials subsequently housed at UCR under accession number 208. The survey uncovered two archaeological sites. The archaeologists noted this site as a prehistoric site consisting of a very dark concentration of ash, burned and fire-cracked rock, and at least two formed artifacts, a mano fragment and a quartzite cutting tool were recovered. The geographical location of the area is known to have been occupied by the Marrya'yam (Serrano) during the protohistoric time period.

In 2018, Dudek conducted cultural resources inventory on approximately 686.9 acres of land in Lucerne Valley, San Bernardino County, California at the request of Lendlease Energy Development, ahead of the Calcite Solar Project. The project, "Cultural Resources Inventory and Evaluation Report for the Calcite Solar Project", was led by Micah Hale. The cultural resource study uncovered 14 sites, seven historic roads, and five isolates in the project area. A total of three test units were excavated, each measuring at approximately 0.5 x 0.25m with 20cm increments to depths no more than 40–60 cm. The materials collected during the project was housed at the University of California, Riverside under accession number 326. During tribal consultation representatives of the Yuhaaviatam of San Manuel Nation (also known as the San Manuel Band of Mission Indians) and the Morongo Band of Mission Indians identified this project as falling within Serrano ancestral territory.

In 1989, the University of California, Riverside Archaeological Research Unit (UCR-ARU) conducted a cultural resource assessment of 132.6 acres of land located in the Manix Basin region of western San Bernardino County at the request of Ting-Seng Ho, ahead of a development project. The project, UCRARU #1002, "Environmental Impact Evaluation: An Archaeological Assessment of Assessor's Parcel 539–081–03, Located in Manix Basin in San Bernardino County, California", was led by Philip Wilke and Brooke Arkush. During the assessment, an on-foot survey was conducted with the collection of surface materials subsequently housed at UCR under accession number 480. The assessment uncovered three prehistoric sites and five prehistoric isolates. All three sites are the result of lithic reduction activity, while all five isolates are stone artifacts. The archaeologists noted the presences of lithic cores, various types of flakes, biface fragments, ground stone artifacts, a bifacial core, and one hammerstone. During tribal consultation representatives of the Yuhaaviatam of San Manuel Nation (*previously* listed as San Manuel Band of Mission Indians, California) and the Morongo Band of Mission Indians, California identified this project as falling within Serrano ancestral territory.

Determinations

The University of California, Riverside has determined that:

- The five unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- The 77 objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge

of an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural items described in this notice and the Morongo Band of Mission Indians, California, and the Yuhaaviatam of San Manuel Nation (*previously* listed as San Manuel Band of Mission Indians, California).

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **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 February 18, 2025. If competing requests for repatriation are received, the University of California, Riverside 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 University of California, Riverside is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01011 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039316;
PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: Northwestern University, Evanston, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Northwestern University 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.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Dr. Eli Suzukovich III, Northwestern University, 633 Clark Street, Evanston, IL 60208, telephone (847) 491-4133, email eli.iii@northwestern.edu (preferred contact).

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 Northwestern University, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains in Northwestern University's custody include 238 individual bones and fragments and represent a MNI of 44 individuals from the Fisher Mounds Site (11WI5) located in Will County Illinois. This determination is based on the number of sacrum and os coxa, scapulae, clavicles, atlas bones, complete/partial spinal columns, facial bones, and sternums. Along with human remains, there is one associated funerary object (ceramic pot rim) marked as "Fisher Trail ed 11Wi5, 10RZ-L9, 4-2-1." The human remains and associated funerary object were excavated from Will County, IL by George Langford and by the University of Chicago between 1912 and 1941. The collection dates to approximately A.D. 800-1400 and the late 17th century. No hazardous substances are known to have been used to treat any of the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

Northwestern University has determined that:

- The human remains described in this notice represent the physical remains of 44 individuals of Native American ancestry.

- The one associated funerary object described in this notice is reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the human remains and associated funerary object described in this notice and the Absentee-Shawnee Tribe of Indians of Oklahoma; Citizen Potawatomi Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Ho-Chunk Nation of Wisconsin; Iowa Tribe of Kansas and Nebraska; Iowa Tribe of Oklahoma; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Miami Tribe of Oklahoma; Minnesota Chippewa Tribe, Minnesota (Fond du Lac Band; Mille Lacs Band); Nottawaseppi Huron Band of the Potawatomi, Michigan; Omaha Tribe of Nebraska; Otoe-Missouria Tribe of Indians, Oklahoma; Peoria Tribe of Indians of Oklahoma; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Prairie Band Potawatomi Nation; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Shawnee Tribe; and the Winnebago Tribe of Nebraska.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the University of Illinois Urbana-Champaign 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

Illinois Urbana-Champaign 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01009 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039315;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: University of Florida, Florida Museum of Natural History, Gainesville, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Florida, Florida Museum of Natural History (FLMNH), 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.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Megan Fry, NAGPRA Coordinator and Bioarchaeologist, University of Florida, Florida Museum of Natural History, 1659 Museum Road, Gainesville, FL 32611, telephone (352) 273-1921, email megan.fry@floridamuseum.ufl.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 FLMNH, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Waddell's Mill (8JA65)

Human remains representing, at least, one individual has been identified from the Waddell's Mill Site (8JA65). The 8,512 associated funerary objects include faunal bone, faunal shell, ceramic sherds, lithic flakes, glass shards, charred and uncharred plant remains, faunal coprolite, and unfired clay fragments. The site was excavated numerous times between 1952-1973. The site is located in Jackson County, Florida, approximately seven miles northwest of Marianna, Florida. The site is situated on a limestone hill of the Crystal River Formation. The Ancestor was found buried in a cave shelter (Cave 1) on the mound which sits along the spring-fed pond. The site dates to the Middle Woodland through the Mission Period (A.D. 200 to 17th Century) but is predominantly associated with the Fort Walton Period. The FLMNH undertook building-wide fumigation with Vikane (sulfuryl fluoride) several times since this collection has entered the museum. No other exposure to potentially hazardous substances is known to FLMNH.

Marine Street (8SJ?)

Human remains representing, at least, seven individuals have been identified. There are no associated funerary objects. Human remains were uncovered as part of a construction project on the corner of Marine St. and Arsenal St. in St. Augustine, St. Johns County, Florida in June of 1973. They were donated to the Historic St. Augustine Preservation Board, who subsequently transferred them to the FLMNH, also in June of 1973. The FLMNH undertook building wide fumigation with Vikane (sulfuryl fluoride) several times since this collection has entered the museum. No other exposure to potentially hazardous substances is known.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The FLMNH has determined that:

- The human remains described in this notice represent the physical remains of eight individuals of Native American ancestry from two sites.
- The 8,512 objects described in this notice are reasonably believed to have been placed intentionally with or near

individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the human remains and associated funerary objects described in this notice and the Seminole Tribe of Florida and The Muscogee (Creek) Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the FLMNH 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 FLMNH 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01008 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039325;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Intended Disposition: U.S. Department of Agriculture, Forest Service, Nebraska National Forests and Grasslands, Chadron, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and

Repatriation Act (NAGPRA), the U.S. Department of Agriculture, Forest Service, Nebraska National Forests and Grasslands intends to carry out the disposition of human remains and an associated funerary object removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains associated funerary object in this notice may occur on or after February 18, 2025. If no claim for disposition is received by January 16, 2026, the human remains and associated funerary object in this notice will become unclaimed human remains and associated funerary object.

ADDRESSES: Jack Isaacs, Nebraska National Forests and Grasslands, Forest Supervisor, 125 North Main Street, Chadron, NE 69337, telephone (308) 430-1379, email jack.isaacs@usda.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 Nebraska National Forests and Grasslands, and additional information on the human remains and associated funerary object in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual has been reasonably identified. The one associated funerary object is a projectile point. On November 17, 2021, in Sioux County, Nebraska human remains (a skull with teeth, two small bones, a long bone, two femur bones and two long slender bones) and a single associated cultural item (projectile point) were removed. Part of the burial remains *in situ* and will be removed so the remains of the ancestor can be reunited per the wishes of the Tribe listed in this notice.

Determinations

The Nebraska National Forests and Grasslands has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The one object described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of

death or later as part of the death rite or ceremony.

- The Oglala Sioux Tribe has priority for disposition of the human remains and associated funerary object described in this notice.

Claims for Disposition

Written claims for disposition of the human remains and associated funerary object in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by January 16, 2026, the human remains and associated funerary object in this notice will become unclaimed human remains and associated funerary object. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization 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 they have priority for disposition.

Disposition of the human remains and associated funerary object in this notice may occur on or after February 18, 2025. If competing claims for disposition are received, the Nebraska National Forests and Grasslands must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains and associated funerary object are considered a single request and not competing requests. The Nebraska National Forests and Grasslands is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01016 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

**[NPS-WASO-NAGPRA-NPS0039321;
PPWOCRADNO-PCU00RP14.R50000]**

Notice of Intended Repatriation: Field Museum, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Field Museum intends to repatriate certain cultural items that meet the definition of sacred objects or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after February 18, 2025.

ADDRESSES: June Carpenter, NAGPRA Director, Field Museum, 1400 S Lake Shore Drive, Chicago, IL 60605, telephone (312) 665-7820, email jcarpenter@fieldmuseum.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 Field Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 54 cultural items have been requested for repatriation. The 19 sacred objects are two baskets, two lots of tobacco, three pipes, two meal plaques, one soup paddle, two game balls, two flutes, two ear sticks, one stick covered in quail scalps, and two bunches of human hair. The 35 objects of cultural patrimony are six baskets, one weft case, one basket warp, one leach mat, seven bone awls, one amole brush, 10 bird snares, one pigeon snare pole, one bone die, one lance and hoop game, three charm stones, one yarn belt, and one gorget. In 1901, the cultural items were removed from Fresno, Madera, and Mariposa Counties in California. The items were collected by Dr. John Hudson on behalf of the Field Museum during a two-year expedition among the Native populations of California and accessioned by the Museum in 1901.

Determinations

The Field Museum has determined that:

- The 19 sacred objects described in this notice are specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization.

- The 35 objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural items described in this notice and the Picayune Rancheria of Chukchansi Indians of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **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 February 18, 2025. If competing requests for repatriation are received, the Field 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 Field Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01012 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039317;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: No Man's Land Museum, Goodwell, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the No Man's Land Museum has completed an inventory of human remains and associated funerary objects and has determined that there is no lineal descendant and no Indian Tribe or Native Hawaiian organization with cultural affiliation.

DATES: Upon request, repatriation of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Sue Weissinger, No Man's Land Museum, 214 E Avenue, Goodwell, OK 73939, telephone (580) 349-2670, email nmlhs@outlook.com.

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 No Man's Land Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified. The six associated funerary objects are five harrell points and one stone knife blade. The individual was excavated by an unknown party on the Sprowles Ranch near Cheyenne, Oklahoma in Roger Mills County and loaned to the No Man's Land Museum on January 22, 1965. It was in a cairn as evidenced by two photographs that were loaned along with five Harrell points and one stone knife blade.

Human remains representing, at least, one individual have been identified. The one associated funerary object is horse bones. The individual was excavated one mile west and one-half mile south of Four Corners on Highway 64 in Texas County, Oklahoma. It was loaned to the No Man's Land Museum on August 10, 1936.

Human remains representing, at least, one individual have been identified. No associated funerary objects are present. The individual adult was removed from a site near Felt, Cimarron County, Oklahoma and donated on May 4, 1974.

It is unknown if harmful substances were used.

Consultation

Invitations to consult were sent to the Apache Tribe of Oklahoma; Cheyenne and Arapaho Tribes, Oklahoma;

Comanche Nation, Oklahoma; The Osage Nation; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma. The Cheyenne and Arapaho Tribes, Oklahoma; Comanche Nation, Oklahoma; The Osage Nation; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma agreed to consult. The Quapaw Nation declined to comment.

Cultural Affiliation

The following types of information about the cultural affiliation of the human remains and associated funerary objects in this notice are available: anthropological, archaeological, geographical, and expert opinion. The information, including the results of consultation, identified:

1. No earlier group connected to the human remains or associated funerary object.

2. No Indian Tribe or Native Hawaiian organization connected to the human remains or associated funerary objects.

3. No relationship of shared group identity between the earlier group and the Indian Tribe or Native Hawaiian organization that can be reasonably traced through time.

Determinations

The No Man's Land Museum has determined that:

- The human remains described in this notice represent the physical remains of three individuals of Native American ancestry.

- The seven objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- No known lineal descendant who can trace ancestry to the human remains and associated funerary objects in this notice has been identified.

- No Indian Tribe or Native Hawaiian organization with cultural affiliation to the human remains and associated funerary objects in this notice has been clearly or reasonably identified.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native

Hawaiian organization with cultural affiliation.

Upon request, repatriation of the human remains and associated funerary objects described in this notice may occur on or after February 18, 2025. If competing requests for repatriation are received, the No Man's Land Museum 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 No Man's Land Museum is responsible for sending a copy of this notice to any consulting lineal descendant, Indian Tribe, or Native Hawaiian organization.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01010 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039310;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Department of Conservation and Environment, 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 Conservation and Environment, Division of Archaeology (TDEC-TDOA) 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.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Phillip R. Hodge, Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC-TDOA), 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-TDOA, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least 13 individuals have been identified. The six associated funerary objects are two deer ulnae, one lot of faunal material, one lot of ceramic sherds, one lot of freshwater shell fragments, and one lot of associated funerary objects that have not been inventoried.

Sweetwater Island (40LD186), Loudon County, TN

Ancestral remains of at minimum two individuals were recovered by TDEC-TDOA personnel from Sweetwater Island in the Tennessee River in 1974. No record exists as to the specific circumstances surrounding their collection. The Eastern Band of Cherokee Indians claimed these ancestors on June 10, 2021. Consultation took place on May 24, June 6, and June 24, 2024. There is no known exposure to hazardous substances or treatments.

Unknown Site, Lenoir City, Loudon County, TN

Ancestral remains of at minimum two individuals and three associated funerary objects consisting of one lot of ceramic sherds, one lot of freshwater shell fragments, and one lot of faunal material were recovered during construction in Lenoir City, Tennessee in June 2023. Those were turned over to local law enforcement, transferred to the Knox County Forensic Center, and then transferred to the TDEC-TDOA for repatriation. These ancestors and associated funerary objects had not been previously reported to National NAGPRA. Consultation took place on May 24, June 6, and June 24, 2024. There is no known exposure to hazardous substances or treatments. In consultation on May 24, 2024 TDEC-TDOA suggested that these ancestors be included in the current claim. All Tribal Partners have agreed to this course of action.

McMahan Mound (40SV1), Sevierville, Sevier County, TN

Ancestral remains of at minimum two individuals and one lot of associated funerary objects that have not been

inventoried were recovered by TDEC-TDOA in 1976 prior to construction of a highway bypass. The Eastern Band of Cherokee Indians claimed these ancestors on June 10, 2021. The original TDEC-TDOA NAGPRA inventory lists a single individual from this site. During review of site documentation prior to consultation, TDEC-TDOA staff identified a second ancestor as well as artifacts from associated feature fill. Consultation took place on May 24, June 6, and June 24, 2024. Tribal partners requested in consultation on May 24, 2024 that the associated funerary objects be lotted and not formally inventoried. There is no known exposure to hazardous substances or treatments.

Great Smoky Mountain Children's Home (40SV53), Sevierville, Sevier County, TN

Ancestral remains of a minimum number of three commingled individuals were exposed by mechanical excavation at the Great Smoky Mountain Children's Home in Sevierville, Tennessee in 2014. Those remains were transferred to the Division of Archaeology for repatriation. The Eastern Band of Cherokee Indians claimed these ancestors on June 10, 2021. Consultation took place on May 24, June 6, and June 24, 2024. There is no known exposure to hazardous substances or treatments.

Unknown Site, Sevierville, Sevier County TN

Ancestral remains of a minimum of four individuals and two associated funerary objects consisting of two deer ulnae, originate from an unknown site in Sevierville, Sevier County, Tennessee. Original NAGPRA inventory sheet suggest they were collected in 1931. No additional records exist as to the timing, donor, or circumstances of acquisition. Consultation took place on May 24, June 6, and June 24, 2024. In consultation on May 24, 2024 TDEC-TDOA suggested that these ancestors be included in the current claim. All Tribal Partners have agreed to this course of action. There is no known exposure to hazardous substances or treatments.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The TDEC-TDOA has determined that:

- The human remains described in this notice represent the physical remains of at least 13 individuals of Native American ancestry.

- The two associated funerary objects and four lots of associated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the human remains and associated funerary objects described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; The Muscogee (Creek) 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 authorized representative identified in this notice under **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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the TDEC-TDOA 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-TDOA 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01004 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039311;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the California State University, Sacramento has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after February 18, 2025.

ADDRESSES: Dr. Mark R. Wheeler, Senior Advisor to President Luke Wood, California State University, Sacramento, 6000 J Street Sacramento, CA 95819, telephone (916) 460-0490, email mark.wheeler@csus.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 California State University, Sacramento, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified from an unknown location in Modoc County, California. The human remains were found by a local rancher in 1974. They were turned over to a Modoc National Forest archaeologist by the sheriff's office. After determining that the remains were Native American, the archaeologist transferred the remains to Sacramento State. They have since been housed at the University under accession 81-CSUS-332.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the

information available about the human remains described in this notice.

Determinations

The California State University, Sacramento has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.

- There is a connection between the human remains described in this notice and the Alturas Indian Rancheria, California; Cedarville Rancheria, California; Fort Bidwell Indian Community of the Fort Bidwell Reservation of California; Klamath Tribes; Modoc Nation; and the Pit River Tribe, California (includes XL Ranch, Big Bend, Likely, Lookout, Montgomery Creek, and Roaring Creek Rancherias).

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under

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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the California State University, Sacramento must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The California State University, Sacramento 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01005 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-NAGPRA-NPS0039314;
PPWOCRADNO-PCU00RP14.R50000]

**Notice of Intended Repatriation:
Michigan State University, East
Lansing, MI**

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Michigan State University intends to repatriate a certain cultural item that meets the definition of an unassociated funerary object and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after February 18, 2025.

ADDRESSES: Judith Stoddart, Michigan State University, 287 Delta Court, East Lansing, MI 48824, telephone (517) 432-2524, email stoddart@msu.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 Michigan State University, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one cultural item has been requested for repatriation. The one unassociated funerary object is a preserved textile fragment in plaster (catalog number 2002.29.27). The textile was removed from the Sunnerville Mound (20CS6) in Pokagon Township, Cass County, Michigan. The textile was likely removed from the mound in 1888 by Eliot Crane, who sold/gave away the objects recovered (most to the Kent Scientific Institute). We believe Crane gave some of these textiles to local collectors and eventually it made it into Donald Boudeman's collection, which was donated to the Michigan State University Museum in 1961 by Donna Boudeman after his passing. While the textile has been modified by placing it in plaster, no hazardous substances are known to have been used.

Determinations

Michigan State University has determined that:

- The one unassociated funerary object described in this notice is reasonably believed to have been placed intentionally with or near human remains, and is connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary object has been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural item described in this notice and the Pokagon Band of Potawatomi Indians, Michigan and Indiana.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the authorized representative identified in this notice under **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 item in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, Michigan State University 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. Michigan State University is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01007 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-NAGPRA-NPS0039312;
PPWOCRADNO-PCU00RP14.R50000]

**Notice of Inventory Completion:
Peabody Museum of Archaeology and
Ethnology, Harvard University,
Cambridge, MA**

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the U.S. Indian Vocational School, Bernalillo County, NM.

DATES: Repatriation of the human remains in this notice may occur on or after February 18, 2025.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496-2374, email jpickering@fas.harvard.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 PMAE, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at minimum, four individuals were collected at the U.S. Indian Vocational School, Bernalillo County, NM. The human remains are hair clippings collected from one individual who was recorded as being 15 years old, one individual who was recorded as being 14 years old, one individual who was recorded as being 13 years old, and one individual who was recorded as being 12 years old and identified as "Zia." Reuben Perry took the hair clippings at the U.S. Indian Vocational School between 1930 and 1933. Perry sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE.

in 1935. No associated funerary objects are present.

Cultural Affiliation

Based on the available information and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains described in this notice.

Determinations

The PMAE has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- There is a reasonable connection between the human remains described in this notice and the Pueblo of Zia, New Mexico.

Requests for Repatriation

Written requests for repatriation of the human remains 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 in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01006 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-12-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039323;
PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: Sam Noble Museum of Natural History, Norman, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Sam Noble Oklahoma Museum of Natural History (SNOMNH) 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.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025.

ADDRESSES: Dr. Marc Levine, Associate Curator of Archaeology, Sam Noble Oklahoma Museum of Natural History, University of Oklahoma, 2401 Chautauqua Avenue, Norman, OK 73072-7029, telephone (405) 325-1994, email mlevine@ou.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 SNOMNH, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, 281 individuals were removed from the Raymond Mackey site (34Lf29) in LeFlore County, OK. This site was excavated by the Works Progress Administration in 1940 and transferred to the Museum the same year. The human remains include 62 adult females, 32 adult males, 21 adolescents, 25 children, two infants, one fetus, 60 probable adult females, 41 probable adult males, two females for whom age could not be determined, 18 adults for whom sex could not be determined, and 17 individuals for whom neither age nor sex could be determined. No known individuals were identified. The 169 associated funerary objects are two

potsherds, 39 projectile points, one projectile point fragment, three stone manos, two hammerstones, one stone hoe, one boatstone, six stone bifaces, seven bags of stone biface fragments, 17 paintstones, one worked stone, one stone flake, one unmodified piece of quartz, one partial dog skeleton, two bone awls, four bags of awl fragments, two bone beads, two bags of bone fish hook fragments, one bag of bone pin fragments, one worked deer antler, one worked deer ulna, three bags of worked animal bone, 14 bags of deer antler fragments, 44 bags of animal bone fragments, two shell beads, one conch disc, six bags of mussel shell fragments, one snail shell, one burned nut, and one bag of ash. The human remains and associated funerary objects from site 34Lf29 were interred during the Woodland Period (300 B.C.–A.D. 900).

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The SNOMNH has determined that:

- The human remains described in this notice represent the physical remains of 281 individuals were of Native American ancestry.
- The 169 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Caddo Nation of Oklahoma and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **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 an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after February 18, 2025. If competing requests for repatriation are received, the SNOMNH 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 SNOMNH 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 10.10.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025–01014 Filed 1–15–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039327;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition: Naval Weapons Station, Yorktown, VA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Naval Weapons Station Yorktown (NWSY) intends to carry out the disposition of human remains removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains in this notice may occur on or after February 18, 2025. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Mike Makin, Cultural Resources Manager at NWSY, 160 Main Road, Building 406, York County, VA 23691, telephone (757) 887–4148, email douglas.m.makin.civ@us.navy.mil.

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 NWSY and additional information on the human remains or cultural items in this notice,

including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual have been reasonably identified. No associated funerary objects are present. These human remains were recovered on 9 April 2003 during archaeological excavations at 44YO0002, the site of the Woodland and Contact Period village of Kiskiack located at NWSY in York County, VA. They were recovered from a 1920s trench that disturbed an earlier period burial. Most of the burial was left undisturbed and only material from the trench was removed.

Determinations

NWSY has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The Pamunkey Indian Tribe has priority for disposition of the human remains described in this notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization 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 they have priority for disposition.

Disposition of the human remains in this notice may occur on or after February 18, 2025. If competing claims for disposition are received, NWSY must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. NWSY is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025–01013 Filed 1–15–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039327;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition: U.S. Department of Agriculture, Forest Service, Chugach National Forest, Anchorage, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of Agriculture, Forest Service, Chugach National Forest intends to carry out the disposition of human remains removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains in this notice may occur on or after February 18, 2025. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Jeff E. Schramm, Forest Supervisor, Chugach National Forest, Supervisor's Office, 161 E 1st Ave., Door 8, Anchorage, AK 99501, telephone (907) 743–9500, email jeff.schramm@usda.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 Chugach National Forest, and additional information on the human remains in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual have been reasonably identified.

In 1992, human remains were recovered near the Eagle Glacier Nordic Training Center cabin, within the Municipality of Anchorage, near Girdwood, AK by a private individual.

The private individual was referred to the State of Alaska Office of History and Archaeology by the State Crime Laboratory. The remains were transferred to the Supervisor's Office of the Chugach National Forest in Anchorage, AK on October 12, 1995. The human remains are one small fragmentary mandible which is well-worn from exposure to the elements.

Determinations

The Chugach National Forest has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The Eklutna Native Village and the Knik Tribe have priority for disposition of the human remains described in this notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by January 16, 2026, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization 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 they have priority for disposition.

Disposition of the human remains in this notice may occur on or after February 18, 2025. If competing claims for disposition are received, the Chugach National Forest, must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. The Chugach National Forest is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01018 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0039326; PPWOCRADNO-PCU00RP14.R50000]

Notice of Intended Disposition: U.S. Department of Agriculture, Forest Service, Nebraska National Forests and Grasslands, Chadron, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of Agriculture, Forest Service, Nebraska National Forests and Grasslands intends to carry out the disposition of human remains and associated funerary objects removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025. If no claim for disposition is received by January 16, 2026, the human remains and associated funerary objects in this notice will become unclaimed human remains and associated funerary objects.

ADDRESSES: Jack Isaacs, Nebraska National Forests and Grasslands, Forest Supervisor, 125 North Main Street, Chadron, NE 69337, telephone (308) 430-1379, email jack.isaacs@usda.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 Nebraska National Forests and Grasslands, and additional information on the human remains and associated funerary objects in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual has been reasonably identified. Two associated funerary objects are present. On August 29 and August 30, 2022, in Pennington County, South Dakota human remains (including a skull with teeth, mandible, clavicle, vertebrae, ribs, pelvis, two femur bones and other bones) and the two potentially associated funerary items (one small round stone and one unspecified object) were removed.

Determinations

The Nebraska National Forests and Grasslands has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The two objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- The Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana; Cheyenne and Arapaho Tribes, Oklahoma; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota; Northern Arapaho Tribe of the Wind River Reservation, Wyoming; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Oglala Sioux Tribe; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota; Spirit Lake Tribe, North Dakota; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; and the Yankton Sioux Tribe of South Dakota have priority for disposition of the human remains and associated funerary objects described in this notice.

Claims for Disposition

Written claims for disposition of the human remains and associated funerary objects in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by January 16, 2026, the human remains and associated funerary objects in this notice will become unclaimed human remains and associated funerary objects. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization 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 they have priority for disposition.

Disposition of the human remains and associated funerary objects in this notice may occur on or after February 18, 2025. If competing claims for disposition are received, the Nebraska National Forests and Grasslands must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains and

associated funerary objects are considered a single request and not competing requests. The Nebraska National Forests and Grasslands is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: January 6, 2025.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2025-01017 Filed 1-15-25; 8:45 am]

BILLING CODE 4312-52-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Photovoltaic Trunk Bus Cable Assemblies and Components Thereof*, DN 3802; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Shoals Technologies Group, LLC on January 10, 2025. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain photovoltaic trunk bus cable assemblies and components thereof. The complaint names as respondents: Voltage, LLC of Chapel Hill, NC; and Ningbo Voltage Smart Production Co. of China. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period.

Proposed respondents, other interested parties, members of the public, and interested government agencies are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this

notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3802") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDIS3Help@usitc.gov.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews,

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: January 10, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-00940 Filed 1-15-25; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0068]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; FBI Records Modification Form (FD-1115)

AGENCY: Criminal Justice Information Services (CJIS) Division, Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The CJIS Division, FBI, DOJ, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until March 17, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Brian A. Cain, Management and Program Analyst, FBI, CJIS, Criminal History Information and Policy Unit, BTC-3, 1000 Custer Hollow Road, Clarksburg, WV 26306; phone: 304-625-5590 or email bacain@fbi.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: The FBI Records Modification Form (FD-1115) is necessary to assure criminal history information is appropriately collected,

retained, amended, and thus disseminated in a manner that ensure the accuracy of the record to protect individual privacy as required by 28 CFR 20.1. In addition, the form provides a consistent method for agencies to submit request to edit their records when edits cannot be performed electronically.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection

2. *The Title of the Form/Collection:* FBI Records Modification Form

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* FD-1115; CJIS, FBI, DOJ.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public State, local and Tribal governments as well as Federal Government. The obligation to respond is mandatory per 28 CFR 20.37 as agencies contributing data to the Next Generation Identification NGI System are responsible for accuracy, completeness, currency, and integrity.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated number of yearly responses for the FBI Records Modification Form (FD-1115) is 134,031. The estimated time to complete the form is 3.5 minutes.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual burden hours for this collection is 7818 hours. $(134,031 \times 3.5 \text{ minutes}/60 = 7,818 \text{ hours})$.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* N/A.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency (annually)	Total annual responses	Time per response (min.)	Total annual burden (hours)
Ex: Survey (individuals or households)	134,031	1	134,031	3.5	7,818
Unduplicated Totals	134,031		134,031		7,818

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC.

Dated: January 13, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025-00988 Filed 1-15-25; 8:45 am]

BILLING CODE 4410-02-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Safety and Health Act Variance Regulations

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before February 18, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202-693-0213, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: Under several provisions of the OSH Act, employers may apply for four different types of variances from the requirements of OSHA standards. Employers submit variance applications voluntarily to OSHA, and the applications specify alternative means of complying with the requirements of OSHA standards. The four types of variances are: temporary variances (section 6(b)(6)(A) of the OSH Act; 29 U.S.C. 655); experimental variances (section 6(b)(6)(C) of the OSH Act; 29

U.S.C. 655); permanent variances (section 6(d) of the Act; 29 U.S.C. 655); and national-defense variances (section 16 of the OSH Act; 29 U.S.C. 665). OSHA codified these statutory provisions under 29 CFR part 1905 (“Rules of Practice for Variances, Limitations, Variations, Tolerances, and Exemptions under the William-Steiger Occupational Safety and Health Act of 1970”). For additional substantive information about this ICR, see the related notice published in the **Federal Register** on September 16, 2024 (89 FR 75587).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL-OSHA.

Title of Collection: Occupational Safety and Health Act Variance Regulations.

OMB Control Number: 1218-0265.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 12.

Total Estimated Number of Responses: 48.

Total Estimated Annual Time Burden: 366 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025-00861 Filed 1-15-25; 8:45 am]

BILLING CODE 4510-26-P

MERIT SYSTEMS PROTECTION BOARD

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: U.S. Merit Systems Protection Board.

ACTION: Notice and request for comments.

SUMMARY: The U.S. Merit Systems Protection Board (MSPB), as part of its continuing effort to reduce paperwork and respondent burden, intends to request approval of a new information collection from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. MSPB is submitting this Information Collection Request (ICR), entitled Accommodation Request Form, OMB Control No. 3124-0NEW, for approval in accordance with Federal regulations, and is requesting public comments. This collection was developed as part of MSPB’s effort to streamline the process for collecting information from employees and applicants to MSPB, as well as participants in MSPB functions (parties and/or participants in MSPB appeals, respondents to surveys, and all other individuals engaged in activity conducted by the MSPB), who seek a reasonable accommodation in order for MSPB to carry out its functions with respect to these individuals. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: Consideration will be given to all comments received by March 17, 2025.

ADDRESSES: Submit comments by using only one of the following methods:

(1) *Email.* Submit comments to privacy@mspb.gov.

(2) *Mail.* Submit comments to D. Fon Muttamara, Chief Privacy Officer, Office of the Clerk of the Board, U.S. Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419.

(3) *Fax.* Submit comments to (202) 653-7130.

All comments must reference “OMB Control No. 3124-0NEW.” Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to

MSPB's website (www.mspb.gov) and will include any personal information you provide. Therefore, submitting this information makes it public.

FOR FURTHER INFORMATION CONTACT: D. Fon Muttamara, Chief Privacy Officer, at privacy@mspb.gov or (202) 653-7200. You may submit written questions to the Office of the Clerk of the Board by any of the following methods: by email to privacy@mspb.gov or by mail to Clerk of the Board, U.S. Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419. Please include "OMB Control No. 3124-0NEW" with your questions.

SUPPLEMENTARY INFORMATION: In accordance with title V of the Rehabilitation Act of 1973 (Rehabilitation Act), as amended, and title VII of the Civil Rights Act of 1964 (Civil Rights Act), as amended, MSPB is seeking approval of a new information collection for MSPB's reasonable accommodation process, including MSPB's Accommodation Request Form and a script for participants in MSPB programs to submit accommodation requests. The proposed information collection activity covers MSPB's collection, maintenance, and use of records on applicants for employment, employees, and participants in MSPB programs who request or receive reasonable accommodations or other appropriate modifications from MSPB for disability, medical, pregnancy-related, or religious reasons.

Title V of the Rehabilitation Act of 1973, as amended, prohibits discrimination in services and employment on the basis of disability; title VII of the Civil Rights Act of 1964, in relevant part, prohibits discrimination on the basis of religion; the Pregnancy Discrimination Act prohibits discrimination on the basis of pregnancy. Each Act, along with the Pregnant Workers Fairness Act, requires employers to provide reasonable accommodations, respectively, related to an employee's disability, pregnancy-related condition, or religious beliefs, that conflict with work requirements, unless the accommodation would cause the employer an undue hardship.¹ In general, an accommodation is any change in the work environment or in the way things are customarily done that enables an individual with a disability to enjoy equal employment opportunities. MSPB considers the

following factors, where applicable, when adjudicating reasonable accommodations requests received: (1) Description of the accommodations requested by applicants for employment or employees seeking modification or adjustments; (2) description of the medical conditions or pregnancy-related conditions that impact the ability to apply for employment or for employees to carry out work-related duties and functions; (3) description of bodily functions impacted by the disabling medical or pregnancy-related conditions; (4) description of treatment, medication, or other mitigating factors used to treat the disabling medical conditions; (5) description of the sincerely held religious beliefs that conflict with a work requirement; and (6) supporting documentation (e.g., medical records, doctor's notes, documentation regarding religious beliefs, etc.) for the request.

Reasonable accommodations on the basis of disability typically fall into the following categories: (1) Modifications or adjustments to a job application process that enable a qualified applicant with a disability to be considered for a position; (2) modifications or adjustments to the work environment, or to the manner or circumstances under which the position held or desired is customarily performed, that enable a qualified individual with a disability to perform the essential functions of that position; (3) modifications or adjustments that enable a qualified employee with a disability to enjoy equal benefits and privileges of employment as are enjoyed by other similarly-situated employees without disabilities; and (4) modifications to agency operating procedures to enable a qualified individual with a disability full access to agency functions. In some instances, individuals may request modification to their workspace, schedule, duties, or other requirements for documented medical reasons that may not qualify as a disability but may necessitate an appropriate modification to workplace policies and practices.

MSPB's Office of Equal Employment Opportunity is responsible for processing requests for reasonable accommodations from applicants for employment at MSPB and MSPB employees who seek an accommodation due to a disability, medical, pregnancy-related, or religious reasons as well as processing requests based on documented medical reasons that may not qualify as a disability but that may necessitate an appropriate modification to workplace policies and practices. For participants in MSPB programs who are not applicants for employment or MSPB

employees, MSPB's Accessibility Program Manager, within the Office of Information Resources Management, is responsible for processing these requests.

The request and any related records provided to support the request, any evaluation conducted internally or by a third party under contract with MSPB, the decision regarding whether to grant or deny a request, and the details and conditions of the reasonable accommodation are all included in this collection.

Title: Information Collection Submission for MSPB's Reasonable Accommodation Request.

OMB Number: 3124-0NEW.

Type of Information Collection: This will be a new information collection.

ICR Status: MSPB intends to request approval of a new information collection from OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 and 3507). 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.

Abstract of Proposed Collection: This collection is part of MSPB's compliance efforts to collect information to facilitate adjudication of reasonable accommodations requests by employees of or applicants to the MSPB, and by participants in MSPB programs, e.g., parties to appeals, respondents to surveys, etc. See The Rehabilitation Act of 1973, 29 U.S.C. 701, 791, 794; title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e; 29 CFR part 1605 (Guidelines on Discrimination Because of Religion); 29 CFR part 1614 (Federal Sector Equal Employment Opportunity); 29 CFR part 1630 (Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act); E.O. 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation (July 26, 2000); and E.O. 13548, Increasing Federal Employment of Individuals with Disabilities (July 26, 2010); The Pregnant Workers Fairness Act (effective June 27, 2023). Responses to any collection of information under this ICR are voluntary.

Affected Public: Individuals and Households; Businesses and Organizations.

Estimated Total Number of Respondents: 90.

Estimated Frequency of Responses: Once per request.

Estimated Total Average Number of Responses for Each Respondent: 1.

Estimated Total Annual Burden Hours: 70.

¹ Pregnancy includes current pregnancy; past pregnancy; potential pregnancy; medical condition(s) related to pregnancy or childbirth including breastfeeding/lactation; having or choosing not to have an abortion; and birth control (contraception).

Estimated Total Cost: \$2,653.

Comments: Comments should be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to: (a) evaluate whether the collection of information is necessary for the proper performance of the functions of MSPB, including whether the information shall have practical utility; (b) evaluate the accuracy of MSPB's estimate of the burden of the collection of information; (c) enhance the quality, utility, and clarity of the information to be collected; (d) minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) evaluate the estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Gina K. Grippando,
Clerk of the Board.

[FR Doc. 2025-00956 Filed 1-15-25; 8:45 am]

BILLING CODE 7400-01-P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Science and Engineering Policy (SEP) hereby gives notice of the scheduling of a videoconference 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: Tuesday, January 21, 2025, from 2:00 p.m.–2:45 p.m. Eastern.

PLACE: The meeting will be held by videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA, 22314. Members of the public can observe this meeting through a YouTube livestream. The YouTube link will be available from

the NSB meetings web page—<https://www.nsf.gov/nsb/meetings/index.jsp>.

STATUS: Open.

MATTERS TO BE CONSIDERED: Chair's opening remarks; Discussion of Detailed Narrative Outline and vote on *Talent* report for *Indicators 2026*.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is Chris Blair, cblair@nsf.gov, 703-292-7000.

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2025-01225 Filed 1-14-25; 4:15 pm]

BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science & Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code:

Committee on Equal Opportunities in Science & Engineering (#1173) (Virtual).

Date and Time: February 13, 2025; 1 p.m.–5:30 p.m. (eastern) and February 14, 2025; 10 a.m.–3:30 p.m. (eastern)

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual). Meeting Registration: Virtual attendance information will be forthcoming on the CEOSE website at <http://www.nsf.gov/od/oia/activities/ceose/index.jsp>.

Type of Meeting: Open.

Contact Persons: Dr. Bernice Anderson, Senior Advisor and CEOSE Executive Secretary, Office of Integrative Activities (OIA); National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. Contact Information: Phone: 703-292-8040, Email: banderso@nsf.gov.

Minutes: Meeting minutes and other information may be obtained from the CEOSE Executive Secretary at the above address or the website at <http://www.nsf.gov/od/oia/activities/ceose/index.jsp>.

Purpose of Meeting: To study data, programs, policies, and other information pertinent to the National Science Foundation and to provide advice and recommendations concerning broadening participation in science and engineering.

Agenda: CEOSE Agenda-at-a-Glance (February 13–14, 2025)

Day 1

1 p.m.–2 p.m. Opening, Welcome, Introduction

2 p.m.–2:30 p.m. Presentation: Report of the CEOSE Executive Liaison
2:30 p.m.–3 p.m. Presentation: Broadening Participation in the SBE Sciences
3 p.m.–3:15 p.m. *Break*
3:15 p.m.–4:30 p.m. Panel: Institutional Transformation
4:30 p.m.–5:30 p.m. Discussion: Reports of the CEOSE AC Liaisons

Day 2

10 a.m.–10:15 a.m. Opening Remarks
10:15 a.m.–11:15 a.m. Discussion: Dissemination of the 2023–2024 CEOSE Report
11:15 a.m.–12 p.m. Discussion: 2025–2026 CEOSE Report
12 p.m.–1:30 p.m. Working Lunch: Topics/Advice to Share with NSF Senior Leadership
1:30 p.m.–2 p.m. Discussion with NSF Leadership
2 p.m.–2:15 p.m. *Break*
2:15 p.m.–3 p.m. Reflections and Advice to New Members
3 p.m.–3:30 p.m. Announcements, Closing Remarks, Adjournment

Dated: January 13, 2025.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2025-00982 Filed 1-15-25; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2024-0217]

Draft Interim Staff Guidance: Content of Risk Assessment and Severe Accident Information in Light-Water Power Reactor Construction Permit Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting public comment on its draft Interim Staff Guidance (ISG) “Content of Risk Assessment and Severe Accident Information in Light-Water Power Reactor Construction Permit Applications.” This draft ISG clarifies the scope and depth of the NRC staff review of the content of risk assessment and severe accident information in a construction permit (CP) application for a light-water power reactor. The purpose of this draft ISG is to clarify existing guidance in NUREG-0800, “Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition

(NUREG-0800, formerly issued as NUREG-75 087),” (“the SRP”; Ref. 1).

DATES: Submit comments by February 18, 2025. Comments received after this date will be considered if it is practical to do so, but the Commission 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-2024-0217. 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.

- *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: Brian Benney, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2767; email: Brian.Benney@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0217 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-2024-0217.

- *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, at 301-415-4737, or by email to

PDR.Resource@nrc.gov. The draft ISG, “Content of Risk Assessment and Severe Accident Information in Light-Water Power Reactor Construction Permit Applications,” is available in ADAMS under Accession No. ML24192A277.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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-2024-0217 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. Discussion

The NRC anticipates the submission of power reactor construction permit (CP) applications in the next few years based on pre-application engagement initiated by several prospective applicants and vendors. The review of these applications falls within the two-step licensing process under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” and involves the issuance of a CP before an operating license (OL). The NRC last issued a power reactor CP in the 1970s. Most recently, the NRC issued combined construction permit and operating licenses (combined licenses or COLs) for power reactors through the one-step licensing process

under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” using the guidance in the SRP and Regulatory Guide (RG) 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition),” issued June 2007 (ADAMS Package Accession No. ML070720184). The NRC has periodically updated some of the SRP guidance and issued Revision 1 to RG 1.206, “Applications for Nuclear Power Plants,” in October 2018 (ADAMS Accession No. ML18131A181). The licensing process under 10 CFR part 50 allows an applicant to begin construction with preliminary design information instead of the final design required for a COL under 10 CFR part 52. Although the two-step licensing process provides flexibility and allows a more limited safety review before construction, the proceeding on the CP does not resolve issues that may be considered in the OL proceeding except in limited circumstances. In particular, the CP proceeding does not in most cases finally resolve requests for specific exemptions to 10 CFR part 50 regulatory requirements. The final safety analysis report (FSAR) submitted with the OL application must describe in detail the final design of the facility as constructed; identify the changes from the criteria, design, and bases in the CP preliminary safety analysis report (PSAR); and discuss the bases for and safety significance of the changes from the PSAR. Before issuing an OL, the NRC staff will review the applicant’s final design in the FSAR to determine whether all the Commission’s safety requirements have been met. The SRP contains the NRC staff review guidance for light-water reactor (LWR) applications submitted under 10 CFR part 50 or 10 CFR part 52. In addition to the CP review guidance in the SRP and RG 1.70, Revision 3, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” issued November 1978 (Ref. 6) (ADAMS Package Accession No. ML011340122), offers some insights on the level of detail that is required for the PSAR included in the CP application, but these insights may be limited to the degree that the guidance does not account for subsequent requirements, positions, or advances in technical knowledge. RG 1.206, Revision 1, provides guidance for 10 CFR part 52 applications, including for early site permits and COLs, as well as insights on the level of detail needed for final design information if the CP applicant chooses to provide such information. On October 31, 2022, the NRC staff

issued ISG DNRL–ISG–2022–01, “Safety Review of Light-Water Power Reactor Construction Permit Applications,” (ADAMS Accession No. ML22189A099), to facilitate safety reviews of LWR CP applications and to supplement the guidance in the SRP. DNRL–ISG–2022–01 describes the regulatory requirements, applicable review guidance in the SRP, and special topics for an LWR CP application. DNRL–ISG–2022–01 provides guidance on the staff review of the preliminary design information in the PSAR including the description and safety assessment of the site on which the facility is to be located. DNRL–ISG–2022–01 does not provide specific information relevant to the review of probabilistic risk assessment and alternative risk evaluations supporting an LWR CP application but points generally to the SRP to provide the NRC staff with an acceptable approach for reviewing such information. The staff has developed this draft ISG to clarify the scope and depth of the staff review of the content of risk assessment and severe accident information in a CP application for a light-water power reactor.

III. Backfitting, Forward Fitting, and Issue Finality

This draft ISG provides guidance for the NRC staff review of light-water power reactor construction permit applications. Issuance of this ISG as final would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and as described in NRC Management Directive (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests”; would not constitute forward fitting as that term is defined and described in MD 8.4; and would not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality.

For the Nuclear Regulatory Commission.

Dated: January 13, 2025.

Michelle Hayes,

Chief, Licensing and Regulatory Infrastructure Branch, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2025–00989 Filed 1–15–25; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1275 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1097, K2025–1096.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00919 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 595 to Competitive Product List*. Documents

are available at www.prc.gov, Docket Nos. MC2025–1103, K2025–1102.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00925 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1287 to Competitive Product List*. Documents are available at

www.prc.gov, Docket Nos. MC2025–1111, K2025–1110.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00936 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1274 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1096, K2025–1095.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00918 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1269 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1090, K2025–1089.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00913 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal

Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 593 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1094, K2025–1093.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00923 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1260 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1079, K2025–1078.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00903 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1265 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1084, K2025–1083.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00908 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1251 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2025–1069, K2025–1068.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00877 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1263 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1082, K2025–1081.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00906 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1266 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1085, K2025–1084.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00909 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1249 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1066, K2025–1065.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00875 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1276 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1098, K2025–1097.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00920 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1256 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1074, K2025–1073.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00882 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1267 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1088, K2025–1087.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00910 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 591 to Competitive Product List*. Documents

are available at www.prc.gov, Docket Nos. MC2025–1086, K2025–1085.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00921 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1245 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1062, K2025–1061.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00871 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1248 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1065, K2025–1064.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00874 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1254 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1072, K2025–1071.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00880 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal

Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 594 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1102, K2025–1101.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00924 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1255 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1073, K2025–1072.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00881 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1281 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1105, K2025–1104.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00930 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1268 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2025–1089, K2025–1088.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00911 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 592 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1087, K2025–1086.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00922 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1252 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1070, K2025–1069.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00878 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1258 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1076, K2025–1075.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00884 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal

Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 587 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1059, K2025–1058.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00866 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1271 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1092, K2025–1091.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00915 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 589 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1067, K2025–1066.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00868 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1250 to Competitive Product List*. Documents are available at

www.prc.gov, Docket Nos. MC2025–1068, K2025–1067.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00876 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1286 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1110, K2025–1109.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00935 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1273 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1095, K2025–1094.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00917 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1279 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1101, K2025–1100.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00928 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal

Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1261 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1080, K2025–1079.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00904 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 588 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1061, K2025–1060.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00867 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1257 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1075, K2025–1074.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00883 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1283 to Competitive Product List.

Documents are available at www.prc.gov, Docket Nos. MC2025–1107, K2025–1106.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00932 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1282 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1106, K2025–1105.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00931 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1272 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1093, K2025–1092.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00916 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1253 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1071, K2025–1070.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00879 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1246 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025-1063, K2025-1062.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025-00872 Filed 1-15-25; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1288 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025-1112, K2025-1111.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025-00937 Filed 1-15-25; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1278 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025-1100, K2025-1099.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025-00927 Filed 1-15-25; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1280 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2025-1104, K2025-1103.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025-00929 Filed 1-15-25; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1244 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025-1060, K2025-1059.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025-00870 Filed 1-15-25; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1259 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1077, K2025–1076.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00885 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement**

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List. **DATES:** *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1277 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1099, K2025–1098.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00926 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement**

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 590 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1078, K2025–1077.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00869 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement**

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1270 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1091, K2025–1090.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00914 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement**

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1284 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1108, K2025–1107.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00933 Filed 1–15–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement**

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 7, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1262 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2025–1081, K2025–1080.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00905 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 6, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1247 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1064, K2025–1063.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00873 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.
DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 10, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1285 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1109, K2025–1108.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00934 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 16, 2025.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 8, 2025, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1264 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1083, K2025–1082.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–00907 Filed 1–15–25; 8:45 am]
BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–102150; File No. SR–SAPPHIRE–2024–43]

Self-Regulatory Organizations; MIAx Sapphire, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule To Establish Fees for Industry Members Related to Reasonably Budgeted CAT Costs of the National Market System Plan Governing the Consolidated Audit Trail for 2025

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 27, 2024, MIAx Sapphire, LLC (“MIAx Sapphire” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Fee Schedule (“Fee Schedule”) to establish fees for Industry Members⁵ related to reasonably budgeted CAT costs of the National Market System Plan Governing the Consolidated Audit Trail (the “CAT

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ An “Industry Member” is defined as “a member of a national securities exchange or a member of a national securities association.” See Miami International Securities Exchange LLC (“MIAx Rule”) Rule 1701(u). The Exchange notes that MIAx Chapter XVII is incorporated by reference into the Exchange's rulebook. As such, MIAx Chapter XVII also applies to the Exchange. See also Section 1.1 of the CAT NMS Plan. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and/or the CAT Compliance Rule. See MIAx Rule 1701.

NMS Plan” or “Plan”) for 2025. These fees would be payable to Consolidated Audit Trail, LLC (“CAT LLC” or the “Company”) and referred to as CAT Fee 2025–1, and would be described in a section of the Exchange’s fee schedule entitled “Consolidated Audit Trail Funding Fees.” The fee rate for CAT Fee 2025–1 would be \$0.000022 per executed equivalent share. CAT Executing Brokers will receive their first monthly invoice for CAT Fee 2025–1 in February 2025 calculated based on their transactions as CAT Executing Brokers for the Buyer (“CEBB”) and/or CAT Executing Brokers for the Seller (“CEBS”) in January 2025. CAT Fee 2025–1 is anticipated to be in place for six months, and is anticipated to recover approximately one-half of the costs set forth in the reasonably budgeted CAT costs for 2025. CAT LLC intends for CAT Fee 2025–1 to replace CAT Fee 2024–1 (which has a fee rate of \$0.000035).⁶

The proposed rule change, including the Exchange’s statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings>, at MIAX Sapphire’s principal office, and on the Commission’s website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-SAPPHIRE-2024-43.

II. 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.⁷ Comments may be submitted electronically by using the Commission’s internet comment form (<https://www.sec.gov/rules-regulations/self-regulatory-organization->

[rulemaking/national-securities-exchanges?file_number=SR-SAPPHIRE-2024-43](https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-SAPPHIRE-2024-43)) or by sending an email to rule-comments@sec.gov. Please include file number SR-SAPPHIRE-2024–43 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to file number SR-SAPPHIRE–2024–43. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-SAPPHIRE-2024-43). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-SAPPHIRE–2024–43 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–00891 Filed 1–15–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–102152; File No. SR–EMERALD–2024–31]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule To Establish Fees for Industry Members Related to Reasonably Budgeted CAT Costs of the National Market System Plan Governing the Consolidated Audit Trail for 2025

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 27, 2024, MIAX Emerald, LLC (“MIAX Emerald” or “Exchange”) filed with the Securities and Exchange Commission

(“Commission”) the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s Fee Schedule (“Fee Schedule”) to establish fees for Industry Members⁵ related to reasonably budgeted CAT costs of the National Market System Plan Governing the Consolidated Audit Trail (the “CAT NMS Plan” or “Plan”) for 2025. These fees would be payable to Consolidated Audit Trail, LLC (“CAT LLC” or the “Company”) and referred to as CAT Fee 2025–1, and would be described in a section of the Exchange’s fee schedule entitled “Consolidated Audit Trail Funding Fees.” The fee rate for CAT Fee 2025–1 would be \$0.000022 per executed equivalent share. CAT Executing Brokers will receive their first monthly invoice for CAT Fee 2025–1 in February 2025 calculated based on their transactions as CAT Executing Brokers for the Buyer (“CEBB”) and/or CAT Executing Brokers for the Seller (“CEBS”) in January 2025. CAT Fee 2025–1 is anticipated to be in place for six months, and is anticipated to recover approximately one-half of the costs set forth in the reasonably budgeted CAT costs for 2025. CAT LLC intends for CAT Fee 2025–1 to replace CAT Fee

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ An “Industry Member” is defined as “a member of a national securities exchange or a member of a national securities association.” See Miami International Securities Exchange, LLC (“MIAX Rule”) Rule 1701(u). The Exchange notes that MIAX Chapter XVII is incorporated by reference into the Exchange’s rulebook. As such, MIAX Chapter XVII also applies to the Exchange. See also Section 1.1 of the CAT NMS Plan. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and/or the CAT Compliance Rule. See MIAX Rule 1701.

⁶ See paragraph (a)(3) of Consolidated Audit Trail Funding Fees. See Exchange Fee Schedule, Section 8(a). See also Securities Exchange Act Rel. No. 100875 (Aug. 29, 2024) 89 FR 72623 (Sept. 5, 2024) (SR–SAPPHIRE–2024–24) (“Fee Filing for CAT Fee 2024–1”).

⁷ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of SRO.

⁸ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C.78s(b)(1).

² 17 CFR 240.19b–4.

2024–1 (which has a fee rate of \$0.000035).⁶

The proposed rule change, including the Exchange's statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings>, at MIAX Emerald's principal office, and on the Commission's website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-EMERALD-2024-31.

II. 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.⁷ Comments may be submitted electronically by using the Commission's internet comment form (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-EMERALD-2024-31) or by sending an email to rule-comments@sec.gov. Please include file number SR-EMERALD-2024-31 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-EMERALD-2024-31. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-EMERALD-2024-31). Do not include personal identifiable information in submissions; you should submit only information

that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-EMERALD-2024-31 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-00892 Filed 1-15-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-102144; File No. SR-LTSE-2024-13]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the LTSE Fee Schedule

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 27, 2024, Long-Term Stock Exchange, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the LTSE Fee Schedule to modify the fees and rebates applicable to transactions in

securities priced below \$1.00 per share ("Sub-Dollar Securities") that are executed on the Exchange. The Exchange proposes to implement the changes to the fee schedule pursuant to this proposal on December 12, 2024.

The proposed rule change, including the Exchange's statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange's website at <http://ltse.com/regulation/rule-filings> and on the Commission's website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-LTSE-2024-13.

II. 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.⁵ Comments may be submitted electronically by using the Commission's internet comment form (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-LTSE-2024-13) or by sending an email to rule-comments@sec.gov. Please include file number SR-LTSE-2024-13 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-LTSE-2024-13. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-LTSE-2024-13). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright

⁶ See paragraph (a)(3) of Consolidated Audit Trail Funding Fees. See MIAX Fee Schedule, Section 9(a). See also Securities Exchange Act Rel. No. 100825 (Aug. 27, 2024) 89 FR 71524 (Sept. 3, 2024) (SR-EMERALD-2024-23) ("Fee Filing for CAT Fee 2024-1").

⁷ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of SRO.

⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

protection. All submissions should refer to file number SR–LTSE–2024–13 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–00889 Filed 1–15–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–102153; File No. SR–MIAX–2024–49]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule To Establish Fees for Industry Members Related to Reasonably Budgeted CAT Costs of the National Market System Plan Governing the Consolidated Audit Trail for 2025

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 27, 2024, Miami International Securities Exchange, LLC (“MIAX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule

(“Fee Schedule”) to establish fees for Industry Members⁵ related to reasonably budgeted CAT costs of the National Market System Plan Governing the Consolidated Audit Trail (the “CAT NMS Plan” or “Plan”) for 2025. These fees would be payable to Consolidated Audit Trail, LLC (“CAT LLC” or the “Company”) and referred to as CAT Fee 2025–1, and would be described in a section of the Exchange’s fee schedule entitled “Consolidated Audit Trail Funding Fees.” The fee rate for CAT Fee 2025–1 would be \$0.000022 per executed equivalent share. CAT Executing Brokers will receive their first monthly invoice for CAT Fee 2025–1 in February 2025 calculated based on their transactions as CAT Executing Brokers for the Buyer (“CEBB”) and/or CAT Executing Brokers for the Seller (“CEBS”) in January 2025. CAT Fee 2025–1 is anticipated to be in place for six months, and is anticipated to recover approximately one-half of the costs set forth in the reasonably budgeted CAT costs for 2025. CAT LLC intends for CAT Fee 2025–1 to replace CAT Fee 2024–1 (which has a fee rate of \$0.000035).⁶

The proposed rule change, including the Exchange’s statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings>, at MIAX’s principal office, and on the Commission’s website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-MIAX-2024-49.

II. 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.⁷

⁵ An “Industry Member” is defined as “a member of a national securities exchange or a member of a national securities association.” See Exchange Rule 1701(u). See also Section 1.1 of the CAT NMS Plan. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and/or the CAT Compliance Rule. See Exchange Rule 1701.

⁶ See paragraph (a)(3) of Consolidated Audit Trail Funding Fees. See Exchange Fee Schedule, Section 8(a). See also Securities Exchange Act Rel. No. 100827 (Aug. 27, 2024) 89 FR 71472 (Sept. 3, 2024) (SR–MIAX–2024–33) (“Fee Filing for CAT Fee 2024–1”).

⁷ 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

Comments may be submitted electronically by using the Commission’s internet comment form (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-MIAX-2024-49) or by sending an email to rule-comments@sec.gov. Please include file number SR–MIAX–2024–49 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to file number SR–MIAX–2024–49. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-MIAX-2024-49). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2024–49 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–00893 Filed 1–15–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35445; File No. 812–15568]

HarbourVest Private Investments Fund, et al.

January 10, 2025.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).
ACTION: Notice.

Notice of application for an order (“Order”) under sections 17(d) and 57(i) of the Investment Company Act of 1940

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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of SRO.

⁸ 17 CFR 200.30–3(a)(12).

⁶ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

(the “Act”) and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies (“BDCs”) and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: HarbourVest Private Investments Fund, HarbourVest Registered Advisers L.P., HarbourVest Partners, LLC, HarbourVest Partners L.P., HarbourVest Advisers L.P., HarbourVest Partners (Ireland) Limited, HarbourVest Partners (Canada) Limited, HarbourVest Air Canada Fund L.P., HarbourVest Amitim Fund L.P., Angerik HV L.P., HarbourVest AP7 PE Investment L.P., HarbourVest Asia Pacific 5 Investment Holding L.P., HarbourVest Asia Pacific 5 Secondary L.P., HarbourVest Asia Pacific Fund 5 L.P., HarbourVest Asia Pacific 5 AIF SCSP, HarbourVest Blue Ridge Fund L.P., HarbourVest Broadway Co-Investment L.P., HarbourVest Bvk Co-Investment Fund 2022 SCSP, Calstrs Lower Middle Market Fund IV, LLC, Calstrs Lower Middle Market Fund V, L.P., Calstrs Lower Middle Market Fund VI L.P., Calstrs Lower Middle Market Fund VII L.P., HarbourVest Canada Growth Fund L.P., HarbourVest Canada Growth Fund II L.P., HarbourVest Canada Growth Fund III L.P., HarbourVest Cc Portfolio Fund L.P., HarbourVest Centre Street Co-Investment Fund L.P., CHV Investments Fund L.P., HarbourVest Citrine Fund L.P., HarbourVest Partners Cleantech Fund II L.P., HarbourVest Co-Invest 2017 Private Equity Partners L.P., HarbourVest Co-Invest 2018 Private Equity Partners L.P., HarbourVest Co-Invest 2019 Private Equity Partners L.P., HarbourVest Co-Invest 2020 Private Equity Partners L.P., HarbourVest Co-Invest 2021 Private Equity Partners L.P., HarbourVest Co-Invest 2022 Private Equity Partners L.P., HarbourVest Co-Invest 2023 Private Equity Partners L.P., HarbourVest Partners Co-Investment Fund IV L.P., HarbourVest Partners Co-Investment IV AIF L.P., HarbourVest Partners Co-Investment Fund IV Aiv L.P., HarbourVest Co-Investment Opportunities Fund L.P., HarbourVest Partners Co-Investment Fund V L.P., HarbourVest Partners Co-Investment V AIF L.P., HarbourVest Partners Co-Investment Fund V AIV L.P., HarbourVest Partners Co-Investment VI Aggregator L.P., HarbourVest Partners

Co-Investment Fund VI L.P., HarbourVest Partners Co-Investment VI AIF SCSP, HCF6 Holdings LLC, Hcf5 Holdings LLC, HarbourVest Co-Investment VII Buyout Aggregator L.P., HarbourVest Co-Investment Fund VII Growth L.P., HarbourVest Co-Investment Fund VII Buyout L.P., HarbourVest Co-Investment Fund VII Combined L.P., HarbourVest Credit Opportunities II AIF SCSP, HarbourVest Credit Opportunities Fund II L.P., HarbourVest COF III Investment L.P., HarbourVest Credit Opportunities Fund III L.P., HarbourVest Credit Opportunities III AIF SCSP, Csc Private Investments L.P., HarbourVest Ct Co-Investment Fund L.P., HarbourVest Ct Private Debt Fund L.P., HarbourVest D2022 Fund L.P., HarbourVest Dai-Ichi Life PE Fund L.P., Denso Hv Pep L.P., Denso Hv Pep II Holdings LLC, Denso Hv Pep II L.P., HarbourVest Dl II Investment Holding A (L) L.P., HarbourVest Dl II Investment Holding A (U) L.P., HarbourVest Dl II Investment Holding B (L) LLC, HarbourVest Dl II Investment Holding B (U) L.P., HarbourVest Direct Lending Fund II (U) L.P., HarbourVest Direct Lending II Parallel Fund (U) L.P., HarbourVest Direct Lending II AIF (U) SCSP, HarbourVest Direct Lending Fund II (L) L.P., HarbourVest Direct Lending II Parallel Fund (L) L.P., HarbourVest Dl Investment Holding I (L) LLC, HarbourVest Direct Lending Fund (L) L.P., HarbourVest Direct Lending AIF (L) SCSP, HarbourVest Dover Street IX Investment L.P., Dover Street IX L.P., Dover Street IX AIF L.P., Dover Street 2014 Holdings LLC, Dover VII Holdings LLC, Dover Street VIII Holdings L.P., HarbourVest Dover Street X Investment L.P., Dover Street X L.P., Dover Street X AIF SCSP, HarbourVest Dover Street Xi Investment L.P., Dover Street Xi L.P., Dover Street Xi AIF SCSP, HarbourVest Emmpt PE Fund L.P., Enervest LLC, HarbourVest FFV Fund L.P., HarbourVest Finance Street AIV L.P., HarbourVest Finance Street II AIV L.P., HarbourVest Finance Street II L.P., HarbourVest Finance Street III AIV L.P., HarbourVest Finance Street III L.P., The First Capital Access Fund, L.P., HarbourVest Frenchmen Street Fund L.P., HarbourVest FRS R3 LLC, HarbourVest Partners IX-Buyout Fund L.P., HarbourVest Partners IX-Credit Opportunities Fund L.P., HarbourVest Partners IX-Venture Fund L.P., HarbourVest Partners X AIF Buyout L.P., HarbourVest Partners X AIF Venture L.P., HarbourVest Partners X Buyout Fund L.P., HarbourVest Partners X Secondary L.P., HarbourVest Partners X Venture Fund L.P., HarbourVest

Partners XI Buyout Fund L.P., HarbourVest Partners XI Buyout AIF L.P., HarbourVest Partners XI Micro Buyout Fund L.P., HarbourVest Partners XI Micro Buyout AIF L.P., HV Xi Secondary L.P., HarbourVest Partners XI Venture AIF L.P., HarbourVest Partners XI Venture Fund L.P., HarbourVest Partners XII Buyout Fund L.P., HarbourVest Partners XII Buyout AIF SCSP, HarbourVest Partners XII Micro Buyout Fund L.P., HarbourVest Partners XII Micro Buyout AIF SCSP, HV XII Secondary L.P., HarbourVest Partners XII Venture Fund L.P., HarbourVest Partners Xii Venture AIF SCSP, HarbourVest Partners Xiii Buyout Fund L.P., HarbourVest Partners Xiii Buyout AIF SCSP, Hv Xiii Secondary L.P., HarbourVest Partners Xiii Small Cap Fund L.P., HarbourVest Partners Xiii Small Cap AIF SCSP, HarbourVest Partners Xiii Venture Fund L.P., HarbourVest Partners Xiii Venture AIF SCSP, Gf2018 Holdings LLC, Gf2019 Holdings LLC, Hv 2019 Global Holdings LLC, HarbourVest Global Annual Private Equity Fund L.P., HarbourVest 2015 Global Fund L.P., HarbourVest 2016 Global Fund L.P., HarbourVest 2016 Global AIF L.P., HarbourVest 2017 Global Fund L.P., HarbourVest 2017 Global AIF L.P., HarbourVest 2018 Global Fund L.P., Hv 2018 Global Investment L.P., HarbourVest 2018 Global AIF L.P., HarbourVest 2019 Global Investment L.P., HarbourVest 2019 Global Fund L.P., HarbourVest 2019 Global AIF SCSP, HarbourVest 2020 Global Investment L.P., HarbourVest 2020 Global Fund L.P., HarbourVest 2020 Global AIF SCSP, HarbourVest 2021 Global Investment L.P., HarbourVest 2021 Global Fund L.P., HarbourVest 2021 Global AIF SCSP, HarbourVest 2022 Global Investment L.P., HarbourVest 2022 Global Fund L.P., HarbourVest 2022 Global AIF SCSP, HarbourVest 2023 Global Fund L.P., HarbourVest 2023 Global Investment L.P., HarbourVest 2023 Global AIF SCSP, HarbourVest 2024 Global Investment L.P., HarbourVest 2024 Global Fund L.P., HarbourVest 2024 Global AIF SCSP, HarbourVest 2025 Global Investment L.P., HarbourVest 2025 Global Fund L.P., HarbourVest 2025 Global AIF SCSP, Great Lakes Fund L.P., HarbourVest Guardian Co-Investment Fund L.P., HarbourVest Braemar Holdings LLC, HarbourVest Ci Secondaries L.P., HarbourVest Harvest Fund II L.P., HarbourVest Harvest Fund L.P., Hcf4 Holdings LLC, HarbourVest Global Private Solution Sicav S.A.—Diversified Private Equity Fund, HGPS—DPE Delaware Holdings LLC, HGPS—

DPE Luxembourg Holdings SCSP, HarbourVest Infrastructure Income Portfolio 1 L.P., HarbourVest Infrastructure Income Portfolio 1 Holdings L.P., HarbourVest Infrastructure Income Portfolio 2 L.P., HarbourVest Infrastructure Income Portfolio 3 L.P., Hipep Ix De Holdings LLC, Hipep Ix Investment Holding L.P., Hipep Ix Secondary L.P., Hipep Ix Fund L.P., Hipep Ix AIF SCSP, Hipep Select Asia Fund L.P., Hipep Select Asia Fund II L.P., Hipep Select Asia Fund III L.P., Hipep VII Emerging Markets Fund L.P., Hipep VII Em Holdings LLC, Hipep VII Europe Holdings LLC, Hipep VII Partnership Holdings LLC, Hipep VII Secondary Holdings LLC, Hipep VII (AIF) Asia Pacific Fund L.P., Hipep VII (AIF) Partnership Fund L.P., Hipep VII Asia Pacific Fund L.P., Hipep VII Europe Fund L.P., Hipep VII Partnership Fund L.P., Hipep VII Secondary L.P., Hipep VIII Partnership Fund L.P., Hipep VIII Partnership AIF L.P., Hipep X Fund L.P., Hipep X Holdings LLC, Hipep X Secondary L.P., HarbourVest Homestead Fund L.P., HarbourVest Homestead Holdings LLC, Horizon Impact Fund L.P., Hv 2022 Global Holdings LLC, Hv 2023 Global Holdings LLC, HarbourVest Adelaide L.P., Hv Amitim Uniform Holdings LLC, HarbourVest Ap7 Holdings 2 LLC, HarbourVest Asia Pacific Fund VIII L.P., HarbourVest Asia Pacific VIII AIF L.P., HarbourVest Blue Secondary 2018 L.P., HarbourVest Braemar Fund L.P., HarbourVest Cb Global Co-Inv Fund L.P., HarbourVest Finance Street L.P., Hv Great Lakes Series I 2020 Holdings LLC, Hv Harvest Holdings LLC, Hv International VIII Secondary L.P., Hv Meranti III A1 Holdings LLC, Hv Nest Uniform Holdings LLC, Hv New Street Franklin Series Holdings LLC, HarbourVest Pathway Holdings LLC, Hv Ra II LLC, HarbourVest Red Dragon L.P., Hv Si—Apollo Sengai Fund L.P., Hv Special Situations Fund L.P., Hv VIII Holdings LLC, Hv Z Global Private Equity Fund, L.P., Hv Z Global Private Equity Holdings LLC, HarbourVest Zebra 1 L.P., HarbourVest Zebra 2 L.P., HarbourVest Zebra 3 L.P., HVSHP L.P., HVSHP Holdings LLC, HarbourVest Iof3 Holdings L.P., HarbourVest Infrastructure Opportunities Fund III L.P., HarbourVest Infrastructure Opportunities III AIF SCSP, Juni Private Equity Fund H (Usd) L.P., Juni Private Equity Fund H (Usd) Holdings 1 L.P., Kpi-HarbourVest Multi-Strategy Fund I L.P., Kps-HarbourVest Multi-Strategy Fund I L.P., Kpi-HarbourVest Multi-Strategy Investment Holdings LLC, HarbourVest Ktcu Co-Investment Fund L.P., Kwasa Nexus Fund L.P.,

Lindenstone PE SCSP, Longhorn Hv Co-Investment 1 L.P., Longhorn Hv Co-Investment 2 L.P., Longhorn Hv Co-Investment Opps A L.P., Longhorn Hv Co-Investment Opps B L.P., Longhorn Hv Reveille 1 L.P., HarbourVest Lungo III Fund Scs, HarbourVest Lungo IV Fund SCSP, The Maple Fund L.P., Meranti Fund II L.P., Meranti Fund III L.P., Meranti Fund L.P., Meranti Holdings LLC, Meranti II Holdings LLC, HarbourVest Mercurius L.P., HarbourVest Partners Mezzanine Income Fund L.P., Migdal-HarbourVest 2016 Fund L.P., Migdal-HarbourVest 2016 Holdings LLC, HarbourVest Mvpe 5 SCSP, HarbourVest Mvpe 5 Holdings LLC, Mvpe 6 SCSP, Mvpe 6 Holdings LLC, Mvpf 2 SCSP, HarbourVest Mvpf SCSP, HarbourVest Mvpf Holdings LLC, HarbourVest Nespf L.P., HarbourVest Nest Co-Investment L.P., Nour Fund I L.P., Nps Co-Investment (A) Fund L.P., Nps Co-Investment (A) Holdings LLC, Nps Co-Investment (A) Holdings L.P., Nps Co-Investment Fund II L.P., Nps Fund II Holdings L.P., Nyscrf Pioneer Partnership Fund A—II, L.P., Nyscrf Pioneer Partnership Fund III L.P., Nyscrf Transition Annex Fund L.P., HarbourVest/Nyscrs Co-Invest Fund L.P., HarbourVest/Nyscrs Co-Invest Fund II L.P., HarbourVest/Nyscrs Co-Invest Fund III L.P., HarbourVest Ontario Private Equity Fund L.P., HarbourVest Orbit AIF SCSP, HarbourVest Pa Co-Investment Fund L.P., Pacific Coast Senior Credit Finance 1 L.P., Pacific Coast Senior Credit L.P., HarbourVest L Global PE SMA L.P., HarbourVest L Global PE Holdings LLC, HarbourVest Pc Secondaries 2020 Fund L.P., HarbourVest Pc Secondaries 2022 Fund L.P., HarbourVest Pc Secondaries 2024 Fund L.P., HarbourVest Private Equity Continuation Solutions Aggregator L.P., HarbourVest Private Equity Continuation Solutions L.P., HarbourVest Private Equity Continuation Solutions AIF SCSP, Pecs Overflow Fund L.P., Peninsula HarbourVest Fund L.P., HarbourVest Persla PE Fund L.P., HarbourVest Poba Co-Investment Fund L.P., HarbourVest New Street Fund L.P., Ra4 Holdings LLC, HarbourVest Real Assets—Energy Fund L.P., HarbourVest Real Assets—Energy Fund II L.P., HarbourVest Real Assets Fund III L.P., HarbourVest Ra4 Holdings L.P., HarbourVest Real Assets Fund IV L.P., HarbourVest Real Assets IV AIF SCSP, HarbourVest Real Assets Olive Fund L.P., HarbourVest Reynolds Fund I L.P., HarbourVest Secondary 2017 Private Equity Partners L.P., HarbourVest Secondary 2018 Private Equity Partners L.P., HarbourVest Secondary 2019 Private Equity Partners

L.P., Dover Street 2014 Overflow Fund L.P., Secondary Overflow Fund III L.P., Secondary Overflow Fund IV L.P., Secondary Overflow Fund V L.P., HarbourVest Skew Base AIF L.P., HarbourVest Slo Fund L.P., HarbourVest Slo Holdings LLC, Hvst-Tope LLC, Smrs-Capp LLC, Smrs-Hvdl LLC, Smrs-Tope LLC, Smrs-Ncrp LLC, Stc HarbourVest Pecs Fund L.P., Stc HarbourVest Private Debt Fund L.P., HarbourVest Partners Stewardship Investment L.P., HarbourVest Partners Stewardship Fund L.P., HarbourVest Partners Stewardship AIF SCSP, HarbourVest Summit Hill Fund L.P., Sunvest II LLC, Sunvest LLC, HarbourVest Tbw L.P., HarbourVest Tju Declaration Fund L.P., HarbourVest Tmrs Polaris SMA L.P., Trsl Co-Investment Fund L.P., Vanguard HarbourVest 2020 Private Equity Fund L.P., Vanguard HarbourVest 2021 Private Equity Fund L.P., Vanguard HarbourVest 2021 Private Equity Holdings LLC, Vanguard HarbourVest 2022 Private Equity Fund L.P., Vanguard HarbourVest 2022 Private Equity Holdings LLC, Vanguard HarbourVest 2023 Private Equity Fund L.P., Vanguard HarbourVest 2024 Private Equity Fund L.P., VRS HV 2013 Separate Account LLC, VRS HV 2016 Separate Account LLC, HarbourVest Vsma1 Asia Fund L.P., HarbourVest Vsma1 Asia Holdings LLC, HarbourVest Vulcanus L.P., HarbourVest Wespah Impact Investment Fund L.P., HarbourVest Co-Invest 2024 Private Equity Partners L.P., HarbourVest Emmpt PE Holdings LLC, HarbourVest Ffv Holdings LLC, Hv Si—Apollo Sengai Holdings LLC, HarbourVest Red Dragon Holdings LLC, HarbourVest Tju Declaration Holdings LLC, HarbourVest As Fund L.P., HarbourVest Alberta Fund L.P., HarbourVest Suncor Fund L.P., HarbourVest Vsma1 Credit Fund L.P., PECS Delaware Overflow Fund L.P., Vanguard HarbourVest 2025 Private Equity Fund L.P., HGPS Secondary Holdings LLC.

FILING DATES: The application was filed on April 24, 2024, and amended on October 15, 2024 and December 19, 2024.

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 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, February 5, 2025, 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 at Secretaries-Office@sec.gov.

ADDRESSES: *The Commission:* Secretaries-Office@sec.gov. Applicants: Monique Austin, HarbourVest Private Investments Fund, at maustin@harbourvest.com; and Daniel Chisholm, HarbourVest Private Investments Fund, at dchisholm@harbourvest.com; and Rajib Chanda, Simpson Thacher & Bartlett LLP, Rajib.Chanda@stblaw.com; and Ryan Brizek, Simpson Thacher & Bartlett LLP, ryan.brizek@stblaw.com.

FOR FURTHER INFORMATION CONTACT: Taylor Evenson, Senior Counsel, or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended and restated application, dated December 19, 2024, 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. 2025–00886 Filed 1–15–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–102154; File No. SR–PEARL–2024–64]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the MIAX Pearl Options Fee Schedule To Establish Fees for Industry Members Related to Reasonably Budgeted CAT Costs of the National Market System Plan Governing the Consolidated Audit Trail for 2025

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 27, 2024, MIAX PEARL, LLC (“MIAX Pearl” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the fee schedule applicable to options trading on the Exchange (“Fee Schedule”) to establish fees for Industry Members⁵ related to reasonably budgeted CAT costs of the National Market System Plan Governing the

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ An “Industry Member” is defined as “a member of a national securities exchange or a member of a national securities association.” See Miami International Securities Exchange, LLC (“MIAX Rule”) Rule 1701(u). The Exchange notes that MIAX Chapter XVII is incorporated by reference into the Exchange's rulebook. As such, MIAX Chapter XVII also applies to the Exchange. See also Section 1.1 of the CAT NMS Plan. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and/or the CAT Compliance Rule. See MIAX Rule 1701.

Consolidated Audit Trail (the “CAT NMS Plan” or “Plan”) for 2025. These fees would be payable to Consolidated Audit Trail, LLC (“CAT LLC” or the “Company”) and referred to as CAT Fee 2025–1, and would be described in a section of the Exchange's fee schedule entitled “Consolidated Audit Trail Funding Fees.” The fee rate for CAT Fee 2025–1 would be \$0.000022 per executed equivalent share. CAT Executing Brokers will receive their first monthly invoice for CAT Fee 2025–1 in February 2025 calculated based on their transactions as CAT Executing Brokers for the Buyer (“CEBB”) and/or CAT Executing Brokers for the Seller (“CEBS”) in January 2025. CAT Fee 2025–1 is anticipated to be in place for six months, and is anticipated to recover approximately one-half of the costs set forth in the reasonably budgeted CAT costs for 2025. CAT LLC intends for CAT Fee 2025–1 to replace CAT Fee 2024–1 (which has a fee rate of \$0.000035).⁶

The proposed rule change, including the Exchange's statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings>, at MIAX Pearl's principal office, and on the Commission's website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-64.

II. 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.⁷ Comments may be submitted electronically by using the Commission's internet comment form (<https://www.sec.gov/rules-regulations/>

⁶ See paragraph (a)(3) of Consolidated Audit Trail Funding Fees. See Exchange Fee Schedule, Section 8(a). See also Securities Exchange Act Rel. No. 100872 (Aug. 29, 2024) 89 FR 72501 (Sept. 5, 2024) (SR–PEARL–2024–34) (“Fee Filing for CAT Fee 2024–1”).

⁷ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of SRO.

self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-64) or by sending an email to rule-comments@sec.gov. Please include file number SR-PEARL-2024-64 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-PEARL-2024-64. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-64). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-PEARL-2024-64 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-00894 Filed 1-15-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 90 FR 2759, January 13, 2025.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, January 16, 2025, at 2:00 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Thursday, January 16, 2025, at 2:00 p.m., has been changed to Thursday, January 16, 2025, at 1:00 p.m.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Authority: 5 U.S.C. 552b.

Dated: January 14, 2025.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2025-01298 Filed 1-14-25; 4:15 pm]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-102156; File No. SR-CboeBYX-2024-009]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change, as Modified by Amendment No. 1, to Amend Exchange Rule 11.25(e) To Allow Users To Utilize the Exchange's Match Trade Prevention Functionality When Entering Periodic Auction Orders Onto the Exchange for Execution

January 10, 2025.

On June 6, 2024, Cboe BYX Exchange, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Exchange Rule 11.25(e) to allow Users to utilize the Exchange's Match Trade Prevention functionality when entering Periodic Auction Orders onto the Exchange for execution. The proposed rule change was published for comment in the **Federal Register** on June 21, 2024.³ On August 5, 2024, the Commission extended the time period within which to approve, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to September 19, 2024.⁴ On September 18, 2024, the Exchange filed Amendment No. 1 to the proposed rule change.⁵ On September 19, 2024, the Commission issued notice of the proposed rule change, as modified by Amendment No. 1, and simultaneously instituted proceedings under Section 19(b)(2)(B) of the Act⁶ to determine

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 100337 (June 14, 2024), 89 FR 52148 ("Notice").

⁴ See Securities Exchange Act Release No. 100649, 89 FR 65420 (August 9, 2024). The Commission has received no comment letters on the proposed rule change.

⁵ Amendment No. 1 modifies the proposed rule change by: (1) amending rule text relating to Exchange Match Trade Prevention functionality when entering Periodic Auction Orders onto the Exchange for execution; and (2) adding new rule text describing how the Exchange will handle Periodic Auction Orders entered as a Minimum Quantity Order with a Match Trade Prevention modifier.

⁶ 15 U.S.C. 78s(b)(2)(B).

whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁷ On December 16, 2024, pursuant to Section 19(b)(2) of the Exchange Act,⁸ the Commission designated a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendment No. 1.⁹ On January 8, 2025, the Exchange withdrew the proposed rule change (SR-CboeBYX-2024-009).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-00896 Filed 1-15-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-102145; File No. SR-IEX-2024-31]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend IEX's Fee Schedule Concerning Transaction Pricing for Certain Sub-Dollar Orders

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 31, 2024, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f) thereunder.⁴ The Commission

⁷ See Securities Exchange Act Release No. 101105, 89 FR 78418 (September 25, 2024).

⁸ 15 U.S.C. 78s(b)(2).

⁹ See Securities Exchange Act Release No. 104276, 89 FR 104276 (December 20, 2024). The Commission designated February 16, 2025, as the date by which the Commission shall approve or disapprove the proposed rule change.

¹⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the

⁸ 17 CFR 200.30-3(a)(12).

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 amend the fees applicable to Members,⁵ pursuant to IEX Rule 15.110(a) and (c), to revise the fee for an order that routes to and removes liquidity on an away exchange at a price below \$1.00 so that the IEX fee will be the cost charged, or rebate paid, by the away exchange plus 0.02% of the total dollar value of the execution, instead of the cost charged by the away exchange plus \$0.0001 per share. No other fee changes are proposed. Changes to the Fee Schedule pursuant to this proposal are effective upon filing,⁶ and will be operative on January 1, 2025.

The proposed rule change, including the Exchange's statement of the purpose of, and statutory basis for, the proposed rule change, is available on the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and on the Commission's website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-IEX-2024-31.

II. 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.⁷ Comments may be submitted electronically by using the Commission's internet comment form (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-IEX-2024-31) or by sending an email to rule-comments@sec.gov. Please include file number SR-IEX-2024-31 on the subject

Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ See IEX Rule 1.160(s).

⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

⁷ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-IEX-2024-31. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-IEX-2024-31). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-IEX-2024-31 and should be submitted on or before February 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-00890 Filed 1-15-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-102155; File No. SR-PEARL-2024-6]]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the MIAX Pearl Equities Fee Schedule To Establish Fees for Industry Members Related to Reasonably Budgeted CAT Costs of the National Market System Plan Governing the Consolidated Audit Trail for 2025

January 10, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 27, 2024, MIAX PEARL, LLC ("MIAX Pearl" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Item I below, which Item has been substantially prepared by the Exchange. The Exchange has designated this proposal for immediate effectiveness pursuant to

Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Fee Schedule applicable to equity securities trading on the Exchange ("Fee Schedule") to establish fees for Industry Members⁵ related to reasonably budgeted CAT costs of the National Market System Plan Governing the Consolidated Audit Trail (the "CAT NMS Plan" or "Plan") for 2025. These fees would be payable to Consolidated Audit Trail, LLC ("CAT LLC" or the "Company") and referred to as CAT Fee 2025-1, and would be described in a section of the Exchange's fee schedule entitled "Consolidated Audit Trail Funding Fees." The fee rate for CAT Fee 2025-1 would be \$0.000022 per executed equivalent share. CAT Executing Brokers will receive their first monthly invoice for CAT Fee 2025-1 in February 2025 calculated based on their transactions as CAT Executing Brokers for the Buyer ("CEBB") and/or CAT Executing Brokers for the Seller ("CEBS") in January 2025. CAT Fee 2025-1 is anticipated to be in place for six months, and is anticipated to recover approximately one-half of the costs set forth in the reasonably budgeted CAT costs for 2025. CAT LLC intends for CAT Fee 2025-1 to replace CAT Fee 2024-1 (which has a fee rate of \$0.000035).⁶

The proposed rule change, including the Exchange's statement of the purpose

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f). At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

⁵ An "Industry Member" is defined as "a member of a national securities exchange or a member of a national securities association." See Miami International Securities Exchange, LLC ("MIAX Rule") Rule 1701(u). The Exchange notes that MIAX Chapter XVII is incorporated by reference into the Exchange's rulebook. As such, MIAX Chapter XVII also applies to the Exchange. See also Section 1.1 of the CAT NMS Plan. Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the CAT NMS Plan and/or the CAT Compliance Rule. See MIAX Rule 1701.

⁶ See paragraph (a)(3) of Consolidated Audit Trail Funding Fees. See Exchange Fee Schedule, Section 6(a). See also Securities Exchange Act Rel. No. 100873 (Aug. 29, 2024) 89 FR 72600 (Sept. 5, 2024) (SR-PEARL-2024-33) ("Fee Filing for CAT Fee 2024-1").

⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

of, and statutory basis for, the proposed rule change, is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings>, at MIAX Pearl's principal office, and on the Commission's website at https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-65.

II. 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.⁷ Comments may be submitted electronically by using the Commission's internet comment form (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-65) or by sending an email to rule-comments@sec.gov. Please include file number SR-PEARL-2024-65 on the subject line. Alternatively, paper comments may be sent to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-PEARL-2024-65. 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 (https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking/national-securities-exchanges?file_number=SR-PEARL-2024-65). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-PEARL-2024-65 and should be submitted on or before February 6, 2025.

⁷ 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of SRO.

⁸ 17 CFR 200.30-3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-00895 Filed 1-15-25; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Transfer of Responsibility

AGENCY: U.S. Small Business Administration.

ACTION: Notice of transfer of responsibility.

SUMMARY: This document provides the public with notice that the Administrator of the Small Business Administration (SBA) has transferred the responsibilities previously assigned to the Agency Licensing Committee related to the licensing of Small Business Investment Companies and transferred those responsibilities to the Chief Financial Officer, Chief Operating Officer, and Chief of Staff through the Agency's internal clearance process.

FOR FURTHER INFORMATION CONTACT: Arthur Spivey, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416; (202) 205-7098 or arthur.spivey@sba.gov.

SUPPLEMENTARY INFORMATION: This document provides the public with notice of the Administrator's transfer of responsibilities previously assigned to the Agency Licensing Committee (September 21, 2023, 88 FR 65222) to review and make recommendations to the Administrator relative to licenses to operate as a small business investment company under the Small Business Investment Act of 1958, as amended, and transferred those responsibilities to the Chief Financial Officer, Chief Operating Officer, and Chief of Staff through the Agency's internal clearance process.

This transfer reads as follows:

Pursuant to the authority vested in me pursuant to section 301 of the Small Business Investment Act of 1958, as amended, the responsibilities previously assigned to the Agency Licensing Committee to take any and all actions necessary to review applications for licensing under section 301 of the Small Business Investment Act of 1958, as amended, and to recommend which such applications should be approved is hereby transferred to the Chief Financial Officer, Chief Operating Officer, and

Chief of Staff through the agency's internal clearance process.

Isabella Casillas Guzman,
Administrator.

[FR Doc. 2025-00864 Filed 1-15-25; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

National Small Business Development Center Advisory Board

AGENCY: Small Business Administration.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The U.S. Small Business Administration (SBA) is announcing the date, time, location and agenda for a meeting of the National Small Business Development Center Advisory Board (NSBDCAB). Members will convene as an independent source of advice and recommendations on matters related to the Small Business Development Center Program. The meeting will be held in-person and virtually for NSBDCAB Members and the public.

DATES: Wednesday, February 12, 2025, from 1 p.m. to 2:30 p.m. eastern standard time.

ADDRESSES: The NSBDCAB meeting will be held in-person at the Washington Marriott Georgetown, located at 1221 22nd Street NW, Georgetown, Washington, DC 20037 and virtually via Microsoft Teams. The access link will be provided to members of the public upon request.

FOR FURTHER INFORMATION CONTACT: Rachel Karton, Designated Federal Officer, Office of Small Business Development Centers (OSBDC), SBA, 409 Third Street SW, Washington, DC 20416; Rachel.newman-karton@sba.gov; 202-619-1816.

Anyone wishing to submit questions to the NSBDCAB can do so by submitting them via email to Rachel.newman-karton@sba.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) of the Federal Advisory Committee Act (5 U.S.C. appendix 2), the SBA announces a meeting of the National SBDC Advisory Board (NSBDCAB). This NSBDCAB provides advice and counsel to the SBA Administrator and Associate Administrator for Small Business Development Centers. The purpose of the meeting is to consider recommendations to SBA on matters pertaining to the Small Business Development Center Program.

Public Comment

Any member of the public may submit pertinent questions and comments concerning NSBDCAB affairs in advance by February 5, 2025. Individuals may email *Rachel.newman-karton@sba.gov* with subject line—“[Name/Organization] Comment for 2/5/25 Public Meeting.” The NSBDCAB will respond to a selection of questions or statements with most relevance to the topic of small business enterprise. Please note that public comments are typically shared during the final few minutes of the NSBDCAB meeting.

Advance notice of attendance is required. Those wishing to attend the meeting are encouraged to RSVP, by February 3, 2025, using the contact information above.

This event will be held over Microsoft Teams. For technical assistance, please visit the Microsoft Teams Support Page.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2025–00997 Filed 1–15–25; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[FAA–2024–2488]

Agency Information Collection

Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: “Generic Clearance for Customer Interactions”

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 October 23, 2024, Customer Interactions provide the Federal Aviation Administration valuable information and connect the agency to the public. The Federal Aviation Administration would utilize a Generic Clearance for Customer Interactions that support the Agency’s mission to become more accessible and transparent.

DATES: Written comments should be submitted by February 18, 2025.

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:

Barbara Hall by email at: *Barbara.l.hall@faa.gov*; phone: 817–222–5448

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA’s performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection.

OMB Control Number: 2120–0772.

Title: Generic Clearance for Customer Interactions.

Form Numbers: NA.

Type of Review: Extensional of an information collection.

Background: Individual citizens or organizations may voluntarily respond to this collection. This collection of information will support the Federal Aviation Administration’s mission. The Agency will collect qualitative and quantitative data that informs scientific research; aviation assessments and monitoring efforts; validate models or tools; and enhance the quantity and quality of data collected across communities. The agency will use this data to create an avenue to incorporate local knowledge and needs, and to contribute to increased data sharing, open data, and government transparency. The Federal Aviation Administration may sponsor the collection of this type of information in connection with aviation projects. All such collections will follow Agency policies and regulations. Collections under this generic ICR will be from volunteers who participate on their own initiative through an open and transparent process.

Respondents: 110,000 Individual citizens or organizations who interact with the agency may voluntarily respond to this collection.

Frequency: As Needed

Estimated Average Burden per Response: 5 minutes.

Estimated Total Annual Burden: 18,330.

Issued in Fort Worth, TX on January 13, 2025.

Barbara Hall,

Information Collection Officer, ASP–110, AFN.

[FR Doc. 2025–01024 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–2024–0230]

Commercial Driver’s License Standards: Application for Exemption; Daimler Trucks North America, LLC

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; granting of application for exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its final decision to grant a 5-year exemption to Daimler Trucks North America, LLC (Daimler) for six drivers who hold foreign commercial licenses from the requirement to hold a commercial driver’s license (CDL) issued by a U.S. State when operating a commercial motor vehicle (CMV). This exemption will permit the six drivers to test-drive Daimler vehicles on U.S. roads to better understand product requirements in “real-world” environments and verify results. FMCSA reviewed the drivers’ commercial license records provided by Daimler and believes the requirements for a German commercial license, the work restrictions imposed on Daimler drivers by their nonimmigrant visas, and the terms and conditions set forth below, will ensure that Daimler’s operation under this exemption will likely achieve a level of safety equivalent to or greater than the level that would be achieved in the absence of the exemption.

DATES: The exemption is effective January 16, 2025 and expires January 16, 2030.

FOR FURTHER INFORMATION CONTACT: Ms. Bernadette Walker, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; 202–385–2415; *bernadette.walker@dot.gov*. If you have questions on viewing or submitting material to the docket, contact Dockets Services at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, go to www.regulations.gov, insert the docket number “FMCSA–2024–0230” in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed click “Browse Comments.”

To view documents mentioned in this notice as being available in the docket, go to www.regulations.gov, insert the docket number “FMCSA–2024–0230” in the keyword box, click “Search,” and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulatory Requirements

Under 49 CFR 383.23, no person is permitted to operate a CMV without having taken and passed knowledge and driving skills tests for a commercial

learner’s permit or CDL that meet the Federal standards contained in subparts F, G, and H of Part 383 for the CMV that person operates or expects to operate.

Applicant’s Request

Daimler’s application for exemption was described in detail in a **Federal Register** notice published on October 15, 2024 (89 FR 83078) and will not be repeated here, as the facts have not changed.

IV. Public Comments

The Agency received no comments in response the notice of Daimler’s application.

V. FMCSA Decision

FMCSA has determined that the process for obtaining a commercial license in Germany is comparable to the process for obtaining a State-issued CDL and adequately ensures that these drivers can safely operate a CMV in the United States. Based on the information provided by Daimler, including the drivers’ experience and safety records, FMCSA concludes that the exemption, subject to the terms and conditions set forth in section VI, would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption, in accordance with 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions for the Exemption

This exemption applies only to the following six Daimler drivers: Christopher Kappes, Andreas Munch, Franz-Alexander Baumgartner, Fabian Schab, Malte Kleindick, and Lucas Jung. These drivers are granted an exemption from the requirement in 49 CFR 383.23, allowing them to drive CMVs in the United States without a State-issued CDL. When operating under this exemption, the six drivers are subject to the following terms and conditions:

- (1) The driver and Daimler must comply with all other applicable provisions of the FMCSRs (49 CFR parts 350 through 399);
- (2) The driver must be in possession of the exemption document and a valid German commercial license;
- (3) The driver must be employed by and operate the CMV within the scope of their duties for Daimler;
- (4) At all times while operating a CMV under this exemption, the driver must be accompanied by a holder of a State-issued CDL who is familiar with the routes traveled;

(5) Daimler must notify FMCSA in writing within 5 business days of any accident, as defined in 49 CFR 390.5, involving any of the exempted drivers;

(6) Daimler must notify FMCSA in writing if any of the exempted drivers is convicted of an offense listed in § 383.51 or a disqualifying offense under § 391.15 of the FMCSRs; and

(7) Daimler must subject the exempted drivers to a drug and alcohol testing program substantially equivalent to the requirements in 49 CFR part 382 (excluding the Clearinghouse requirements in subpart G). Daimler must ensure that the testing program for the drivers complies with the procedures set forth in 49 CFR part 40, as required by 49 CFR 382.105.

Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Notification to FMCSA

Under the exemption, Daimler must notify FMCSA within 5 business days of any positive drug or alcohol tests, or accident (as defined in 49 CFR 390.5), involving Daimler while operating a CMV under the terms of this exemption. The notification about accidents must include the following information:

- a. Identifier of the Exemption: “Daimler—[driver name]”;
- b. Name of operating carrier and USDOT number;
- c. Date of the accident;
- d. City or town, and State, in which the accident occurred, or closest to the accident scene;
- e. Driver’s name and license number;
- f. Co-driver’s name (if any) and license number;
- g. Vehicle number and State license number;
- h. Number of individuals suffering physical injury;
- i. Number of fatalities;
- j. The police-reported cause of the accident, if provided by the enforcement agency;
- k. Whether the driver was cited for violation of any traffic laws, motor carrier safety regulations; and
- l. The total on-duty time accumulated during the 7 consecutive days prior to the date of the accident, and the total on-duty time and driving time in the work shift prior to the accident.

VII. Termination

FMCSA has no reason to believe the motor carrier and drivers covered by

this exemption will experience any deterioration of their safety record. However, should this occur, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption. FMCSA will immediately revoke the exemption in the event of a failure to comply with its terms and conditions, the exemption has resulted in a lower level of safety than was maintained before the exemption was granted, or continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. chapter 313.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2025–01001 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0070]

Inspection, Repair and Maintenance; Inspector Qualifications; Application for an Exemption From the American Trucking Associations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; grant of exemption.

SUMMARY: FMCSA grants a limited 5-year exemption to the American Trucking Associations (ATA) on behalf of motor carriers, intermodal equipment providers (IEPs), and individuals, from the requirements that an individual must complete 1 year of training, experience, or a combination thereof prior to being qualified to conduct annual commercial motor vehicle (CMV) inspections and to conduct brake-related inspection, repair and maintenance tasks on CMVs. The exemption covers individuals who successfully complete a training program that is self-certified by the training provider as consistent with a set of recommended practices (RPs) developed by the ATA's Technology and Maintenance Council (TMC) and motor carriers and IEPs who rely on these training programs and individuals to satisfy FMCSA's rules. The Agency has determined that granting the exemption from the requirements for 1 year of training, experience, or a combination thereof for individuals who successfully complete, and educators who provide, a performance-based inspector training program consistent

with the TMC RPs, would likely achieve a level of safety equivalent to or greater than the level of safety provided by the regulatory requirements.

DATES: This exemption is effective January 16, 2025 and expires on January 16, 2030.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, FMCSA; 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–9209; *MCPSV@dot.gov*.

SUPPLEMENTARY INFORMATION:

I. Viewing Comments and Documents

To view comments, go to www.regulations.gov, insert the docket number “FMCSA–2021–0070” in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, click “Browse Comments.”

To view documents mentioned in this notice as being available in the docket, go to www.regulations.gov, insert the docket number “FMCSA–2021–0070” in the keyword box, click “Search,” and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)) and provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the person or class of persons receiving the exemption, the regulatory provision from which the exemption is

granted, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemptions may be renewed (49 CFR 381.300(b)).

III. Background

A. Current Regulatory Requirements

The FMCSRs require motor carriers and IEPs to ensure that individuals performing annual inspections of CMVs (49 CFR 396.19), including individuals who inspect, maintain, repair, or service CMV brake systems (49 CFR 396.25), are properly qualified to perform such assignments. Under §§ 396.19(a)(3)(ii) and 396.25(d)(3)(ii), part of the qualifications to conduct those inspections is that an individual have training, experience, or a combination thereof totaling at least 1 year as outlined in those sections.

B. Applicant's Request

ATA applied on behalf of individuals seeking inspector qualifications for an exemption from the requirements in 49 CFR 396.19(a)(3)(ii) and 396.25(d)(3)(ii) that an individual must complete training, experience, or a combination thereof totaling at least 1 year prior to being qualified as an inspector. ATA requested that FMCSA permit educators to self-certify their training programs based on the TMC RPs and permit technicians who complete those training programs to be qualified to inspect CMVs in less than 1 year.

ATA stated that educators that provide a TMC RP-based training program develop technicians with the skills and knowledge to be highly proficient and qualified inspectors in less than a year. TMC's Educator Committee recommended training of a minimum of 210 hours for individuals having some level of experience and competency to a maximum of 540 hours for those new to CMVs. The committee estimated that approximately one-third of the instruction would be classroom based, with the remainder of the curriculum being laboratory/hands-on based. ATA also proposed to “grandfather” individuals with some level of experience who can “test out” of the training by passing the National Institute for Automotive Service Excellence (ASE) Medium-Heavy Truck Certification Tests T4—Brakes and T8—Preventative Maintenance Inspection by demonstrating successful preventive maintenance inspection (PMI) to a qualified inspector or educator. After meeting the requirements, ATA stated

that individuals should be exempt from the one-year requirement.

A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Public Comments

FMCSA published a notice in the **Federal Register** on July 14, 2021, asking for public comment on the exemption request (86 FR 37208). The Agency received one comment from the American Bus Association (ABA).

The ABA supported the exemption. It stated that, given the shortage of drivers, safety professionals, and maintenance personnel following the COVID-19 pandemic, this exemption will positively impact the CMV industry by expanding accessibility and opportunities for professional development and staffing. The ABA also suggested that the program should be considered like commercial training programs designed to train students in brake maintenance/inspection and in CMV operation and maintenance, which are already encompassed in the relevant regulations; therefore, an exemption for educators should not be necessary.

FMCSA Response: FMCSA agrees with ABA regarding the positive impact of the exemption on the CMV industry, to help address a shortage of maintenance personnel.

Although FMCSA regulations do not directly apply to training programs, FMCSA emphasizes that each self-certifying training provider must ensure its training program is consistent with ATA's TMC RPs such that the individual is qualified in less than 1 year to conduct annual CMV inspections and brake-related inspection, repair, and maintenance tasks on CMVs. This approach would differ from existing programs designed to train students in CMV operation and maintenance that require training or experience totaling at least 1 year, which also include brake instruction.

V. Equivalent or Greater Level of Safety Analysis

TMC's Study Groups and Task Forces have developed a series of best practices and standards for the maintenance and operation of CMVs and equipment that together will serve to provide training providers with the necessary content to deliver comprehensive training programs and assessments that provide individuals with the knowledge and skills to become qualified inspectors.

ATA has developed more than 500 RPs that outline individual procedures for inspecting, repairing, or replacing components on CMVs. These RPs are available in a document titled "A Guide

to TMC Recommended Practices." The RPs are categorized into 15 sections based on the CMV systems and components, such as Electrical and Lighting, Tires & Wheels, Engine, Cab & Controls, Fleet Maintenance Management, Chassis and Brake Systems, Trailers Bodies and Material Handling, Cost Control Methods, Sustainability and Environmental Technologies, Onboard Vehicle Electronics, Last Mile and Vocational Vehicles, Specialty Trucks, Service Provider, Collision and Corrosion Control, and Offboard Data Systems. Generally, each RP includes:

- **Preface:** This section provides important warnings and disclaimers to the user.
- **Scope and Purpose:** This section defines the purpose and scope of the RP and identifies the intended audience.
- **Background:** This section provides an explanation of the need for the RP and a brief overview of the content.
- **Recommended Practices:** This section provides the step-by-step guidance and procedures for addressing the issue.

- **References:** This section lists any additional sources of information or references that are relevant to the RP.

FMCSA has evaluated the exemption application and the comment received. For the reasons discussed below, FMCSA has determined that granting an exemption from the requirements that motor carriers and IEPs ensure that individuals performing annual inspections have 1 year of training, experience, or a combination thereof would likely achieve a level of safety equivalent to or greater than the level of safety provided by the regulatory requirements if the individuals instead successfully complete a performance-based inspector training program consistent with the TMC RPs.

TMC's RPs are compiled in accordance with a disciplined development process, subject to peer review, offer an appeals and formal decision-making process, are accessible, and provide a way for stakeholders to comment and contribute. The RPs are subject to a review cycle of no more than 5 years, during which time an RP must be reissued, revised, and if appropriate, withdrawn. FMCSA believes that by using a structured training program that follows the RP intended to accelerate an individual's knowledge and skills, the individual could gain more real-world experience and practical knowledge in less than the 1 year required by the FMCSRs. The collaborative effort involving industry experts ensures that the training material is relevant, up-to-date, and

effective in addressing common issues technicians and inspectors face in their day-to-day work environment. The RPs also undergo a thorough review and validation by a group of knowledgeable and experienced professionals within the industry. This review process helps to ensure the accuracy, reliability, and quality of training content, which benefits from the expertise of professionals with firsthand experience in the field. In summary, an inspector training program based on the TMC RP curricula would provide practical and relevant training experiences, as it provides industry best practices and real-world expertise. The RP peer review process contributes to an additional level of validation to the training, ensuring that it meets high quality standards and prepares individuals to effectively carry out their inspection responsibilities.

FMCSA also reviewed the TMC RP applicable to the inspection items in Appendix A to 49 CFR part 396 that establish the framework for the training program. FMCSA finds that the establishment of recommended inspection and repair practices and training guidelines through a program based on TMC RPs will have a positive impact on highway safety and competence in the field. In addition, FMCSA supports ATA's TMC recommendation that the training program duration should be at least 540 hours (approximately 13.5 work weeks) for new individuals, divided into one-third (1/3) classroom-based instruction and two-third (2/3) laboratory hands-on based instruction. FMCSA has determined that the combination of hours, classroom, and hands-on experience is sufficient to provide the individual with a level of knowledge, proficiency, and experience to perform quality PMI inspections.

FMCSA also agrees with the concept of allowing individuals who have completed fewer than 12 months of combined training and experience (and thus not yet qualified inspectors per the current FMCSRs) to "test out" by taking and successfully passing the ASE T4 and T8 tests. However, the Agency believes that this approach should be limited to individuals who have already completed a minimum of 330 hours (approximately 8.25 work weeks) of combined training and experience, followed by a minimum of 210 hours (approximately 5.25 work weeks) of combined training and experience under a curriculum that the training provider has self-certified as based on the TMC RPs (a combined total equivalent to the 540 hours proposed by ATA). Paragraph VI(B)(1)(b)(ii) in the

Terms and Conditions below reflects this alternative approach.

As noted above and based on a review of the comprehensive materials that ATA has developed, FMCSA has determined that an individual who successfully completes a training program consistent with the TMC RPs and under the terms and conditions of the exemption granted will likely possess the skills and knowledge to be as proficient and efficient an inspector as one who has completed 1 year of training, experience, or a combination thereof.

VI. FMCSA Decision

A. Granting of Exemption

FMCSA hereby grants a limited 5-year exemption to motor carriers and IEPs from the requirements in 49 CFR 396.19(a)(3)(ii) and 396.25(d)(3)(ii) to ensure that an individual complete training, experience, or a combination thereof totaling at least 1 year, provided that those individuals successfully complete an inspector training program that has self-certified with the ATA as meeting the requirements of the terms and conditions below. The inspector qualification requirements in 49 CFR 396.19(a)(1) and (2) and 396.25(d)(1) and (2) continue to apply.

These exemptions are effective January 16, 2025 through January 15, 2030 11:59 p.m. local time, unless rescinded earlier by FMCSA.

B. Terms and Conditions of the Exemption

This exemption allows individuals to meet the inspector qualification requirements of 49 CFR 396.19(a)(3)(ii) and 396.25(d)(3)(ii) if they have completed a training course using a curriculum consistent with the RPs developed by the TMC, subject to all the following terms and conditions:

1. The training provider must self-certify that its inspector training program satisfies all the requirements of these terms and conditions. Each program must:

a. Provide an inspector training program that is consistent with ATA's TMC RPs which are updated from time to time and includes at a minimum *PMI Guidelines for Class 7 & 8 Diesel Powered Tractors*, *PMI Guidelines for Light & Medium-Duty Vehicles (excluding guidelines applicable to light-duty vehicles)*, *PMI Guidelines for Trailers & Material Handling*, *PMI Trainer/Instructor for Class 7 & 8 Diesel Powered Tractors*.

b. Provide at least:

i. 540 hours of classroom and hands-on instruction exclusive of time for new

individual entrants to satisfy the requirements described below, or;

ii. 210 hours of classroom and hands-on instruction exclusive of time for individual entrants who have already completed at least 330 hours of combined classroom and hands-on experience and who have taken and successfully passed the ASE T4 and T8 tests.

c. Provide instructional training such that approximately one-third of the instruction is classroom based and two-thirds of the instruction is laboratory or hands-on, consistent with the ATA's TMC RPs.

d. Provide notice to ATA of the training program's self-certification, including the effective date of self-certification.

e. Provide graduates with certificates of program completion that indicate the individual has satisfactorily completed an inspector training program consistent with the terms of this exemption.

f. Maintain a list of individuals to whom it has issued a certificate as described in paragraph (d), confirm whether an individual has successfully completed its inspector training program, and provide such documentation upon the request of FMCSA, or a motor carrier or EIP that employs, seeks to employ, or otherwise utilizes, the individual as a qualified inspector.

g. Allow FMCSA access to any documents or records relating to the inspector training program it provides that may be necessary for FMCSA to evaluate the educator's compliance with the terms and conditions of this exemption.

2. ATA must maintain, publish, and provide to FMCSA, a public list of the training programs that have self-certified as having curricula that meet the terms and conditions of this exemption. ATA must remove from the list of self-certified training programs any training provider that FMCSA or ATA determines does not comply with the terms and conditions of the exemption.

3. Motor carriers and IEPs using an individual qualified under the terms and conditions of this exemption to perform annual inspections under 49 CFR 396.17 must ensure that the individual's training program was on ATA's list of self-certified training programs as of the date on the individual's certificate of program completion and must continue to retain evidence of the individual's qualifications, as required by 49 CFR 396.19(b) and 49 CFR 396.25(e).

The terms and conditions of this exemption do not delegate any FMCSA

responsibility to ATA. The exemption also does not authorize ATA to collect a fee on behalf of the government, or to state or imply that any third party's payment for ATA's training services is in lieu of an otherwise applicable government fee. ATA is not offering goods or services to FMCSA. Granting this exemption does not create any expectation of payment or obligation to pay future claims.

VII. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to an entity operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

VIII. Termination

Interested parties possessing information demonstrating that the exemptions granted herein do not result in the requisite statutory level of safety should immediately notify FMCSA by email at MCPSV@dot.gov.

The exemptions will be immediately rescinded if: (1) ATA, training providers, motor carriers, IEPs, or individuals fail to comply with the terms and conditions of the exemptions; (2) the exemptions have resulted in a lower level of safety than was maintained before the exemptions were granted; or (3) continuation of the exemptions would not be consistent with the goals and objectives of 49 U.S.C. 31136 or chapter 313.

Vincent G. White,
Deputy Administrator.

[FR Doc. 2025-00898 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2018-0347]

Commercial Driver's License Standards: Application for Exemption; Navistar, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of provisional renewal of exemption; request for comments.

SUMMARY: FMCSA announces its decision to provisionally renew the

exemption currently held by Navistar, Inc. (Navistar) from the commercial driver's license (CDL) regulations for one of its commercial motor vehicle (CMV) drivers. The provisional exemption renewal allows Mr. Thomas Nickels, Senior Vice President of the Cabin and Chassis R&D Group for Navistar's parent company, TRANTON SE, to test drive various Navistar test fleet vehicles on U.S. roads. The provisional exemption renewal is limited to six months. After a review of the public comments to this notice, FMCSA will issue a decision whether the exemption should be renewed through November 2029.

DATES: The provisional renewal of the exemption is effective from November 21, 2024, and expires on May 21, 2025. Comments must be received on or before February 18, 2025.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2018–0347 by any of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. See the Public Participation and Request for Comments section below for further information.
- **Mail:** Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- **Hand Delivery or Courier:** West Building, Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- **Fax:** (202) 493–2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA–2018–0347). Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit the ground level of the U.S. Department of Transportation, West Building, at 1200 New Jersey Avenue SE, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption renewal request. DOT posts

these comments, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed under the “Department Wide System of Records Notices” at www.dot.gov/privacy/privacy-act-system-records-notices. The comments are searchable by the name of the submitter and are posted without edit.

FOR FURTHER INFORMATION CONTACT:

Pearlie Robinson, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; FMCSA; (202) 366–4225; pearlie.robinson@dot.gov. If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2018–0347), indicate the specific section of this document to which the comment applies and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number FMCSA–2018–0347 in the “Search” box, and click “Search.” When the new screen appears, click on “Documents” button, then click the “Comment” button associated with the latest notice posted. Another screen will appear, on which you will insert the required information. Choose whether you are submitting your comment as an individual, an organization, or anonymous. Click “Submit Comment.”

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material

received during the comment period. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analyses. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish the decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt and the effective period and will explain all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulation(s) Requirements

Under 49 CFR 383.23, no person shall operate a CMV without having taken and passed knowledge and driving skills tests for a commercial learner's permit or CDL that meet the Federal standards contained in subparts F, G, and H of Part 383 for the CMV that person operates or expects to operate. Such drivers are also subject to the controlled substances and alcohol testing requirements of 49 CFR part 382.

Application for Renewal of Exemption

Navistar has requested an exemption renewal for one of its engineers from 49 CFR 383.23 for five years. The driver, Thomas Nickels, holds a valid German commercial license but due to residency requirements would be able to obtain only a non-domiciled CDL. Mr. Nickels is the Senior Vice President of the Cabin & Chassis R&D group for Navistar's parent company, TRATON SE in Germany.

FMCSA initially granted an exemption covering Mr. Nickels and

another Navistar driver on November 21, 2019 (84 FR 64400). This exemption was effective on November 21, 2019, and expired on November 21, 2024. Navistar requested a renewal only for Mr. Nickels.

The exemption renewal would allow Mr. Nickels to test drive various Navistar test fleets in interstate or intrastate commerce. Mr. Nickels would be driving Class 6 trucks and Class 8 tractor trailers with Navistar's new integrated technologies to support Navistar field tests on public roads to better understand product requirements for these systems in "real world" environments in the U.S. market. According to Navistar, Mr. Nickels will drive for no more than 8 hours per day for 2 consecutive days with 50 percent of the test driving on two-lane State highways and 50 percent on Interstate highways. The driving will consist of no more than 600 miles during a two-day period, at most 300 miles per day. In all cases, he will be accompanied by an individual who holds a State-issued CDL, who is familiar with the routes to be traveled. A copy of the application is in the docket.

IV. Equivalent Level Safety

To ensure an equivalent level of safety, Navistar states that the requirements for a German commercial license ensure the same level of safety as if Mr. Nickels held a State-issued CDL. Navistar explained that Mr. Nickels is familiar with the operation of CMVs worldwide. In addition, Navistar provided a statement of driving history for Mr. Nickels.

FMCSA is unaware of any evidence of a degradation of safety attributable to the current exemption for Mr. Nickels. Further, there is no indication that renewal of this exemption would have an adverse impact on safety.

In 2019, the Agency granted similar exemptions to Navistar drivers on two occasions [April 15, 2019 (84 FR 15283); December 27, 2019 (84 FR 71525)].

FMCSA concludes that provisionally renewing the exemption granted on November 21, 2019, for six months, under the terms and conditions listed below, will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

V. Exemption Decision

A. Grant of Provisional Renewal of Exemption

FMCSA provisionally renews the exemption for a subsequent period of six months, instead of the five years requested by Navistar, subject to the

terms and conditions of this decision and the absence of adverse public comments that would cause the Agency to terminate the exemption. If evidence of insufficient safety is not provided, FMCSA anticipates granting a full five-year exemption on or before the provisional exemption expires. The exemption from the requirements of 49 CFR 383.23 is otherwise effective beginning November 21, 2024, through May 21, 2025, 11:59 p.m. local time, unless revoked.

B. Applicability of Exemption

This exemption applies only to Navistar's driver Thomas Nickels. This driver is granted an exemption from the CDL requirement in 49 CFR 383.23 to allow him to drive CMVs in the United States without a State-issued CDL. Consequently, this driver is not subject to the requirements of 49 CFR part 382.

C. Terms and Conditions

When operating under this exemption, Navistar and Mr. Nickels are subject to the following terms and conditions:

(1) The driver and carrier must comply with all other applicable provisions of the FMCSRs (49 CFR parts 350–399);

(2) The driver must be in possession of the exemption document and a valid German commercial license;

(3) The driver must be employed by, and operate the CMV within the scope of his duties for, Navistar;

(4) At all times while operating a CMV under this exemption, the driver must be accompanied by a holder of a State-issued CDL who is familiar with the routes traveled;

(5) Navistar must notify FMCSA in writing within 5 business days of any accident, as defined in 49 CFR 390.5, involving this driver; and

(6) Navistar must notify FMCSA in writing if the driver is convicted of a disqualifying offense under § 383.51 or § 391.15 of the FMCSRs.

(7) Navistar must implement a drug and alcohol testing program substantially equivalent to the applicable requirements in 49 CFR part 382, subparts A–F, and require that Mr. Nickels be subject to those requirements. Navistar must provide documentation of its drug and alcohol testing program upon request to FMCSA.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable

to interstate or intrastate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Notification to FMCSA

Navistar must notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5), involving any of the motor carrier's CMVs operating under the terms of this exemption. The notification must include the following information:

- a. Identifier of the Exemption: "Navistar—Nickels;"
- b. Name of operating carrier and USDOT number;
- c. Date of the crash;
- d. City or town, and State, in which the accident occurred, or closest to the crash scene;
- e. Driver's name and license number;
- f. Co-driver's name (if any) and license number;
- g. Vehicle number and State license number;
- h. Number of individuals suffering physical injury;
- i. Number of fatalities;
- j. The police-reported cause of the crash, if provided by the enforcement agency;
- k. Whether the driver was cited for violation of any traffic laws, motor carrier safety regulations; and
- l. The total on-duty time accumulated during the 7 consecutive days prior to the date of the crash, and the total on-duty time and driving time in the work shift prior to the crash.

Reports filed under this provision shall be emailed to mcpsd@dot.gov.

F. Termination

FMCSA does not believe the driver covered by this exemption will experience any deterioration of their safety record. However, the exemption will be rescinded if: (1) Navistar or the driver operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objects of 49 U.S.C. 31136(e) and 31315(b).

VI. Request for Comments

FMCSA requests public comment from all interested persons regarding Navistar's application for a renewal of the exemption. The Agency will evaluate any adverse evidence submitted and, if it determines safety is

being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA may take immediate steps to revoke or modify the exemption.

Vincent G. White,
Deputy Administrator.

[FR Doc. 2025-00938 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2019-0159]

Parts and Accessories Necessary for Safe Operation; Exemption Renewal From Vision Systems North America, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; granting of renewal of exemption.

SUMMARY: FMCSA announces its final decision to renew the exemption granted to Vision Systems North America, Inc. (VSNA) to allow motor carriers to operate commercial motor vehicles (CMV) with the company's Smart-Vision high-definition camera monitoring system (Smart-Vision) installed as an alternative to the two rear-vision mirrors required by the Federal Motor Carrier Safety Regulations (FMCSRs).

DATES: This renewed exemption is effective January 15, 2025, through January 15, 2030.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Chief, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001; (202) 366-9209; MCPSV@dot.gov. If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, go to www.regulations.gov, insert the docket number "FMCSA-2019-0159" in the keyword box, and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first notice listed, and click "Browse Comments." To view documents mentioned in this notice as being available in the docket, go to

www.regulations.gov, insert the docket number "FMCSA-2019-0159" in the keyword box, click "Search," and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulatory Requirements

FMCSA requires in 49 CFR 393.80(a) that each bus, truck, and truck tractor be equipped with two rear-vision mirrors, one at each side. The mirrors must be positioned to reflect to the driver a view of the highway to the rear and the area along both sides of the CMV. Section 393.80(a) also requires that the National Highway Traffic Safety Administration's standard for mirrors on motor vehicles in Federal Motor Vehicle Safety Standard (FMVSS) No. 111 be met. Paragraph S7.1 of FMVSS No. 111 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a gross vehicle weight rating

(GVWR) greater than 4,536 kg and less than 11,340 kg and each bus, other than a school bus, with a GVWR of more than 4,536 kg. Paragraph S8.1 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a GVWR of 11,340 kg or more.

IV. Application for Renewal of Exemption

The renewal application for exemption from VSNA was described in detail in a **Federal Register** notice published on October 18, 2024 (89 FR 83937) and will not be repeated here as the facts have not changed.

V. Public Comments

The Agency received one comment supporting the exemption renewal and no comments opposing it.

Matthew Buchannan, an individual commenter, stated, "I fully support this request. These have shown to be very reliable in all weather conditions day or night. Also, they give the benefit of removing the blind spots created by the mirrors themselves. I believe that these systems should be allowed on a permanent basis and not just another extension."

VI. FMCSA Safety Analysis and Agency Decision

FMCSA is not aware of any evidence showing that the operation of VSNA's Smart-Vision system in accordance with the conditions of the original exemption has resulted in any degradation in safety. Moreover, the information VSNA provided in its application supports the view that the company's Smart-Vision system maintains the requisite statutory level of safety. Therefore, for the reasons discussed above and in the prior notice granting the original exemption request, FMCSA concludes that renewing the exemption granted on January 15, 2025, for a subsequent 5 years, on the terms and conditions set forth in this exemption renewal decision, will likely maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

VII. Exemption Decision

A. Grant of Exemption

FMCSA renews the exemption for a subsequent period of 5 years subject to the terms and conditions of this decision. The exemption from the requirements of 49 CFR 393.80 is effective January 15, 2025, through January 15, 2030, 11:59 p.m. local time, unless revoked.

B. Applicability of Exemption

During the temporary exemption period, motor carriers operating CMVs may install and use the VSNA's Smart-Vision system in lieu of the two rear-vision mirrors required by § 393.80.

C. Terms and Conditions

1. This exemption is limited to the VSNA's Smart-Vision system installed on CMVs and does not apply to any other camera-based mirror replacement system/technology.

2. Motor carriers using the VSNA's Smart-Vision system installed on CMVs must report to FMCSA on an annual basis to MCPSV@dot.gov: (1) the total number of CMVs operating under the terms and conditions of the exemption; and (2) any crashes, other than front-end crashes, involving CMVs operating under the exemption. The reports are due by the end of the calendar year beginning from the effective date of this exemption.

3. Drivers operating CMVs under this exemption must inspect the Smart-Vision system each time before operating the CMV and be satisfied that it is in proper working order.

4. Drivers operating CMVs under this exemption must inspect the Smart-Vision system at the end of each day and note any defects in the equipment on the driver vehicle inspection report. The motor carrier must repair any defects noted by the driver before it operates the CMV again.

5. The motor carrier must periodically inspect the Smart-Vision system in addition to the existing inspection required at least once every 12 months.

6. Motor carriers using the VSNA's Smart-Vision system installed on CMVs must notify FMCSA within 5 business days after they become aware, or otherwise determine, that the continued use of Smart-Vision system covered by this exemption is no longer likely to maintain a level of safety that is at least equivalent to the level that would be achieved absent this exemption. Notification must be made by sending an email to FMCSA at MCPSV@dot.gov.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Termination

FMCSA does not believe that motor carriers and CMVs covered by the exemption will experience any deterioration of their safety record. The Agency will, however, rescind the exemption if: (1) motor carriers and/or CMVs operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption results in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objective of 49 U.S.C. 31136 or chapter 313.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2025-00900 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2024-0124]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letters received November 12, 2024, and December 11, 2024, the Salt Lake City Department of Public Services in conjunction with the City of North Salt Lake (Petitioners), petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 222 (Use of Locomotive Horns at Public Highway-Rail Grade Crossings).¹ FRA assigned the petition Docket Number FRA-2024-0124.

Specifically, Petitioners request relief from § 222.35(b)(1), *What are the minimum requirements for quiet zones?*—Active grade crossing warning devices, which states that each public highway-rail grade crossing in a quiet zone “must be equipped, no later than the quiet zone implementation date, with active grade crossing warning devices comprising both flashing lights and gates which control traffic over the crossing.” Petitioners request a two-year waiver from the regulation “until the

design and construction of [a] new signal mast and gate arms” can be completed near two railroad crossings (IDs 805664P and 805836V) that are within the Woods Cross Quiet Zone.

In support of its request, Petitioners state that the relief pertains only to industry tracks where no accidents or incidents have occurred since 1979, according to FRA's records. Additionally, Petitioners explain that the installation of gate arms and “other safety improvements” at both crossings are currently in process to bring each crossing into compliance.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at www.regulations.gov. Follow the online instructions for submitting comments.

Communications received by March 17, 2025 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of the U.S. Department of Transportation's (DOT) dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

¹ The City of North Salt Lake initially requested relief under Docket Number FRA-2024-0115, and a Federal Register notice was published in that docket. See <https://www.regulations.gov/docket/FRA-2024-0115>. The Salt Lake City Department of Public Services submitted an initial request in this docket and then sent an additional letter that combined both requests into Docket Number FRA-2024-0124. Comments submitted to both of the notices in FRA-2024-0115 and FRA-2014-0124 will be considered.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2025-00970 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2025-0015]

Establishment of an Emergency Relief Docket for Calendar Year 2025

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of establishment of public docket.

SUMMARY: This Notice announces the establishment of FRA's emergency relief docket (ERD) for calendar year 2025. The designated ERD for calendar year 2025 is docket number FRA-2025-0015.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for further information regarding submitting petitions and/or comments to docket number FRA-2025-0015.

SUPPLEMENTARY INFORMATION: On May 19, 2009, FRA published a direct final rule establishing ERDs and the procedures for handling petitions for emergency waivers of safety rules, regulations, or standards during an emergency situation or event. 74 FR 23329. That direct final rule became effective on July 20, 2009, and made minor modifications to 49 CFR 211.45 in FRA's Rules of Practice in 49 CFR part 211. Section 211.45(b) provides that each calendar year FRA will establish an ERD in the publicly accessible DOT docket system (available at www.regulations.gov). Section 211.45(b) further provides that FRA will publish a notice in the **Federal Register** identifying by docket number the ERD for that year. FRA established the ERD and emergency waiver procedures to provide an expedited process for FRA to address the needs of the public and the railroad industry during emergency situations or events. This Notice announces the designated ERD for calendar year 2025 is docket number FRA-2025-0015.

As detailed in § 211.45, if the FRA Administrator determines an emergency event as defined in 49 CFR 211.45(a) has occurred, or that an imminent threat of such an emergency occurring exists, and public safety would benefit from providing the railroad industry with operational relief, the emergency waiver procedures of 49 CFR 211.45 will go

into effect. In such an event, the FRA Administrator will issue a statement in the ERD indicating the emergency waiver procedures are in effect and FRA will make every effort to post the statement on its website at railroads.dot.gov. Any party desiring relief from FRA regulatory requirements as a result of the emergency should submit a petition for emergency waiver under 49 CFR 211.45(e) and (f). Specific instructions for filing petitions for emergency waivers under 49 CFR 211.45 are found at 49 CFR 211.45(f). Specific instructions for filing comments in response to petitions for emergency waivers are at 49 CFR 211.45(h).

Privacy

Anyone can search the electronic form of any written communications and comments received into any of DOT's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.transportation.gov/privacy. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2025-00971 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2024-0126]

CSX Transportation, Inc. Petition for Approval of Product Safety Plan

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on November 11, 2024, CSX Transportation, Inc. (CSX) submitted a petition for FRA approval of its Product Safety Plan (PSP) for the Trip Optimizer Air Brake Control product (also referred to as "TO

Air Brake Control" or "Air Brake Control"). As this petition involves a railroad's PSP, FRA is publishing this notice and inviting public comment on the document.

DATES: Written comments must be received on or before March 17, 2025. FRA will consider comments filed after this date to the extent practicable.

ADDRESSES: *Comments:* Comments related to this notice may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number (FRA-2024-0126). Please note that comments submitted online via www.regulations.gov are not immediately posted to the docket. Several business days may elapse after a comment has been submitted online before it is posted to the docket.

Privacy Act: DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, commenters are encouraged to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Docket: For access to the docket to read comments received, please visit <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816-516-7168, email: Gabe.Neal@dot.gov.

SUPPLEMENTARY INFORMATION: In accordance with part 236 of title 49 of the Code of Federal Regulations, this document provides the public notice that CSX has petitioned FRA for approval of its PSP for the Trip Optimizer Air Brake Control product (also referred to as "TO Air Brake Control" or "Air Brake Control"). FRA has assigned the petition Docket Number FRA-2024-0126. CSX's PSP has been placed in this docket and is available for public inspection and comment.

CSX states that the Trip Optimizer product is an energy management system installed on locomotives that is used by the train's operator to improve the energy efficiency of train operations. CSX goes on to state that TO Air Brake Control is an expansion of the Trip Optimizer product that was initially deployed by CSX starting in 2008. CSX indicates that TO Air Brake Control functionality is designed to increase the number of miles of automatic operation and thereby decrease fuel consumption and the emissions output from all locomotives in the train. CSX also indicates that a train equipped with TO Air Brake Control will continue to operate under the supervision of a qualified train crew, who are required to assume control of the train and operate in manual mode, when necessary, and to retain overall responsibility for the safe operation of the train.

Interested parties are invited to comment on CSX's PSP by submitting comments to the electronic docket. Please refer to the **ADDRESSES** section above for guidance on how to submit comments to the electronic docket.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2025-00862 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA-2024-0015]

Third Party Contracting Guidance

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of availability of final circular and response to comments.

SUMMARY: The Federal Transit Administration (FTA) has made available on its website the final updated Third-Party Contracting Guidance Circular (C 4220.1G). The updated circular reflects statutory and regulatory changes that have occurred since the last update, provides additional non-binding guidance, and supersedes the previous Third-Party Contracting Guidance Circular C 4220.1F. This notice responds to the comments FTA received on the proposed circular, which was published in the **Federal Register** on November 27, 2024.

DATES: The applicable date of this circular is February 18, 2025.

ADDRESSES: One may view the comments at docket number FTA-2024-0015. For access to the docket, please visit <https://www.regulations.gov> or the Docket Operations office located in the West Building of the United States Department of Transportation, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For third party contracting questions, contact Tara Murphy, Division Chief, Office of Administration, Federal Transit Administration, 1200 New Jersey Ave. SE, Room E41-311, Washington, DC 20590, phone: (202) 366-5647 or email tara.murphy@dot.gov. For legal questions, Christopher Hall, Office of Chief Counsel, same address, Room E56-316, phone (202) 941-9595 or email christopher.hall@dot.gov.

SUPPLEMENTARY INFORMATION:

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I. Overview

This notice announces the availability of FTA Circular C 4220.1G, Third Party Contracting Guidance. C 4220.1G replaces C 4220.1F. The purpose of Circular 4220.1 is to provide updated Third-Party Contracting Guidance for Federal Transit Administration (FTA) assistance programs. This circular incorporates provisions of Federal law enacted since the publication of C 4220.1F, including the Infrastructure Investment and Jobs Act (Pub. L. 117-58, Nov. 15, 2021); the Office of Management and Budget's (OMB) and United States Department of Transportation's (USDOT) updated Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 CFR part 200 (78 FR 78608, Dec. 26, 2013; 89 FR 30046, Apr. 22, 2024) and 2 CFR part 1201 (79 FR 76049, Dec. 19, 2014), respectively; USDOT's regulation implementing the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Uniform Act) (49 CFR part 24, 89 FR 36944, May 3, 2024); and USDOT's Disadvantaged Business Enterprise (DBE) regulation (49 CFR part 26, 89 FR 24963, Apr. 9, 2024).

A copy of the final circular is in the docket and is posted on FTA's Circulars page (<https://www.transit.dot.gov/regulations-and-guidance/fta-circulars/circulars>).

II. Response to Comments

FTA issued a notice of availability and request for comments for the proposed circular, C 4220.1G "Third Party Contracting Guidance" on November 27, 2024 (89 FR 93824). The public comment period closed on December 27, 2024.

FTA received comments from 27 unique commenters including transit authorities, businesses and industry organizations, private individuals, and State and local departments of transportation.

FTA received seven requests to extend the comment period for the proposed circular. FTA declined to extend the comment period because FTA believes that the comment period was sufficient for interested parties to provide comment, evidenced by the number of comments FTA received on the proposed circular. In addition, the circular does not contain any binding requirements that are not already effective through statutory changes or regulatory changes established through a notice and comment process during which interested parties could have provided input.

FTA reviewed all relevant comments and took them into consideration when developing this final circular. FTA addresses these comments in the corresponding sections below. Some comments were outside the scope of the circular, and FTA does not respond to those comments in this notice. Several comments suggested typographical updates or changes. These changes, where appropriate, were incorporated.

In response to comments, FTA made changes to the final guidance which are discussed in detail in the corresponding sections below.

A. Chapter I

Comment: A consulting firm asserted that the concept of "premium" in the definition of the term "best value" is confusing and lacks a clear definition.

FTA Response: FTA declines to define the term "premium" further, as its meaning is context-specific and generally understood within the framework of best value procurements. In this context, premium refers to the additional cost a recipient may choose to pay for a proposal offering superior technical quality, performance, or other non-cost factors. Recipients are encouraged to clearly articulate evaluation criteria and the basis for

determining best value in their procurement documentation to ensure transparency and understanding.

Comment: A consulting firm suggested removing the term “Common Grants Rule” from Chapter I, noting that it is not appropriate in the context of the Americans with Disabilities Act (ADA) and 2 CFR part 200.

FTA Response: FTA has struck the definition, because the term is not actually used in the Circular.

Comment: A consulting firm suggested changing the defined term “grant” to “award” in the definitions to ensure consistency with terminology used in other FTA circulars and reviews.

FTA Response: FTA declines to replace the term “grant” with “award” in this definition, as the purpose of the definition is to define grants specifically, as distinct from other forms of financial assistance awards. (Compare with the nearby definition of “cooperative agreement” in the circular.) However, FTA has changed the definite article “the” to the indefinite article “an” (“Grant means an instrument . . .”) to reflect the existence of other forms of assistance awards.

Comment: A consulting firm noted that there are no mechanisms or tests to verify the accuracy of self-certifications and suggested instead asking recipients to affirm their agreement to comply with procurement regulations.

FTA Response: FTA declines to revise the approach to self-certifications, as the current process is well established and aligns with Federal requirements and standard oversight practices. Self-certifications serve as a formal acknowledgment of a recipient’s commitment to comply with procurement regulations, and recipients remain responsible for ensuring their accuracy and validity. Additionally, FTA conducts periodic reviews and audits to verify compliance, providing further assurance beyond self-certification.

Comment: A consulting firm suggested deleting references to the Best Practices Procurement Manual (BPPM), arguing that it lacks authority, does not cover all areas, contains incorrect examples, and is often copied by recipients without proper analysis, making it unhelpful for ensuring compliance. Similarly, a state department of transportation noted that the proposed circular, C 4220.1G, referenced the Best Practices Procurement Manual, last updated in 2016, and suggested either removing these references or updating the manual to include new requirements from the

Infrastructure Investment and Jobs Act and 2 CFR part 200, which was last updated in October 2024.

FTA Response: FTA declines to remove references to the Best Practices Procurement Manual (BPPM), as it serves as a valuable resource offering practical examples and guidance to assist recipients in navigating complex procurement requirements. The BPPM does not carry regulatory authority. It complements regulations and FTA’s other guidance by providing illustrative scenarios and best practices. Recipients can use the BPPM as another guidance tool, applying their own judgment and analysis to ensure compliance with Federal procurement standards.

Comment: An individual commenter suggested that in construction manager/general contractor (CM/GC) contracts, the Guaranteed Maximum Price (GMP) should be negotiated before contract award, with a fixed price finalized at 60–90% design completion, and an “off-ramp” available for the owner to seek competitive bids if needed. For Progressive Design-Build contracts (PDB), the commenter highlighted a concern that because the GMP or Target Maximum Price (TMP) is determined late in the design process, it prevents a fair and reasonable price determination at the time of award and may lead to uncontrolled cost escalation without a firmly established in upfront budget.

FTA Response: FTA acknowledges the commenters’ concerns regarding CM/GC and PDB contract structures and has made clarifications in the Circular to address them. With respect to CM/GC contracts, FTA recognizes the value of early contractor involvement in the design process to optimize lifecycle costs, value engineering, and scheduling outcomes. While the reference to CM/GC contributing to design up to the 60–90% design stage reflects common industry practice, it is not intended to preclude earlier involvement where it aligns with project goals. The definition aims to provide general guidance rather than prescriptive instructions on implementing alternative contracting methods.

Regarding the timing of GMP negotiations, FTA acknowledges that practices may vary based on project-specific factors and local preferences. The Circular now clarifies that GMP or equivalent price negotiations may occur either before or after the 60–90% design stage, depending on the recipient’s risk tolerance and procurement strategy. FTA also notes that recipients have the flexibility to structure GMP negotiations to include “off-ramps” for competitive bidding if the GMP does not align with budgetary or value expectations.

For PDB contracts, FTA recognizes the potential risk of cost escalation if the GMP or TMP is established late in the design process. However, PDB remains an allowable contracting method under FTA regulations. FTA emphasizes the importance of strong project management capacity when using alternative contracting approaches to mitigate risks and ensure effective outcomes. Lastly, while the term “Guaranteed Maximum Price” is widely understood in the industry, FTA acknowledges that some recipients may prefer terms like “final construction price” to better reflect their procurement and project management processes.

Comment: A city agency commented that the new definition in Chapter I, Section 5b for Approval, Authorization, Concurrence, Waiver is overly general and suggested retaining the more specific language from the previous version (4220.1F).

FTA Response: FTA declines to revise Chapter I, Section 5b to reintroduce the prior definition from C 4220.1F. The updated definition aligns with Federal procurement standards, and further specificity is unnecessary to meet compliance objectives.

Comment: A city agency commented that Chapter I, Section 5dd should clarify that the term “recipient” refers to the entire legal entity, not just a specific component, as was explicitly stated in the prior version (C 4220.1F).

FTA Response: FTA declines to revise this section to restate that the term “recipient” applies to the entire legal entity. The recipient is the entity with authority to enter into an assistance agreement with FTA and to execute certifications, which may at times be a unit of local government. The updated language provides sufficient clarity and aligns with Federal regulatory standards.

Comment: A city agency commented that Chapter I, Section 6 should reinstate references to the Master Agreement, as its removal has created a gap in clarity.

FTA Response: FTA declines to reinstate the description of the Master Agreement in this section. The purpose of Chapter I Section 6 is to describe FTA’s role and oversight activities. The Master Agreement is not an oversight activity by FTA, but is the document incorporated into every financial assistance award describing the recipient’s obligations.

B. Chapter II

Comment: A consulting firm suggested removing references to

revenue contracts, stating that they are not evaluated for compliance.

FTA Response: The FTA declines to remove references to revenue contracts, as they remain an important aspect of third-party contracting activities.

Comment: A consulting firm suggested removing references to the Federal Acquisition Regulation (FAR), expressing concern that recipients might rely on it as a primary procurement guide rather than using it solely as a reference.

FTA Response: The FTA declines to remove references to the FAR, because it is important to plainly distinguish between the FAR and the procurement standards of 2 CFR part 200 so recipients are not confused. Additionally, recipients may at times use the FAR as an additional source of guidance.

Comment: A city agency commented that Chapter II, Section 2.a(1) distinguishes Cooperative Agreements but does not reference Joint Partnership Agreements, creating inconsistency with earlier chapters.

FTA Response: FTA has revised this section to provide a more concise statement regarding its applicability to grants and cooperative agreements. Grants and cooperative agreements are forms of financial assistance awarded by FTA. FTA declines to revise this section to include a reference to Joint Partnership Agreements, which are not a form of financial assistance awarded by FTA. The current language aligns with applicable regulatory requirements.

Comment: A city agency commented that Chapter II, Section 2.b(8) should expand the definition of Force Account to include activities performed by contractors, as the current definition limits it to a recipient's own forces.

FTA Response: FTA declines to expand the definition of Force Account to include contractor activities. The current definition reflects the Federal intent for force account work to refer specifically to the recipient's own non-contracted workforce.

C. Chapter III

Comment: A consulting firm noted that all ability to accept gifts of "nominal value" should be removed, advocating for a zero-tolerance policy as the best practice.

FTA Response: FTA declines to remove all ability to accept gifts of "nominal value" because 2 CFR 200.318 authorizes a recipient or subrecipient to "set standards for situations where the financial interest is not substantial or a gift is an unsolicited item of nominal value."

Comment: A consulting firm noted that the phrase "sound and complete agreement" is too ambiguous unless specific elements can be stated or evaluated.

FTA Response: FTA disagrees that the term is ambiguous and declines to make a change. The phrase recognizes the broad discretion recipients have to design and form contracts. Furthermore, the statement that recipients should take care to include contract terms that form a sound and complete agreement is advisory. It is not intended to create criteria by which FTA will inspect recipients' contracts for Federal compliance.

Comment: A consulting firm noted that the term "Industry Contract" is unclear and should either be redefined or removed altogether.

FTA Response: FTA disagrees that the term is unclear and declines to redefine or remove the term "Industry Contract." FTA believes the term is contextually clear within the procurement framework and allows for broad application across diverse procurement scenarios.

Comment: A consulting firm noted that the term "reasonable documentation" lacks clarity and is overly subjective, which could lead to inconsistent compliance assessments.

FTA Response: FTA declines to revise the term "reasonable documentation." The term allows for recipients to exercise their discretion across diverse procurement scenarios and aligns with standard Federal practices for documentation. It would be impractical to attempt to specify recordkeeping requirements to apply to everything a recipient might procure, from micro-purchases to mega-projects.

FTA encourages recipients to maintain records sufficient to demonstrate compliance with applicable procurement regulations.

Comment: A consulting firm noted that "access to records" should be a mandatory clause in all third-party contracts.

FTA Response: The commenter was not specific about whose records he means to be accessed by whom. Nonetheless, FTA declines to add such a requirement for another mandatory clause in recipients' contracts. A recipient's obligation to maintain records related to its award and provide access to the Federal Government already is well established. A recipient must take whatever measures are required to assure compliance, which may, in some cases, include making provisions to obtain records from contractors. Specifying a new required clause is not necessary.

Comment: A consulting firm noted that the criteria for using reverse auctions are insufficient and should not be limited to the Simplified Acquisition Threshold (SAT) and commented that clear reasons for their use, similar to Requests for Proposals (RFPs) and Invitations for Bids (IFBs), should be provided.

FTA Response: FTA declines to expand the use of reverse auctions for procurements above the SAT. This is because 2 CFR 200.320 specifies procurement methods to be used for procurements above the SAT and does not include reverse auctions. Reverse auctions are primarily suited for procurements involving standardized goods or services where price is the primary evaluation factor and technical complexity is minimal. Sealed bidding is the procurement method required by regulation for such procurements when they exceed the SAT. 2 CFR 200.320(b)(1).

Comment: A consulting firm noted that audits are not clearly stated as a requirement and may cause confusion for recipients, suggesting their removal.

FTA Response: FTA declines to remove references to audits as they are a requirement pursuant to 2 CFR part 200, subpart F, but has clarified the requirements to describe the procedure more accurately.

Comment: A state department of transportation noted that one of the proposed changes required annual self-certification of the procurement policy. It was recommended to add criteria outlining the attributes that this self-certification should include.

FTA Response: Self-certification is not a change. For many years, FTA has relied on recipients self-certifying their procurement systems annually. The certification is made as part of a recipient's annual Certifications and Assurances, which can be found on FTA's website here (along with previous years' versions): <https://www.transit.dot.gov/funding/grantee-resources/certifications-and-assurances/certifications-assurances>. The Certifications and Assurances are standardized for all recipients and provide the exact text of the certification. Therefore, it is not necessary for the Circular to describe the contents that must be included in such a certification.

Comment: A state department of transportation noted that the Circular recommends reviewing Federal requirements when deploying an e-commerce system but does not specify which requirements to follow. The commenter recommended FTA include these specific Federal requirements.

FTA Response: FTA refers the commenter to Chapter III, Section 3, paragraph e, subparagraphs i-iii for these requirements.

Comment: A transit bus manufacturer suggested using stronger language to encourage electronic procurement methods rather than printed documents in Chapter III, Section 3(e).

FTA Response: FTA declines to revise this section to include stronger language encouraging the use of electronic methods over printed documents. The existing guidance already supports and promotes the use of electronic documentation as a best practice while allowing recipients the flexibility to determine the most appropriate format for their specific circumstances. Mandating stronger language may not account for varying technological capabilities or regulatory requirements across different recipients and procurement environments. Recipients are encouraged to adopt electronic methods where feasible and practical to improve efficiency and reduce administrative burdens.

D. Chapter IV

Comment: An individual commenter urged FTA to explicitly clarify whether third-party contractors must be registered in SAM.gov at the time of offer or quotation to be eligible for an award. The commenter described inconsistencies between the Circular's description of the requirement that a recipient verify a contractor's exclusion status (*i.e.*, suspension or debarment) and the expectations of triennial reviewers, noting that SAM checks often seemed mandatory in practice despite the Circular's statement that checking SAM is strongly recommended.

FTA Response: In response to the comment, FTA has added a statement to clarify that contractors are not required to be registered in SAM to do business with FTA recipients. FTA also has reworded the paragraph about verifying prospective contractors' exclusion status, to clarify that SAM is one of several methods available to a recipient to confirm a prospective contractor's non-exclusion.

Comment: A county requested clarification on the percentage requirements for Disadvantaged Business Enterprises (DBEs) and which clauses must be flowed down to subcontractors in the proposed FTA Circular 4220.1G.

FTA Response: FTA declines to revise Circular 4220.1G to provide the requested clarification because the Circular is focused on procurement standards and not the U.S. Department of Transportation's DBE program. The

Circular directs readers to 49 CFR 26.49 and 2 CFR 200.321(b)(3) for detailed requirements regarding DBE participation. The U.S. DOT's website is another useful source of guidance for administering a DBE program or competing for work as a DBE: <https://www.transportation.gov/civil-rights/disadvantaged-business-enterprise>.

When a recipient is required to set a percentage goal for DBE contracting, the recipient creates its own goal, based on the availability of DBEs in its area. In other words, there is no one DBE goal for FTA recipients. Regarding flow-down clauses, FTA separately will update its guidance on flow-down clauses on the FTA website soon.

Comment: A consulting firm noted that the phrase "sound business judgment" should be removed as it cannot be objectively evaluated.

FTA Response: FTA declines to remove the term "sound business judgment." The term is intentionally broad to allow recipients flexibility in decision-making while maintaining accountability.

Comment: A consulting firm noted that if seat belt use is only encouraged and not mandated, it should be removed from the guidance.

FTA Response: FTA declines to remove references to seat belt use. Executive Order 13043 (note at 23 U.S.C. 402) requires Federal agencies to encourage seat belt use in Federal grants. Furthermore, encouraging seat belt use remains an important safety consideration, even when it is not a requirement.

Comment: A consulting firm noted that if texting policies are only encouraged and not mandated, they should be removed from the guidance.

FTA Response: FTA declines to remove references to texting policies. Executive Order 13513 (note at 23 U.S.C. 402) requires Federal agencies to encourage recipients to adopt policies to ban text messaging while driving in carrying out a Federal award. While not mandatory, encouraging safe texting practices supports broader safety objectives within transit operations.

Comment: A consulting firm noted that the civil rights clauses should be reviewed to determine if they should flow down to contractors and subcontractors, with revisions made as necessary.

FTA Response: FTA intends separately to update its guidance on mandatory clauses and flow-down clauses on FTA's website. The existing guidance in the Circular aligns with the applicable Federal statutes.

Comment: A consulting firm noted that the word "considered" in Chapter

IV, Section 3.b in references to Small and Disadvantaged Business Enterprises should be removed because it cannot be quantitatively measured or evaluated.

FTA Response: FTA declines to remove the term "considered" in relation to Small and Disadvantaged Business Enterprises. Examples of what consideration means are provided in the paragraph at Section 3.b. The text of the Circular closely follows the text of 2 CFR 200.321, which requires, when possible, that the recipient ensure disadvantaged businesses are "considered".

Comment: A consulting firm noted that spare ratios are an agency planning function and not related to procurement. The commenter noted spare ratios already are discussed in FTA's Circular 5010.1F and should not be addressed in Circular 4220.1G. The commenter suggested spare ratios should be tracked through the Triennial Review.

FTA Response: FTA declines to remove references to spare ratios from procurement guidance. Although spare ratios are addressed primarily in Circular 5010.1F, referring to spare ratios in the procurement circular helps ensure a recipient is aware of the spare ratio policy when undertaking a vehicle procurement. The Triennial Review serves as a broad assessment of a recipient's compliance across multiple areas, including procurement, maintenance, and financial management, and does review a recipient's spare ratio.

Comment: An individual commenter noted difficulty finding confirmation of the Micro-purchase threshold increase to \$50,000 in the proposed FTA Circular 4220.1G and mentioned their understanding that the threshold increase became effective on October 2, 2024.

FTA Response: The Federal micro-purchase threshold has not changed; it is still \$10,000. However, as of October 1, 2024, 2 CFR 200.320(a)(1) permits a recipient to certify for itself a higher micro-purchase threshold, up to \$50,000 in certain instances. This higher threshold is not automatic and requires the recipient's self-certification and supporting documentation. The circular discusses this change in Chapter VI, Section 4.

Comment: An individual commenter sought clarification on two points in the proposed Circular 4220.1G: whether the removal of the prohibition on geographic preferences formally stated at 2 CFR 200.319 affected the guidance provided in Chapter VI of the Circular regarding geographic preferences; and clarification of the statement regarding

Patent and Restricted Data Rights as a possible reason for a non-competitive procurement, specifically the statement, “However, the mere existence of such rights does not by itself justify a noncompetitive award,” and whether such scenarios should be treated as unsolicited proposals.

FTA Response: Circular 4220.1G does reflect the removal of the prohibition against geographic preference from 2 CFR 200.319. However, 2 CFR 200.319 was not the only rule affecting geographic preferences in FTA procurements. The Circular presents FTA’s explanation of the current status of geographic preferences across various procurement types, reading relevant statutes and regulations together.

Additionally, the statement that “the mere existence of [patent and restricted data] rights does not by itself justify a noncompetitive award,” does not imply that these scenarios should be treated as unsolicited proposals. It means that just because a single company may own rights necessary to the delivery of the product or service being acquired, does not mean that company is the only possible source for the product or service. Recipients should conduct market research, including consideration of Brand Name or Equal products or services, and document their findings in the procurement file before pursuing a sole source award.

Comment: A State department of transportation noted that in Chapter IV, the section on Small Procurements references DBEs but does not include small businesses or veteran-owned businesses.

FTA Response: The Small Procurement section in Chapter IV does reference women owned businesses. FTA has added reference to veteran owned businesses to correctly reflect the requirements of 2 CFR 200.321. Additionally, FTA refers the commenter to Chapter IV, section 2, “Small and Disadvantaged Business Enterprises,” for information on small and veteran owned businesses.

Comment: A state department of transportation noted that the section of Chapter IV related to small procurements allowed splitting a procurement to increase DBE participation, and that this appeared to be in conflict with other statements in Chapter IV that prohibit dividing procurements to meet the micro-purchase limit. The commenter requested clarification on whether splitting the procurement when using a DBE is permissible if the end result were procurements that met the micro-purchase threshold.

FTA Response: As noted in Chapter IV, Section 1(c)(2), a known requirement must not intentionally be divided into multiple smaller procurements to fall below the simplified acquisition threshold or micro-purchase threshold, regardless of the use of DBEs. The Uniform Requirements and U.S. DOT’s DBE rule suggest ways to increase DBE participation by “dividing procurement transactions into separate procurements” (2 CFR 200.321) or “breaking out contract work items into economically feasible units (for example, smaller tasks or quantities)” (App. A to 49 CFR part 26). These suggestions must be interpreted consistently with the requirement not to undermine full and open competition. For example, it may be possible to unbundle a solicitation for multiple services or supplies that do not necessarily have to be combined under the same contract.

Comment: A law firm on behalf of an industry coalition suggested FTA state that liquidated damages should not exceed incentives but rather should be balanced with incentives.

FTA Response: FTA declines to specify that liquidated damages should not exceed incentives but rather should be balanced with them. Liquidated damages and incentive provisions serve distinct purposes in a contract, with liquidated damages addressing the costs associated with non-performance or delays, and incentives encouraging superior performance or early completion. Balancing these two elements in every contract may not always align with the specific goals or circumstances of the procurement. FTA’s existing guidance allows recipients the flexibility to structure contracts, including liquidated damages and incentives, in a manner that reflects their unique project needs and risk assessments. Recipients are encouraged to ensure that both liquidated damages and incentives are reasonable, justifiable, and aligned with the overall objectives of the procurement.

Comment: A city agency commented that Chapter IV, Section 2.b.5(b) omits the Percentage of Completion Method for progress payments, which was previously included in C 4220.1F. The commenter suggested including language on this method.

FTA Response: FTA declines to add language about the Percentage of Completion Method. Until 2014, the now-superseded Common Rule at 49 CFR 18.21(d) (2014) specified that recipients may use the percentage of completion method to pay their construction contractors. The current procurement standards at 2 CFR part

200 do not mention percentage of completion. Recipients retain flexibility in structuring construction progress payments under Federal requirements.

Comment: A city agency commented that the last sentence at Chapter IV, Section 2.b(9)(d) contains unclear language regarding returning liquidated damages to the award budget, and recommended clarification.

FTA Response: FTA has revised the last sentence of this section for clarity.

Comment: A city agency commented that Chapter IV, Section 2.c(3)(b) should clarify whether DBEs have priority over other small, minority, or disadvantaged business enterprises as defined by the USDOT.

FTA Response: There is no prioritization. Under U.S. DOT’s disadvantaged business enterprise (DBE) rule, a DBE means a for-profit small business that is at least 51% owned by one or more individuals who are both socially and economically disadvantaged. 49 CFR 26.5. The rule rebuttably presumes that women and persons of certain racial descent are socially disadvantaged. 49 CFR 26.67(a). Firm owners whom the rule does not presume to be socially disadvantaged can register their firms as DBEs by demonstrating their disadvantage through a narrative description. 49 CFR 26.67(d).

Comment: A city agency commented that Chapter IV, Section 2.a(1) introduces a requirement for recipients to verify contractor employee classification. They requested additional guidance, including whether FTA will provide a standard contract clause or certification.

FTA Response: The U.S. Office of Management and Budget added this to the Uniform Requirements in 2024. 89 FR 30136. As part of assessing a potential contractor’s responsibility, the rule now requires the recipient or subrecipient to consider the contractor’s proper classification of its employees under the Fair Labor Standards Act. 2 CFR 200.318(h). The rule does not specify that the recipient must make a special investigation or acquire relevant information in any other particular manner. The commenter’s suggestion that a certification or contract clause could be employed may be acceptable. FTA does not have further guidance to provide at this time.

Comment: A city agency asked whether the Circular’s new guidance regarding protection and types of data rights created a change to the required clauses recipients must include in their contracts. The commenter also asked where to find a list of required clauses

now that Appendix D no longer is part of the Circular.

FTA Response: The Circular's guidance regarding data rights has not created a new required clause. FTA intends to update and maintain a table of required clauses separate from Circular 4220.1G on FTA's website.

Comment: Regarding organizational conflicts of interest during contracting, a city agency asked whether a consultant who assisted in drafting reports or partial designs can still bid on future project phases if the recipient discloses the consultant's work to other potential bidders.

FTA Response: The comment presents a fact-specific hypothetical that is beyond the scope of this comment process. FTA encourages the commenter to contact its FTA regional office if it has discovered or is trying to cure an organizational conflict of interest.

Comment: A city agency commented that Chapter IV, Section 2.b(4) creates a barrier for non-profits and SBEs/DBEs by requiring an indirect cost rate for non-A&E services. They suggested flexibility to allow fixed or fully burdened rates, especially for community engagement work.

FTA Response: The cost principles and requirements related to indirect cost rates found in 2 CFR part 200 specify how recipients may charge indirect costs to their FTA awards. FTA does not have rules about how the recipient's *contractors* charge indirect costs to the *recipient*. (An exception to this exists for A&E firms. The law requires a recipient to accept and use an A&E firm's indirect rate established in accordance with the Federal Acquisition Regulation. 49 U.S.C. 5325(b).) That being said, the commenter's local rules may impose such requirements, but FTA cannot comment on local requirements.

Comment: A transit bus manufacturer requested that FTA change its guidance that recipients "may use" progress payments and advance payments to say recipients "should use" such payments. The commenter also requested that FTA rephrase other parts of the section on advance and progress payments and include more examples to promote the use of advance and progress payments by recipients.

FTA Response: FTA declines to replace the permissive "may use" with the more prescriptive "should use". The current language provides recipients with the flexibility to determine the most appropriate procurement approach based on their specific project needs and circumstances, while still adhering to Federal requirements. Additionally, FTA declines to provide exhaustive

descriptions of circumstances where phrases like "in some circumstances" apply. The variability in procurement scenarios across agencies and projects makes it impractical to prescribe a one-size-fits-all definition. Recipients are encouraged to consult with their FTA Regional Offices for guidance when specific scenarios arise that require further clarification.

Comment: In Chapter IV, Section 2(b)(9)(d), Liquidated Damages, a transit bus manufacturer suggested that FTA include statements balancing risk and related penalties, add descriptions of excusable delay on the part of contractors, and add a statement recommending that recipients allow contractors to be reimbursed for costs and damages associated with delivery delays requested or caused solely by the recipient. The commenter noted this is particularly relevant with respect to zero-emission bus delivery delays caused by charging or fueling infrastructure.

FTA Response: FTA declines to revise this section to include specific descriptions of risk-balancing and excusable delay or to recommend contractor reimbursement for costs and damages associated with delivery delays caused solely by the recipient. The existing guidance provides sufficient flexibility for recipients to negotiate contract terms with their vendors, including provisions for liquidated damages, excusable delays, and risk-sharing, tailored to the specific circumstances of their procurements.

Comment: A transit bus manufacturer suggested that in Chapter IV, Section 2(e), where the Circular discusses special considerations for rolling stock procurements, FTA include a paragraph on Excessive Bonding that discourages excessive bonding and includes descriptions of situations deemed excessive. The commenter suggested examples deemed excessive include bonding required when no payments are made until acceptance of vehicles, bonding that exceeds the amount of contracted work remaining or the amount of advance payments or progress payments, and bonding that exceeds the term of the period of performance. The commenter also suggested such a detailed list be included in the section on Excessive Bonding in Chapter VI. This commenter also suggested that Chapter IV, Section 2(e) clarify that Federal law only requires security for rolling stock procurements using advance or progress payments.

FTA Response: FTA declines to revise this section to include a paragraph on Excessive Bonding with a detailed list of

specific situations deemed excessive. Prescribing an exhaustive list of scenarios could unintentionally limit recipients' ability to make risk-based determinations suited to their unique procurement needs. The situations described by the commenter may or may not be excessive based on the specific facts and circumstances of any particular procurement. Therefore, it is better for FTA not to be so prescriptive, and to leave that to the discretion of the parties to the contract. The current guidance already aligns with Federal procurement standards and provides recipients with flexibility to assess bonding requirements based on their project-specific risks and financial considerations.

Regarding the clarification on security for advance or progress payments in rolling stock procurements, FTA affirms that it requires security only for rolling stock procurements involving advance or progress payments. However, this requirement is already addressed in the guidance in the section describing advance and progress payments, which have application beyond just rolling stock procurements, and further clarification is unnecessary. FTA notes that recipients may require security in excess of the minimums required by FTA.

Comment: A transit bus manufacturer requested that FTA include in Chapter IV, Section 2(e)(3) (paragraph referring to FTA's minimum useful life policy for rolling stock), a statement that infrastructure and other property included in rolling stock purchases are also subject to the minimum useful life requirements in Circular 5010.1F. The commenter also requested FTA repeat the list of acceptable methods to determine minimum useful life from Circular 5010.1F, rather than referring to Circulars 5010.1F and 9050.1A.

FTA Response: FTA declines to revise this section to include a statement about the useful life of infrastructure and other property related to rolling stock, or a list of acceptable methods for determining minimum useful life, rather than referencing Circulars 5010.1F and 9050.1A. These circulars already provide detailed guidance on determining minimum useful life and duplicating their content within Circular 4220.1G would create unnecessary redundancy and potential inconsistencies across guidance documents. Recipients are encouraged to consult Circulars 5010.1F and 9050.1A for specific requirements regarding minimum useful life determinations for rolling stock and related infrastructure.

Comment: A transit authority commented that in regions with a limited number of DBEs, meeting the specialized needs of Federally funded procurements is challenging. The commenter stated that the proposed tiered compliance standards and enhanced documentation requirements place significant administrative burdens on agencies without delivering corresponding benefits due to the scarcity of qualified DBEs in the region.

FTA Response: FTA declines to revise the description of the DBE rule. The U.S. DOT DBE rule is a Department-wide rule administered by the Office of the Secretary of Transportation, and changes to it are beyond the scope of this circular update. FTA notes, however, that the DBE rule directs recipients to take into account the availability of DBEs when setting their DBE goals. 49 CFR 26.45.

Comment: A transit authority commented that proactive measures to increase DBE participation, such as breaking contracts into smaller components or altering delivery schedules, are often impractical and may compromise cost efficiency and operational effectiveness. The transit authority commented that mandating these measures risks causing delays and increased costs for critical procurements.

FTA Response: FTA declines to make changes in response to the comment. FTA declines to revise the description of the DBE rule. The U.S. DOT DBE rule is a Department-wide rule administered by the Office of the Secretary of Transportation, and changes to it are beyond the scope of this circular update. The DBE rule does not mandate the actions the commenter described; the DBE rule suggests them as actions a recipient can “consider” as part of good faith efforts to increase DBE participation. 49 CFR part 26, app. A para. IV.

Comment: A transit authority commented that greater flexibility should be provided in compliance expectations for regions with limited DBE availability. The commenter specifically commented that FTA should allow recipients to demonstrate “good faith efforts” without punitive measures if participation goals cannot be met due to local constraints and offer exemptions or modified compliance standards for regions where DBE participation opportunities are demonstrably limited.

FTA Response: FTA declines to make changes in response to the comment. The U.S. DOT DBE rule is a Department-wide rule administered by the Office of the Secretary of Transportation, and

changes to it are beyond the scope of this circular update. The commenter should review the DBE rule, 49 CFR part 26, which does make provision for “good faith efforts” on the part of a recipient.

Comment: A transit authority commented that rather than imposing rigid participation requirements, FTA should prioritize capacity-building initiatives for DBEs in underserved regions. The commenter suggested that this approach would expand the pool of qualified DBEs over time and better align with long-term equity goals.

FTA Response: FTA declines to make changes in response to the comment. The U.S. DOT DBE rule is a Department-wide rule administered by the Office of the Secretary of Transportation, and changes to it are beyond the scope of this circular update.

Comment: A transit authority requested that FTA expand the Circular’s guidance related to software-as-a-service (SaaS) agreements. The commenter requested that FTA add more detail addressing shared data ownership in SaaS agreements, the eligibility of SaaS licensing for Federal funds, and detailed clarification about the respective cybersecurity responsibilities of the customer and the SaaS vendor. The commenter also requested that FTA create a requirement about data portability at the end of a SaaS contract and develop model clauses and forms for recipients to use when procuring SaaS.

FTA Response: FTA declines to make these revisions. The purpose of the Circular is to describe the Federal procurement standards and how they apply to recipients’ transit related procurements. The commenter’s suggestions are far more detailed and specific than the Federal standards and are beyond the scope of this Circular. The guidance in the Circular section acknowledges these data issues at a high level, while not being unnecessarily prescriptive, and allows recipients and their vendors to make these determinations for themselves.

Comment: A transit authority commented that FTA should include a dedicated appendix featuring case studies of successful P3 implementations, highlighting best practices and lessons learned, noting that examples would offer practical insights into how P3s have been structured, financed, and managed effectively in real-world scenarios.

FTA Response: FTA declines to create a dedicated appendix featuring case studies of successful P3 implementations. While case studies can offer valuable insights, the purpose

of FTA Circular 4220.1G is to provide regulatory guidance and requirements for federally funded procurements. The Transit Cooperative Research Program (TCRP) conducts research on P3s and some of their reports may include case studies. Interested stakeholders may review these studies on TCRP’s website: <https://nap.nationalacademies.org/search/?term=public+private+partnerships>.

Comment: A transit authority commented that FTA should simplify compliance requirements for procuring products with recycled content, prioritize high-impact product categories, and allow greater flexibility for product categories with lower environmental impact. They suggested allowing agencies to document “good faith efforts” when such products are either unavailable in the market or cost-prohibitive. Additionally, they recommended a self-certification process to reduce the administrative burden associated with compliance and requested a balance between benefits and practicality.

FTA Response: FTA declines to revise the guidance. The requirements related to procurement of recovered or recycled materials are a governmentwide regulation, 2 CFR 200.323, and FTA cannot amend them. The text in the Circular closely follows the text of the regulation, which already allows for practicality.

Comment: A transit authority commented that FTA should offer technical assistance and training to help agencies effectively incorporate recycled content requirements into their procurement processes. They suggested providing webinars, guides, or resources outlining best practices and market opportunities. They also suggested that FTA should promote collaboration through joint procurements or cooperative purchasing agreements for recycled-content products, which would enable smaller agencies to access competitive pricing and a broader range of product options.

FTA Response: FTA acknowledges the request for additional support to procure recycled-content products, but such efforts are beyond the scope of the Circular update.

Comment: A transit authority commented that FTA should incorporate the following verbiage to Chapter IV, Section 1.a: FTA prohibits, with limited exceptions, the use of capital assistance for the recipient’s operating expenses.

FTA Response: FTA declines to add the suggested language because the existing language in this section already reflects FTA’s policy regarding the use

of capital assistance, and adding specific examples may create unnecessary redundancy or confusion. Recipients are expected to understand and adhere to statutory and regulatory limitations on the use of capital funds, as outlined in the applicable FTA circulars and other guidance documents.

E. Chapter V

Comment: A consulting firm noted that interstate cooperative procurement contracts should also be allowed for non-rolling stock purchases as long as they comply with 2 CFR part 200.

FTA Response: FTA declines to extend the use of interstate cooperative procurement contracts to non-rolling stock purchases. Current guidance aligns with section 3019(b) of the FAST Act, which authorizes such interstate purchasing from cooperative procurement contracts only for rolling stock and related equipment.

Comment: A consulting firm noted that the term “open market” needs to be clearly defined to avoid ambiguity.

FTA Response: FTA declines to define the term “open market” further because the term is contextually understood within procurement practices, and additional definition is unnecessary.

Comment: A state department of transportation commented that the proposed Third-Party Contracting Guidance (FTA C 4220.1G) should explicitly allow state and local agency technology procurement through interstate cooperative purchasing agreements and purchasing schedules, provided the participating states’ procurement policies allow it, regardless of the state in which the agencies are located. The commenter suggested that restricting interstate purchasing schedules would disproportionately harm smaller and rural transit agencies, which often lack the resources to conduct independent procurements or establish state-specific schedules for modern transit technologies.

FTA Response: Section 3019(b) of the FAST Act authorizes such interstate purchasing from cooperative procurements only for rolling stock and related equipment. FTA cannot amend it to include other products.

Comment: A transit technology company commented in support of FTA’s clarifications in Chapter V regarding joint procurement, state or local government purchasing schedules, and intergovernmental agreements. They noted that public sector entities often misunderstand FTA’s stance on these arrangements and believe this clarification will encourage their use,

ultimately improving efficiency and cost-effectiveness in the procurement process.

FTA Response: FTA appreciates the comments of support for the proposed clarifications which are intended to provide transit agencies and stakeholders with guidance that ensures compliance with applicable laws and regulations while promoting efficiency and cost-effectiveness in procurement practices.

Comment: A city agency commented that Chapter V, Section 4.d lacks clarity on why Interstate Purchasing Schedules are restricted, despite aligning with intergovernmental agreement principles. The commenter requested further explanation.

FTA Response: FTA has added clarification to the Circular. Interstate purchasing schedules generally are ineligible for FTA funding because they curtail opportunities for competitive procurements. Section 3019(b) of the FAST Act makes an exception for interstate purchases of rolling stock and related equipment, but only for rolling stock and related equipment.

F. Chapter VI

Comment: A consulting firm noted that evaluation criteria, including how proposals will be scored or rated, should be explicitly stated.

FTA Response: Existing regulation, 2 CFR 200.320(b), requires that solicitations identify all evaluation factors and their relative importance. The Circular already states this requirement.

Comment: A consulting firm noted that the \$50,000 threshold for contracts under the micro-purchase threshold should be tied to the total contract value rather than an annual limit.

FTA Response: FTA has revised the Circular to clarify that the self-certification to use a higher threshold must occur annually. The threshold is not an annual “budget” for micro-purchases.

Comment: A consulting firm noted that task order contracts should be evaluated as competitive procurements among the pool of selected contractors.

FTA Response: FTA declines to make this change, as the suggestion exceeds the requirements in the Federal procurement standards of 2 CFR part 200. The procurement standards do not prescribe how task orders are to be assigned under multiple award contracts. Recipients have discretion to manage their contracts and assign task orders effectively.

Comment: A consulting firm noted that the requirement to “consider workforce impacts” under cost and

price analysis is unclear and should be clarified in terms of method and analysis depth.

FTA Response: In 2024, the U.S. Office of Management and Budget amended 2 CFR 200.324(a) to add that a “recipient or subrecipient should consider potential workforce impacts in their analysis if the procurement transaction will displace public sector employees,” as part of analyzing the cost or price of a procurement. (89 FR 30046). FTA will leave this term broad, to provide maximum discretion to recipients and to accommodate varied workforce considerations across projects.

Comment: A consulting firm noted that cost analysis requirements should explicitly apply to single-bid or single-proposal conditions.

FTA Response: FTA declines to revise the language to explicitly mandate a cost analysis for single-bid or single-proposal conditions. The provision as written notes that a recipient should perform a cost analysis when price competition is inadequate.

Comment: A state department of transportation noted that the requirement to negotiate profit separately was removed from 2 CFR 200.324 in the October 2024 update. However, the circular’s language still included this requirement, creating a perceived conflict between the two regulations.

FTA Response: FTA acknowledges this change to 2 CFR 200.324. It is considered a best practice to perform these tasks, and the Circular had preserved it as a recommendation, not a requirement. FTA has removed this from the final version of the Circular.

Comment: A law firm on behalf of an industry coalition requested that FTA clarify that recipients planning to procure operations services through a multiyear contract should define the scope of work and performance metrics in their Request for Proposals. The commenter also noted that the contract should provide pricing flexibility. The commenter suggested that FTA should encourage recipients to seek input before putting out an RFP and include information that will aid bidders in developing proposals in the RFP. The commenter also suggested that RFPs should provide flexibility regarding substitutions of key staff.

FTA Response: FTA declines to revise the Circular. The existing guidance in Chapter VI already emphasizes the importance of clearly defining requirements, evaluation criteria, and contract expectations in RFPs to ensure fair and effective competition, consistent with regulation, 2 CFR

200.320. Recipients have flexibility in structuring their RFPs and contracts to address the unique needs of their operations services procurements, including considerations for pricing structures and staffing substitutions. Furthermore, while seeking industry input before issuing an RFP may be useful, it is not universally required. The current guidance provides sufficient flexibility for recipients to develop RFPs that align with their procurement objectives while complying with Federal requirements.

Comment: A law firm on behalf of an industry coalition suggested that FTA include a series of recommendations to recipients on what to include in contracts, such as provisions requiring the provision of detailed information from contract bidders, specifying a contract base period, bilateral rather than unilateral options for contract extension, inflation adjustment and force majeure clauses. This commenter also suggested FTA specify that fixed monthly fee and variable rate; variable rate; and cost plus rate structures are all appropriate for operations contracts.

FTA Response: FTA declines to include these specific recommendations. FTA's existing guidance already provides recipients with the flexibility to structure contracts in a manner that best meets their operational and financial needs, provided they remain compliant with Federal procurement requirements. Similarly, FTA declines to prescribe specific pricing structures—such as fixed monthly fees, variable rates, or cost-plus rates—as universally appropriate for recipients. Recipients have discretion to select contract terms and pricing structures based on their procurement objectives, market conditions, and the specific requirements of each procurement.

Comment: A city agency commented that Chapter VI, Section 2.g(1) should clarify whether contracts using negotiated hourly rates fall under the Cost Reimbursement category.

FTA Response: FTA declines to amend the Circular to describe different types of cost reimbursement contracts, because these terms are generally understood in the contracting community, and recipients have broad discretion to craft contracts within the limits of the Federal procurement standards (e.g., cost-plus-percentage-of-cost contracts are ineligible). If the commenter has a question about a specific procurement, the commenter should contact its FTA regional office.

Comment: A city agency commented that Chapter VI, Section h.2(c) should clarify the prohibition on using

qualifications based selection (QBS) procedures to procure actual construction. They suggested adding a cross-reference for exceptions under alternative contracting methods.

FTA Response: FTA has added a cross-reference to the section of the Circular discussing alternative contracting methods.

Comment: A transit bus manufacturer suggested that in Chapter VI, Section 2(g), "Contract Type Specified," FTA include language on price adjustment clauses and contract modifications on price increases.

FTA Response: FTA declines to revise this section. The current guidance already provides recipients with flexibility to structure contracts, including incorporating price adjustment provisions where appropriate, as long as they remain consistent with Federal procurement requirements and principles of fair and reasonable pricing.

G. Chapter VII

FTA is adopting as proposed the proposal to eliminate Chapter VII and replace it with a new paragraph in proposed Chapter III on Recipient Responsibilities and FTA's Role in Procurement Disputes.

Veronica Vanterpool,

Deputy Administrator.

[FR Doc. 2025-00992 Filed 1-15-25; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2025-0001]

Denial of Motor Vehicle Defect Petition

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a defect petition, DP23-003, submitted on July 2, 2023, by Adelberto A. Cordova (the "Petitioner") to NHTSA's Office of Defects Investigation (ODI). The petition requests that NHTSA (the "Agency") investigate an alleged defect in the "ISG 48-volt on-board electrical system," which resulted in a warning light illumination and an inability to start the Petitioner's 2023 Mercedes-Benz GLC300. The Petitioner further requested a recall for 2023 Mercedes-Benz GLC300 vehicles based on this

issue. After conducting a technical review of the Petitioner's submissions, reviewing complaints related to MY 2023 Mercedes-Benz GLC300 warning light illumination as well as the inability to start a vehicle, and reviewing information provided by Mercedes-Benz regarding the ISG 48-volt system, NHTSA has concluded that the issues raised by the petition do not warrant a defect investigation at this time. Accordingly, the Agency has denied the petition.

FOR FURTHER INFORMATION CONTACT: Ms. Alexa Ardron, Vehicle Defects Division D, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE, Washington, DC 20590. Phone: (202)-819-4554. Email: Alexa.Ardron@dot.gov.

SUPPLEMENTARY INFORMATION:

Introduction

Interested persons may petition NHTSA requesting that the Agency initiate an investigation to determine whether a motor vehicle or an item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 U.S.C. 30162(a)(2); 49 CFR 552.1. Upon receipt of a properly filed petition, the Agency conducts a technical review of the petition, material submitted with the petition, and any additional information. 49 U.S.C. 30162(a)(2); 49 CFR 552.6. The technical review may consist solely of a review of information already in the possession of the Agency or it may include the collection of information from the motor vehicle manufacturer and/or other sources. After conducting the technical review and considering appropriate factors, which may include, but are not limited to, the nature of the complaint, allocation of Agency resources, Agency priorities, the likelihood of uncovering sufficient evidence to establish the existence of a defect, and the likelihood of success in any necessary enforcement litigation, the Agency will grant or deny the petition. *See* 49 U.S.C. 30162(a)(2); 49 CFR 552.8.

Background Information

In a letter dated July 2, 2023, Adelberto A. Cordova (the "Petitioner") submitted a petition requesting that NHTSA initiate an investigation into an alleged defect in the ISG 48-volt on-board electrical system, which allegedly resulted in warning light illumination and an inability to start the Petitioner's 2023 Mercedes-Benz GLC300 vehicle.

Thus, the scope of ODI's review was directed to those GLC300 vehicles.

NHTSA has based its decision on a review of the material cited by the Petitioner in his petition, information submitted by Mercedes-Benz in response to an Agency request, and other pertinent information in NHTSA's databases.

Summary of the Petition

The Petitioner alleged that Model Year (MY) 2023 Mercedes-Benz GLC300 vehicles equipped with the 48-volt ISG system can experience a failure resulting in the illumination of warning lights and an inability to start a vehicle. The Petitioner enclosed the following information with the petition:

- A description of the check engine light illuminating;
- A description of communications with a dealership about illumination of the check engine light;
- Copies of select Mercedes-Benz Service Campaign Bulletins;
- A listing of Mercedes-Benz vehicles that are covered under a recall for ISG–48V system issues;
- Excerpts from internet consumer chats that reported no-start conditions;
- A service invoice at a Mercedes-Benz dealership;
- Listings of Mercedes-Benz Xentry system communications; and
- Listings of allegedly related NHTSA recalls.

Office of Defects Investigation Analysis

ODI conducted the following actions while evaluating the Petition:

- Examined the Petition and its enclosures;
 - Reviewed the Petitioner's vehicle history;
 - Sent an Information Request letter to Mercedes-Benz and reviewed Mercedes-Benz's response to that letter; and
 - Searched for similar complaint traffic in NHTSA's consumer complaints database.
- In its August 24, 2023 response to NHTSA's Information Request letter, Mercedes-Benz stated that:
- The cause of the condition reported by the Petitioner was a software deviation in the Central Powertrain Controller (CPC);
 - The CPC is separate from and independent of the 48V mild hybrid ISG system;
 - The CPC condition in question may cause intermittent no-start conditions; and
 - Mercedes-Benz has an active software campaign to correct the CPC software deviation.

ODI conducted a search of NHTSA's consumer complaint database and did not find support for a related stalling trend in the subject vehicles.

Based on available information, it appears that the defect alleged by the Petitioner may be caused by a software error in the CPC software, which is a system separate and independent from the 48-volt system.

ODI concentrated its evaluation on conditions that could lead to a loss of motive power during a drive cycle, and the CPC condition only takes place during a vehicle's startup. Based on this distinction, coupled with the absence of a loss of motive power while driving in the Petitioner's vehicle, and an absence of other applicable loss of motive power allegations in the subject vehicle population in general, ODI finds no basis on which to open a related safety defect investigation at this time.

Mercedes-Benz has an ongoing service campaign to resolve the CPC software error, which caused the illumination of the engine lights and the no-start condition.

After thoroughly assessing the material submitted by the Petitioner, information in NHTSA's databases, and information submitted by Mercedes-Benz in response to an ODI Information Request regarding the Petitioner's allegations, and in consideration of the action Mercedes-Benz is taking to address the software issue, NHTSA does not find that a formal investigation is warranted at this time. Accordingly, the Agency is denying the petition. As with all potential motor vehicle safety risks, NHTSA will continue to review any new information or incidents as they are submitted to the Agency.

Authority: 49 U.S.C. 30162(d) and 49 CFR part 552; delegations of authority at CFR 1.95(a) and 49 CFR part 501.¹

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2025–00969 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–59–P

¹ The authority to determine whether to approve or deny defect petitions under 49 U.S.C. 30162(d) and 49 CFR part 552 has been further delegated to the Associate Administrator for Enforcement.

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modification to Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before January 31, 2025.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on January 8, 2025.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
12098-M	Missions Systems Orchard Park Inc.	173.301(f), 173.302a(a)(1)	To modify the special permit to reflect current testing and inspection criteria, replacing references to cancelled government and industry standards. (modes 1, 2, 4).
14287-M	Troxler Electronic Laboratories, Inc.	173.469, 173.476(a)	To modify the special permit to authorize additional gauges. (mode 1).
14951-M	Hexagon Lincoln, LLC	173.301(f), 173.302(a)	To modify the special permit to no longer reference "working pressure" in paragraph 2.a. (modes 1, 2, 3).
15404-M	Proserv UK Ltd	173.201, 173.302a, 173.304a, 173.301(f).	To modify the special permit by authorizing additional cylinder designs. (modes 1, 2, 3, 4).
21005-M	Federal Cartridge Company ..	173.63(b)	To modify the special permit to increase the number of articles authorized to be packed per inner packaging to 20. (modes 1, 2, 3, 4, 5).
21023-M	Tire Seal, Inc	173.304(d)	To modify the special permit to authorize a flammable gas. (modes 1, 2, 3, 4, 5).
21129-M	Northrop Grumman Systems Corp.	173.301, 173.302	To modify the special permit with Part numbers which have been updated and the developmental changes associated with the tanks. (mode 1).
21191-M	Joyson Safety Systems Acquisition LLC.	172.203(a), 172.301(c), 173.166(e)(6).	To modify the special permit to include NHTSA Recall #24V-756, 20V-736, 21E-080, 21V-504, 21V-632, 24E-024 and 24V-198. (modes 1, 2, 3).
21318-M	Mercedes-Benz Ag	173.185(b)(5)	To modify the special permit to authorize an additional battery and packaging types. (mode 4).
21677-M	Unipart North America Limited	172.101(j)	To modify the special permit to authorize an additional lithium ion battery. (mode 4).

[FR Doc. 2025-00859 Filed 1-15-25; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for New Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety

has received the application described herein.

DATES: Comments must be received on or before February 18, 2025.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on January 8, 2025.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21892-N	Electronic Fluorocarbons, LLC	173.304a(a)	To authorize the transportation in commerce of anhydrous ammonia in DOT 3AAX cylinders. (modes 1, 2, 3).

SPECIAL PERMITS DATA—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21893–N	Bhiwadi Cylinders Private Limited.	173.304(a)	To authorize the transportation in commerce of Class 2 gases in DOT 2Q Variation 2 inner receptacles. (modes 1, 3, 4, 5).
21896–N	Caterpillar Inc	172.101(j), 173.185(a)(1)	To authorize the transportation in commerce of prototype lithium batteries exceeding 35 kg via cargo-only aircraft. (mode 4).
21898–N	Mercedes-Benz Ag	173.309(c)(4)	To authorize the transportation in commerce of Fire Extinguishers, UN1044 that do not conform to the requirements of 49 CFR 173.309. (modes 1, 2, 3, 4, 5).
21899–N	Amtrol Inc	173.302(a)(1), 173.306(g)(1)	To authorize the transportation in commerce of non-DOT specification fully wrapped fiber-reinforced plastic composite cylinders with an outside diameter exceeding 24" in outside diameter containing certain non-flammable and non-toxic gases. (modes 1, 2, 3).
21901–N	Versum Materials US, LLC	173.301(c), 173.301(f)	To authorize the transportation in commerce of DOT–3AA cylinders containing hazardous materials without pressure relief devices. (modes 1, 2, 3).
21903–N	Weldship LLC	180.205(c)(3)	To authorize the derating of the service pressure of one (1) DOT 3AAX cylinder for transportation in commerce of hazardous materials. (mode 1).
21907–N	BMW Manufacturing Co., LLC	173.185(b)(3)(i)	To authorize the transportation in commerce of lithium batteries in alternative packaging. (modes 1, 2).
21908–N	Zipline International Inc	171.22(e)(4), 172.301(c), 172.101(j).	To authorize the transportation of forbidden articles containing flammable gases via cargo-only aircraft. (mode 4).
21909–N	Stericycle, Inc	172.200	To authorize the transportation in commerce of certain Division 6.2 materials without requiring shipping papers. (mode 1).
21910–N	AESC US, LLC	173.185(b)(6)	To authorize the transportation in commerce of multiple lithium batteries in a UN 50H Large Packaging. (mode 1).
21915–N	Diversey, Inc	173.29(a), 173.150(b)(2), 173.154(b)(1).	To authorize the transportation in commerce of emptied containers with a maximum capacity of 2.5 liters of hazardous materials to be shipped by ground only under the limited quantity exception solely for recycling. (modes 1, 2).
21919–N	Dynisco LLC	172.400(a), 172.400(a)(1), 172.200(a), 172.101(a).	To authorize the transportation of pressure transducers that contain very small amounts of sodium potassium alloy (NAK). (modes 4, 5).
21920–N	L3Harris Technologies, Inc	173.302	To authorize the transportation in commerce of certain gases in non-DOT specification pressure vessels, which will be used in space vehicles. (mode 1).
21921–N	O'Bryan Barrel Company, Inc	178.601(e), 178.603, 178.605, 178.606.	To authorize UN 1A1 and UN 1A2 steel drums that have not been periodically retested to be used for the transportation in commerce of the hazardous materials identified in the special permit. (modes 1, 2, 3, 4, 5).
21922–N	Archer Aviation Inc	172.101(j), 173.185(e)	To authorize the transportation in commerce of prototype lithium batteries exceeding 35 kg via air. (mode 4).

[FR Doc. 2025–00858 Filed 1–15–25; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials
Safety Administration****Hazardous Materials: Notice of Actions
on Special Permits****AGENCY:** Pipeline and Hazardous
Materials Safety Administration
(PHMSA), DOT.**ACTION:** Notice of actions on special
permit applications.**SUMMARY:** In accordance with the
procedures governing the application
for, and the processing of, specialpermits from the Department of
Transportation's Hazardous Material
Regulations, notice is hereby given that
the Office of Hazardous Materials Safety
has received the application described
herein.**DATES:** Comments must be received on
or before February 18, 2025.**ADDRESSES:** Record Center, Pipeline and
Hazardous Materials Safety
Administration, U.S. Department of
Transportation, Washington, DC 20590.Comments should refer to the
application number and be submitted in
triplicate. If confirmation of receipt of
comments is desired, include a self-
addressed stamped postcard showing
the special permit number.**FOR FURTHER INFORMATION CONTACT:**Donald Burger, Chief, Office of
Hazardous Materials Safety General
Approvals and Permits Branch, Pipeline
and Hazardous Materials Safety
Administration, U.S. Department of
Transportation, East Building, PHH–13,
1200 New Jersey Avenue Southeast,
Washington, DC 20590–0001, (202) 366–
4535.**SUPPLEMENTARY INFORMATION:** Copies of
the applications are available for
inspection in the Records Center, East
Building, PHH–13, 1200 New Jersey
Avenue Southeast, Washington DC.This notice of receipt of applications
for special permit is published in
accordance with part 107 of the Federal
hazardous materials transportation law
(49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on January 8, 2025.

Donald P. Burger,

*Chief, General Approvals and Permits
Branch.*

SPECIAL PERMITS DATA—GRANTED

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
7694–M	Applied Pressure Vessels, Inc	173.302a, 175.3	To modify the special permit to authorize compressed oxygen.
10232–M	Illinois Tool Works Inc	173.304(d), 173.167, 173.306(i)	To modify the special permit to authorize an additional hazardous material and the removal of a hazardous material.
11156–M	Austin Powder Company	173.62(c), 173.212(b)	To modify the special permit to authorize an additional authorized packaging.
11598–M	Metalcraft, Inc	173.301(f), 173.304a(a)(2)	To modify the special permit to authorize an additional cylinder.
12102–M	Veolia ES Technical Solutions LLC.	173.124(a)(2)(iii)(D)	To modify the special permit to authorize an additional hazardous material.
14154–M	Mission Systems Orchard Park Inc.	180.205, 173.302a(a)(1), 173.304a(a)(1).	To modify the special permit to authorize additional Division 2.2 gases.
16279–M	Daniels Sharpsmart, Inc	173.196(a)	To modify the special permit to authorize the transportation in commerce of Lassa fever virus.
20333–M	Antonov,dp	172.101(j), 172.203(a), 172.301(c), 173.27(b)(2), 175.30(a)(1).	To modify the special permit to authorize an additional hazardous material.
20418–M	Hanwha Cimarron LLC	173.302(a), 173.304	To modify the special permit to authorize an extended service life program.
20511–M	ARMOTECH s.r.o	173.302(a)(1), 173.302(f)(1), 173.302(f)(2).	To modify the special permit to authorize a new cylinder design.
20910–M	Cellblock FCS, LLC	172.200, 172.300, 172.303(a), 172.400, 172.500, 172.600, 172.700(a), 173.185(f).	To modify the special permit to authorize a package marked with the UN3480 and UN3481 identification numbers when the package may not contain the identified hazardous material.
20952–M	Capella Space Corp	173.185(a)(1), 173.301(f)(1), 173.302a(a)(1), 178.35(e).	To modify the special permit to increase the weight restriction as limited by ICAO–TI Special Provision A88.
21377	Proterra Inc	172.101(j)	To modify the special permit to authorize additional lithium-ion batteries.
21470–M	Honeywell Intellectual Properties Inc.	173.302a(a)(1)	To modify the special permit to allow shipment of pressure vessels in a temperature controlled vehicle to ensure the vessel pressure remains below 10,000 psig.
21690–N	Berlin Packaging LLC	173.185(b)(3)(i), 173.185(b)(3)(iii)(A), 173.185(b)(3)(iii)(B), 173.185(b)(6), 173.185(e)(1), 173.185(e)(4), 173.185(f)(1), 173.185(f)(2), 173.185(f)(3), 173.185(f)(3)(iii).	To authorize the manufacture, mark, sale, and use of specially designed packaging for the transportation in commerce of single and multiple lithium batteries, prototype and low production lithium batteries, and damaged, defective, or recalled lithium batteries.
21771–N	Berlin Packaging LLC	173.158(e)	To authorize the manufacture, mark, sale and use of UN specification packagings for the transport of nitric acid of less than 70% concentration where the glass inner packagings are not packed in tightly-closed, intermediate packagings and cushioned with absorbent material.
21772–N	Enervenue, Inc	172.400, 172.300, 173.302(a)	To authorize the transportation in commerce of UN1049, hydrogen, compressed in non-DOT specification cylinders.
21784–N	Daicel Safety Systems (Jiangsu) Co., Ltd.	173.301(a)(1), 178.65(b), 178.65(c)(3), 178.65(e)(1), 178.65(f)(1), 178.65(g), 178.65(i).	To modify the special permit to authorize cargo vessel and to remove the restriction in paragraph 8.I.
21788–N	Zhejiang Dongcheng Printing Industry Co., Ltd.	173.304a(a)(1), 173.304a(d)(3)(ii).	To authorize the manufacture, mark, sale, and use of a non-DOT specification non-refillable inside metal container conforming with all regulations applicable to a DOT specification 2P inside container, except as specified herein, for the transportation in commerce of the hazardous materials authorized by this special permit.
21800–N	Greif, Inc	178.509(b)(1), 178.522(b)(1), 178.707(c)(3)(iii).	To authorize the manufacture, mark, sale, and use of 1H1 plastic drums, 1H2 plastic drums, 31HA1 intermediate bulk containers, 3H1 jerricans, 3H2 jerricans, and 6HA1 composite drums that have been manufactured using recycled resin.
21863–N	Munro & Associates, Inc	172.301(c), 173.220(a)	To authorize the transportation in commerce of a battery-powered vehicle containing a damaged lithium ion battery.

SPECIAL PERMITS DATA—GRANTED—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21869–N	Van Troxel International Inc ..	172.400, 172.500, 172.200, 172.300, 173.302a, 173.304a.	To authorize the transportation in commerce of non-compliant inner containers that have not been appropriately marked.
21878–N	Call2Recycle, Inc	173.185(f)	To authorize the transportation of damaged lithium ion batteries in response to a thermal runaway incident that occurred at the Camino De La Fuente energy storage system in Otay Mesa, California.
21890–N	Blue Origin Florida, LLC	173.302(a)(1), 173.302(b), 173.201.	To authorize post-recovery transportation in commerce of Blue Origin Florida's New Glenn 1st Stage Launch Vehicle.
21897–N	SkyTaxi Sp Z.O.O	172.101(j)(1), 173.27(b)(2), 175.30(a)(1).	To authorize the transportation in commerce of the Division 1.1F explosives identified in paragraph 6. aboard cargo-only aircraft.
21904–N	SkyTaxi Sp Z.O.O	172.101(j)(1), 173.27(b)(2), 175.30(a)(1).	To authorize the transportation in commerce of the Division 1.1E explosives identified in paragraph 6. aboard cargo-only aircraft.
21906–N	Environmental Protection Agency.	171–180	To authorize the transportation in commerce of hazardous materials in support of recovery and relief operations from and within Hurricane Helene disaster areas under conditions that may not meet the Hazardous Materials Regulations.
21914–N	Tennessee Valley Authority ...	171–180	To authorize the transportation in commerce of hazardous materials in support of recovery and relief operations from and within Tropical Storm Helene Disaster areas under conditions that may not meet the Hazardous Materials Regulations.

SPECIAL PERMITS DATA—DENIED

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21885–N	Ecotec Manufacturing, Inc ...	171.8, 171.23(b), 173.304a(a)(1)	To authorize the transportation in commerce of certain Division 2.1 gases in a DOT 2Q container.
210905–N	Day & Zimmermann Lone Star LLC.	172.320(a), 173.27(b)(2), 173.27(b)(3), 173.51(a), 173.51, 173.56(a)(2), 173.57, 173.58, 173.60(b)(14), 173.62(c)(5).	To authorize the transportation of Class 1 explosives to Ukraine by cargo aircraft only.

SPECIAL PERMITS DATA—WITHDRAWN

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21820–N	Reynolds Systems, Inc	172.320, 173.54(a), 173.56(b), 173.57, 173.58.	To authorize the transportation in commerce of detonators that have not been examined or tested.
21837–N	Reckitt Benckiser LLC	172.301(c), 172.315, 173.185(c)(3) ...	To authorize the transportation in commerce of unmarked packages containing limited quantities of hazardous materials or smaller lithium cells or batteries.
21853–N	Riegel USA Inc	172.301	To authorize the transportation in commerce of butane contained in 2P inner receptacles when classified as "UN2037 Gas cartridges, (flammable) without a release device, non-refillable".
21856–N	Lynden Air Cargo, LLC	172.101(j)	To authorize the transportation in commerce of certain cryogenic liquids by air in quantities that exceed the limits specified in Column 9B of the 172.101 Hazardous Materials Table.
21882–N	Capitol Helicopters, Inc	172.200, 172.204(c)(3), 172.301(c), 172.101(j), 173.27(b)(2), 175.75, 175.30(a)(1).	To authorize the transportation in commerce of certain hazardous materials by 14 CFR Part 133 cargo-only aircraft (rotorcraft external load operations) transporting hazardous materials attached to or suspended from the aircraft, and Part 135, as applicable, in remote areas of the US only, without being subject to certain hazard communication requirements, quantity limitations and certain loading and stowage requirements.
21891–N	Medical Systems of Denver, Inc.	173.196(a)	To authorize the transportation in commerce of medical waste for disposal.

SPECIAL PERMITS DATA—WITHDRAWN—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21900–N	Phi Aviation, LLC	172.101(j)	To authorize the transportation in commerce of certain hazardous materials which exceed the authorized quantity limitations for passenger-carrying aircraft
21913–N	Unipart North America Limited.	172.101(j)	To authorize the transportation in commerce of lithium batteries exceeding 35 kg by cargo-only aircraft.

[FR Doc. 2025–00860 Filed 1–15–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

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: This action was issued on January 7, 2025. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Sanctions Compliance, 202–622–2490; or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:**Electronic Availability**

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: <https://ofac.treasury.gov>.

Notice of OFAC Action

On January 7, 2025, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked under the relevant sanctions authority listed below.

Individual:

1. ROGAN, Antal, Hungary; DOB 29 Jan 1972; POB Kormend, Hungary; nationality Hungary; Gender Male; National ID No. 0188261A (Hungary) (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(B)(1) 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), for being a foreign person who is a current or former government official, or a person acting for or on behalf of such an official, who is responsible for or complicit in, or has directly or indirectly engaged in, corruption, including the misappropriation of state assets, the expropriation of private assets for personal gain, corruption related to government contracts or the extraction of natural resources, or bribery.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2025–00973 Filed 1–15–25; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0406]

Agency Information Collection Activity: Verification of VA Benefits

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. **DATES:** Comments must be received on or before March 17, 2025.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202–632–8924, Nancy.Kessinger@va.gov.

VA PRA information: Maribel Aponte, 202–461–8900, vacopaperworkreduct@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Verification of VA Benefits, 26–8937.

OMB Control Number: 2900–0406. <https://www.reginfo.gov/public/do/PRAsearch> (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 26–8937 is designed to assist lenders and VA in the completion of debt checks in a uniform manner. The form restricts information requested to only that needed for the debt check and also eliminates unlimited versions of lender-designed forms. This form is also occasionally used to inform the lender prior to loan closing if a Veteran is eligible for an exemption from the funding fee.

Lenders ensure the completion of the upper portion of VA Form 26–8937, including the veteran's authorization for release of the information, and forward it to the appropriate VA Office. VA personnel perform the debt check, complete the balance of the form, and

return it to the lender, who considers any repayment terms in evaluating the veteran's creditworthiness. Following the closing of any loan, the lender submits the form with the loan report and related documents for post-closing review. The form is reviewed by a loan examiner to ensure that debt check

requirements have been observed in each case.

Affected Public: Individuals and households.

Estimated Annual Burden: 250 hours.

Estimated Average Burden per

Respondent: 5 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 3,000.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2025-00897 Filed 1-15-25; 8:45 am]

BILLING CODE 8320-01-P



FEDERAL REGISTER

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Thursday,

No. 10

January 16, 2025

Part II

Department of Commerce

National Oceanic and Atmospheric Administration

15 CFR Part 922

Papahānaumokuākea National Marine Sanctuary; Final Regulations; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 240213–0047]

RIN 0648–BL33

Papahānaumokuākea National Marine Sanctuary; Final Regulations

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule; notification of availability of final management plan and Record of Decision.

SUMMARY: NOAA is designating Papahānaumokuākea National Marine Sanctuary (sanctuary) to protect nationally significant biological, cultural, and historical resources and to manage this special place as part of the National Marine Sanctuary System. The sanctuary consists of an area of approximately 582,570 square statute miles (439,910 square nautical miles) of Pacific Ocean waters surrounding the Northwestern Hawaiian Islands and the submerged lands thereunder. NOAA is establishing the terms of designation for the sanctuary and the regulations to implement the national marine sanctuary designation. NOAA has also published a final environmental impact statement (final EIS) in coordination with the State of Hawai'i, final management plan, and Record of Decision.

DATES: *Effective Date:* Pursuant to section 304(b) of the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1434(b)), the designation and regulations shall take effect and become final after the close of a review period of forty-five days of continuous session of Congress, beginning on the date on which this Federal rulemaking is published, which is January 16, 2025. During that review period, the Governor of the State of Hawai'i may certify to the Secretary of Commerce that the designation or any of its terms is unacceptable, in which case the designation or any unacceptable term shall not take effect in State waters of the sanctuary. The public can track days of Congressional session at the following website: <https://www.congress.gov/days-in-session>. NOAA will publish an announcement of the effective date of the final regulations in the **Federal Register**.

ADDRESSES: Copies of the final environmental impact statement (EIS) and management plan described in this rule and the record of decision (ROD) are available at <https://sanctuaries.noaa.gov/papahanaumokuakea/>.

FOR FURTHER INFORMATION CONTACT: Eric Roberts, Papahānaumokuākea Marine National Monument Superintendent, at Eric.Roberts@noaa.gov or 808–294–7470.

SUPPLEMENTARY INFORMATION:**I. Introduction***A. Background*

The NMSA (16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce to designate and protect as national marine sanctuaries areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archaeological, educational, or esthetic qualities. Day-to-day management of national marine sanctuaries has been delegated by the Secretary of Commerce to NOAA. The primary objective of the NMSA is to protect the resources of the National Marine Sanctuary System. NOAA is designating marine portions of the Papahānaumokuākea Marine National Monument as a national marine sanctuary to provide comprehensive and coordinated management of the marine areas of Papahānaumokuākea to protect nationally significant biological, cultural, and historical resources. The original Papahānaumokuākea Marine National Monument (PMNM, 0–50 nm), and the Monument Expansion Area (MEA, 50–200 nm), (collectively “Monument”), located around the Northwestern Hawaiian Islands, were established under the Antiquities Act of 1906 (54 U.S.C. 320301 *et seq.*) through, respectively, Presidential Proclamation 8031 of June 15, 2006; as amended by Presidential Proclamation 8112 of February 28, 2007; and Presidential Proclamation 9478 of August 26, 2016. The Monument is administered jointly by four co-trustees—the Department of Commerce (DOC), the Department of the Interior (DOI), the State of Hawai'i, and the Office of Hawaiian Affairs (OHA).

The 2000 Amendments to the NMSA authorized designation of a Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve) to be managed by the Secretary of Commerce. In December 2000, President Clinton issued Executive Order 13178 that began the public process to establish the Reserve, and directed the Secretary of Commerce to initiate the process to designate the Reserve as a national

marine sanctuary. In January 2001, President Clinton issued Executive Order 13196 finalizing the establishment of the Reserve.

In 2006, President Bush established PMNM through Proclamation 8031 to protect and preserve the marine area of the Northwestern Hawaiian Islands and certain lands as necessary for the care and management of the historic and scientific objects therein. The Federal land and interests in land reserved included approximately 139,793 square miles of emergent and submerged lands and waters of the Northwestern Hawaiian Islands. NOAA and the United States Fish and Wildlife Service (USFWS) promulgated implementing regulations at 50 CFR part 404 for PMNM.

In 2016, President Obama established the MEA through Proclamation 9478, which included the waters and submerged lands seaward of the PMNM to the extent of the seaward limit of the United States Exclusive Economic Zone (U.S. EEZ) west of 163° West Longitude. The MEA includes an additional 442,781 square miles. Presidential Proclamation 9478 also directed the Secretary of Commerce to consider initiating the process to designate the MEA and PMNM seaward of the Hawaiian Islands National Wildlife Refuge and Midway Atoll National Wildlife Refuge and Battle of Midway National Memorial as a national marine sanctuary to supplement and complement existing authorities. On December 27, 2020, the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021, further directed NOAA to initiate the process to designate the Monument as a national marine sanctuary.

The sanctuary consists of a total area of approximately 582,570 square miles (439,910 square nautical miles). The precise boundary coordinates are defined in Appendix A to the regulations at 15 CFR part 922, subpart W. The sanctuary boundary encompasses the submerged lands, seamounts, and Pacific Ocean waters from the shoreline seaward to approximately 200 nautical miles west of 163° West Longitude surrounding the Northwestern Hawaiian Islands, which consist of the islands, atolls, and emergent lands stretching from Nihoa in the southeast to Kure Atoll in the northwest. The adjoining marine waters east of 163° West Longitude surrounding Nihoa extend seaward from the shoreline to approximately 50 nautical miles.

The sanctuary is a place of unique environmental resources that provide large-scale ecosystem services for both

the region and the world. The marine habitat includes several interconnected ecosystems, including coral islands surrounded by shallow reef, deeper reef habitat characterized by seamounts, banks, and shoals, mesophotic reefs with extensive algal beds, pelagic waters connected to the greater North Pacific Ocean, and deep-water habitats such as abyssal plains 5,000 meters below sea level. These ecosystems are connected as essential habitats for rare species such as the threatened green turtle and the endangered Hawaiian monk seal, as well as over 14 million seabirds that forage in the pelagic waters to nourish the chicks they are raising on the tiny islets. These waters are home to 20 cetacean species protected by the Marine Mammal Protection Act, with some listed as endangered under the Endangered Species Act. The importance of these waters to the Hawaiian humpback whale is only recently becoming understood. At least a quarter of the nearly 7,000 known marine species found in the region are found nowhere else on Earth.

The area of the sanctuary is also a sacred place to Native Hawaiians, who regard the islands and wildlife as *kūpuna*, or ancestors. The region holds deep cosmological and traditional significance for the people of Hawai'i and the Native Hawaiian culture. Papahānaumokuākea is as much a spiritual space as it is a physical geographical area, deeply rooted in Native Hawaiian creation and settlement stories. Since Native Hawaiian culture considers nature and culture to be one and the same, the protection of one of the last nearly pristine, natural, marine ecosystems in the archipelago is seen as being akin to preserving the living culture.

The area of the sanctuary also includes the location of the Battle of Midway, a turning point in World War II for the allies in the Pacific Theater. Research indicates that there are 60–80 sunken military vessels and hundreds of sunken military aircraft on the seafloor. In addition to Navy steamers and aircraft, there are whaling ships, ancient Japanese sailing ships known as *junks*, motorized East Asian style fishing vessels known as Hawaiian fishing sampans, Pacific colliers, and other vessels from the 19th and 20th centuries. Of these, the locations of more than 30 vessel wreck sites have been confirmed by diving or bathymetric surveys, with only a handful of those identified by vessel name or otherwise evaluated.

B. Purpose and Need for Action

The NMSA (16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce to designate national marine sanctuaries to meet the purposes and policies of the NMSA, including:

- to provide authority for comprehensive and coordinated conservation and management of these marine areas, and activities affecting them, in a manner which complements existing regulatory authorities;
- to maintain the natural biological communities in the national marine sanctuaries, and to protect, and, where appropriate, restore and enhance natural habitats, populations, and ecological processes;
- to enhance public awareness, understanding, appreciation, and wise and sustainable use of the marine environment, and the natural, historical, cultural, and archaeological resources of the National Marine Sanctuary System” (16 U.S.C. 1431(b)(4));
- “to support, promote, and coordinate scientific research on, and long-term monitoring of, the resources of these marine areas” (16 U.S.C. 1431(b)(5)); and
- “to facilitate to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas not prohibited pursuant to other authorities” (16 U.S.C. 1431(b)(6)).

NOAA is designating the marine areas of the Monument as a national marine sanctuary. The purpose of this action is to provide comprehensive and coordinated conservation and management of the marine areas of Papahānaumokuākea to protect nationally significant biological, cultural, and historical resources. Additionally, the purpose of the designation is to implement the provisions of Executive Order 13178, Presidential Proclamation 9478, and the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021.

Accordingly, NOAA is designating this area as a national marine sanctuary to:

- Develop objectives and actions that ensure lasting protection consistent with the existing Monument proclamations;
- Safeguard natural and cultural values of the marine environment;
- Apply additional regulatory and non-regulatory tools to augment and strengthen existing protections for Papahānaumokuākea ecosystems, wildlife, and cultural and maritime heritage resources;
- Authorize NOAA to exercise enforcement authorities, including the

assessment of civil penalties for violations of provisions of the NMSA and regulations and permits issued pursuant to the NMSA (16 U.S.C. 1437);

- impose liability for destruction, loss of, or injury to sanctuary resources and provide natural resource damage assessment authorities for destruction, loss of, or injury to any sanctuary resource; and
- require interagency consultation for any Federal agency action that is likely to destroy, cause the loss of, or injure any sanctuary resource.

C. Designation Process

1. Notice of Intent To Designate a National Marine Sanctuary

On November 19, 2021, NOAA initiated the process to designate marine portions of the Monument as a national marine sanctuary by publishing a Notice of Intent to Conduct Scoping and to Prepare an Environmental Impact Statement for the Proposed Designation of a National Marine Sanctuary within Papahānaumokuākea Marine National Monument (86 FR 64904). The notice of intent stated that NOAA would prepare a draft EIS per the requirements of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and the NMSA. The notice of intent also announced NOAA's intent to fulfill its responsibilities under the National Historic Preservation Act (NHPA; 54 U.S.C. 300101 *et seq.*). The State of Hawai'i published its EIS preparation notice on December 8, 2021. Following publication of these notices, NOAA conducted four virtual public scoping meetings. During the 74-day public comment period from November 19, 2021 through January 31, 2022, 73 individuals and organizations provided written input. An estimated 165 people attended the four scoping meetings, with 9 people providing oral comments. The Summary of Scoping Input on the Notice of Intent and EIS Preparation Notice and State of Hawai'i Responses to Public Scoping Comments are included in the final EIS as Appendix F.

2. Public Comment on Draft Designation Materials

On March 1, 2024, NOAA published a notice of proposed rulemaking and a notice of availability of the draft EIS (89 FR 15272) to release a proposed rule, draft EIS, and draft sanctuary management plan; and to request public comments on the proposed sanctuary designation documents. On March 8, 2024, the State of Hawai'i also informed the public about the availability of the draft EIS through an announcement in

its bulletin, The Environmental Notice, per the Hawai'i Environmental Policy Act (HEPA), Hawai'i Revised Statutes (HRS) Chapter 343–3(c). The USFWS, the State of Hawai'i, and the Department of the Navy served as cooperating agencies in reviewing and assisting with the development of the draft EIS.

The public comment period took place over the course of 68 days from March 1 to May 7, 2024. Public meetings were held to provide additional information and to receive public input in the form of oral and written comments. Comments were accepted in both English and 'ōlelo Hawai'i during 11 public meetings, held between April 6–18, 2024, including two virtual and nine in-person public meetings on O'ahu, Kaua'i, Hawai'i Island, Maui, and Moloka'i. Comments were also accepted through the Federal eRulemaking portal and by traditional mail through May 7, 2024, both in English and 'ōlelo Hawai'i. An estimated 237 people attended the 11 public meetings and 61 individuals provided oral comments. During the public comment period, 488 written comments and 13,385 form letters were received from individuals, organizations, and agencies. A total of 13,934 comments were received, with the overwhelming majority in support of sanctuary designation.

Major themes of comments included sanctuary access, permitting, prohibitions, enforcement, Native Hawaiian indigenous rights and cultural integration, fishing, co-management, resource protection, education and outreach, partnerships, and community participation. After the public comment period closed, the comments were carefully reviewed and cataloged by substantive issues contained in the comments. In preparing the final EIS, final sanctuary management plan, and final rule, NOAA and the State of Hawai'i considered comments received on the draft designation documents, identified substantive comments, and provided responses to these comments. A summary of these comments and the corresponding responses from NOAA are provided in the final EIS Appendix K and in Section V of this rulemaking. In response to these substantive comments, NOAA clarified information and made changes to this final rule, the final EIS, and the final sanctuary management plan, as described further below.

3. Development of Terms of Designation and Regulations

Section 304(a)(4) of the NMSA requires that the terms of designation include: (1) the geographic area that is

included within the sanctuary; (2) the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or esthetic value; and (3) the types of activities that would be subject to regulation by the Secretary to protect these characteristics. Section 304(a)(4) of the NMSA also specifies that the terms of designation may be modified only by the same procedures by which the original designation was made.

The purpose and need for the sanctuary provide the overarching basis for developing the regulations. The designation of the sanctuary will not replace the area's current status as a marine national monument. Existing authorities, including management authorities of all Monument co-trustees, will remain in effect. Sanctuary designation will supplement the existing provisions for management of the Monument and protect resources in the Northwestern Hawaiian Islands. To develop these regulations, NOAA reviewed the following, which currently guide Monument management:

- Executive Order 13178—Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, December 4, 2000;
 - Presidential Proclamation 8031—Establishment of the Northwestern Hawaiian Islands Marine National Monument, June 15, 2006;
 - Presidential Proclamation 8112—Amending Proclamation 8031 of June 15, 2006 to Read “Establishment of the Papahānaumokuākea Marine National Monument,” February 29, 2007;
 - Regulations implementing Presidential Proclamations 8031 and 8112 at 50 CFR part 404; and
 - Presidential Proclamation 9478—Papahānaumokuākea Marine National Monument Expansion, August 26, 2016.
- These executive orders, presidential proclamations, and regulations served as benchmarks for drafting the rule for the sanctuary. Sanctuary designation will only add to, and will not diminish, Monument management measures and protections. NOAA has adopted the management measures from these benchmarks, and, in a few areas, added onto those measures to achieve consistency in regulation and management across the sanctuary. The final rule unifies management of the area by removing discrepancies and gaps in prohibitions, regulated activities, and permit criteria, providing clarity and comprehensive protection for the sanctuary.

In developing this final rule and the sanctuary terms of designation, NOAA also considered: (1) information

received through public scoping and public review of the draft designation documents, cooperating agency review, and coordination with the Monument co-trustees through the seven-member Monument Management Board, which consists of NOAA ONMS, NOAA Fisheries, USFWS Ecological Services, USFWS Refuges, Hawai'i Department of Land and Natural Resources (DLNR) Division of Aquatic Resources, DLNR-Division of Forestry and Wildlife, and OHA; and (2) information from analysis of issues in the EIS, interagency coordination, and internal staff analysis and expertise. NOAA also consulted with the Western Pacific Regional Fishery Management Council as required under the NMSA.

Following publication of the proposed rule, in consideration of public comments and further review, NOAA made minor changes to the terms of designation and the regulations which are described in detail in Section III of this final rule. NOAA provides a detailed discussion of the final regulations in Section IV, subsection A through O, of this rule. The text of the final regulations is presented at the end of this rule.

4. Development of Final Management Plan

A final sanctuary management plan has been prepared in accordance with NMSA section 304(a)(2)(C). Management plans are site-specific documents that ONMS uses to manage individual sanctuaries. The final sanctuary management plan: (1) articulates the sanctuary's vision, mission, goals, and objectives; (2) describes the management activities and initiatives that NOAA will conduct; and (3) provides strategies and assessment measures to guide the sanctuary's short- and mid-range management. In response to public comments, NOAA made minor changes to the final sanctuary management plan, which is included as Appendix A to the final EIS.

5. Final Environmental Impact Statement

In accordance with NEPA (42 U.S.C. 4321 *et seq.*), the NMSA, and HEPA (HRS Chapter 343, HAR Chapter 11–200.1), NOAA and the State of Hawai'i released a final EIS for the national marine sanctuary designation in advance of the publication of this final rule. NOAA is the lead Federal agency in the preparation of the final EIS. The USFWS, State of Hawai'i, the Department of the Navy, and OHA were cooperating agencies for the final EIS. The final EIS describes the purpose and need for the proposed action of

designating a national marine sanctuary, identifies a range of alternatives including the preferred alternative, provides an assessment of resources and uses in the area, and evaluates the potential environmental consequences of the designation including by comparing the beneficial and adverse impacts among alternatives. NOAA has provided a section in the final EIS (see Section 1.5) to outline the substantive changes made between the draft EIS and final EIS.

The final EIS analyzes four alternatives; including a “no action” alternative, in which the area would not be designated as a national marine sanctuary; and three boundary alternatives:

- Alternative 1 is coextensive with the marine portions of the Monument. The boundary includes the marine environment surrounding the Northwestern Hawaiian Islands from the shoreline of the islands and atolls seaward to 200 nautical miles, including all State waters and waters of the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, Midway Atoll and Hawaiian Islands National Wildlife Refuges, the Battle of Midway National Memorial, and State of Hawai‘i Northwestern Hawaiian Islands Marine Refuge. The area encompassed in Alternative 1 is approximately 582,570 square miles (439,910 square nautical miles).
- Alternative 2 includes the marine environment from the shoreline of the islands and atolls seaward to 50 nautical miles. This alternative includes all State waters and waters of the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, Midway Atoll and Hawaiian Islands National Wildlife Refuges, the Battle of Midway National Memorial, and State of Hawai‘i Northwestern Hawaiian Islands Marine Refuge. This alternative does not include the MEA. The area encompassed in Alternative 2 is approximately 139,782 square miles (105,552 square nautical miles).
- Alternative 3 has the same boundaries as Alternative 1, but excludes waters within the Midway Atoll and Hawaiian Islands National Wildlife Refuges and the Battle of Midway National Memorial. These excluded waters include portions of the State of Hawai‘i Northwestern Hawaiian Islands Marine Refuge and the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve that overlap with national wildlife refuge waters. The area encompassed in Alternative 3 is approximately 581,263 square miles (438,923 square nautical miles).

5. Final Preferred Alternative

In accordance with NEPA (42 U.S.C. 4321 *et seq.*) and based on public comments on the draft designation materials and further review, NOAA has maintained Alternative 1 as the agency-preferred alternative (preferred alternative) based on its comparative merits; this alternative serves as the foundation of this final rule (Section 3.4 of the final EIS presents a map and details of this alternative). NOAA selected its final preferred alternative after considering input from the Monument Management Board, the State of Hawai‘i, cooperating agencies, other agencies consulted, and public comments provided on the draft designation documents. Through the analysis in the final EIS, NOAA has determined that the final preferred alternative would provide numerous beneficial impacts, including increased protection and conservation of resources, and improved coordination of conservation and management. NOAA has also considered the potential adverse impacts of the final preferred alternative and anticipates that there would be no significant adverse impacts to biological and physical resources, cultural and historic resources, or socioeconomic resources.

NOAA’s identification of Alternative 1 as the final preferred alternative is based on the need for additional resource protection, scientific research, and public education in areas that would be excluded by selecting the boundaries of Alternatives 2 or 3. Alternative 1 includes the MEA, an area which would benefit from the establishment of a NOAA permitting process, and the promulgation of sanctuary regulations to protect resources. Alternative 1 also includes the waters of Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, which are the areas of the sanctuary subject to the highest level of human activity.

II. Terms of Designation for Papahānaumokuākea National Marine Sanctuary

Section 304(a)(4) of NMSA as amended, 16 U.S.C. 1434(a)(4), requires that the terms of designation be described at the time a new sanctuary is designated, including the geographic area to be included within the sanctuary, the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or esthetic value, and the types of activities that will be subject to regulation to protect those characteristics.

The following represents the terms of designation:

Preamble

Under the authority of the National Marine Sanctuaries Act, as amended (the “Act” or “NMSA”), 16 U.S.C. 1431 *et seq.*, approximately 582,570 square mi (439,910 square nmi) of the waters of the Pacific Ocean surrounding the Northwestern Hawaiian Islands are hereby designated as a national marine sanctuary for the purpose of providing long-term protection and management of the ecological, cultural, and historical resources and the conservation, recreational, scientific, educational, and esthetic qualities of the area.

Article I: Effect of Designation

The NMSA authorizes the issuance of such regulations as are necessary and reasonable to implement the designation, including managing and protecting the ecological, cultural, and historical resources and the conservation, recreational, scientific, educational, and esthetic qualities of Papahānaumokuākea National Marine Sanctuary (the “sanctuary”). Section 1 of Article IV of these terms of designation lists those activities that may be regulated on the effective date of designation, or at some later date, in order to protect sanctuary resources and qualities. Listing an activity does not necessarily mean that it will be regulated. However, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original sanctuary designation was made.

Article II: Description of the Area

The sanctuary encompasses the submerged lands, seamounts, and Pacific Ocean waters from the shoreline seaward to approximately 200 nautical miles west of 163° West Longitude surrounding the Northwestern Hawaiian Islands which consist of the islands, atolls, and emergent lands stretching from Nihoa in the southeast to Hōlanikū (Kure Atoll) in the northwest. The marine waters east of 163° West Longitude surrounding Nihoa extend seaward from the shoreline to approximately 50 nautical miles. The total area of the sanctuary comprises approximately 582,570 square miles (439,910 square nautical miles). The precise boundary coordinates are defined in Appendix A to the regulations at 15 CFR part 922, subpart W.

Article III: Special Characteristics of the Area

Papahānaumokuākea is a place of special national significance that provides large-scale ecosystem services for the region and the world. The marine habitat includes several interconnected ecosystems, including coral islands surrounded by shallow reef, deeper reef habitat characterized by seamounts, banks, and shoals scattered across the area of the sanctuary, mesophotic reefs with extensive algal beds, pelagic waters connected to the greater North Pacific Ocean, and deep-water habitats and abyssal plains 5,000 meters below sea level. These connected ecosystems provide essential habitats for rare species such as the threatened green sea turtle and the endangered Hawaiian monk seal, as well as habitat for more than 14 million seabirds that forage in the pelagic waters to nourish the chicks they are raising on the tiny islets. Papahānaumokuākea is home to 20 cetacean species, protected by the Marine Mammal Protection Act, with some listed as endangered under the Endangered Species Act. At least a quarter of the nearly 7,000 known marine species in the region are found nowhere else on Earth.

The area of the sanctuary is also a place of historical and cultural significance. The area of the sanctuary includes the location of the Battle of Midway, a turning point in World War II for the allies in the Pacific Theater. Research indicates that 60–80 sunken military vessels and hundreds of sunken military aircraft are scattered across the seafloor. In addition to Navy steamers and aircraft, there are whaling ships, ancient Japanese sailing ships known as junks, motorized East Asian style fishing vessels known as Hawaiian fishing sampans, Pacific colliers, and other vessels from the 19th and 20th centuries.

Papahānaumokuākea is also a sacred place to Native Hawaiians, who regard the islands and wildlife as kūpuna, or ancestors. The region holds deep cosmological and traditional significance to the people of Hawai'i and the Native Hawaiian culture, and contains a host of intact and significant archaeological sites found on the islands of Nihoa and Mokumanamana, both of which are on the National Register of Historic Places and Hawai'i Register of Historic Places. Papahānaumokuākea is as much a spiritual space as it is a physical geographical area, rooted deep in Native Hawaiian creation and settlement stories.

Article IV: Scope of Regulations

Section 1. Activities Subject to Regulation

The following activities are subject to regulation, including prohibition, as may be necessary to ensure the protection and effective management of the ecological, cultural, historical, conservation, recreational, scientific, educational, or esthetic resources or qualities of the area:

1. Access to the sanctuary;
2. Ship reporting, ship routing, and other shipping activities;
3. Vessel monitoring;
4. Vessel discharge;
5. Exploring for, developing, or producing oil, gas, or minerals, or any energy development activities;
6. Using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a sanctuary resource;
7. Introducing or otherwise releasing an introduced species from within or into the sanctuary;
8. Deserting a vessel;
9. Commercial fishing;
10. Non-commercial fishing;
11. Possessing fishing gear;
12. Anchoring on or having a vessel anchored on any living or dead coral with an anchor, anchor chain, or anchor rope;
13. Drilling into, dredging, or otherwise altering the submerged lands; or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands;
14. Removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging; or attempting to remove, move, take, harvest, possess, injure, disturb, or damage any living or nonliving sanctuary resource;
15. Attracting any living sanctuary resource;
16. Touching coral, living or dead;
17. Swimming, snorkeling, or closed or open circuit SCUBA diving;
18. Discharging or depositing any material or other matter, or discharging or depositing any material or other matter outside of the sanctuary that subsequently enters the sanctuary;
19. Anchoring a vessel;
20. Native Hawaiian practices;
21. Research and scientific exploration;
22. Scientific research and development by Federal agencies;
23. Activities that will further the educational value of the sanctuary or will assist in the conservation and management of the sanctuary;
24. Recreational activities; and
25. Interfering with, obstructing, delaying, or preventing an investigation,

search, seizure, or disposition of seized property in connection with enforcement of the NMSA or any regulation or permit issued under the NMSA.

Listing an activity here means that the Secretary of Commerce can regulate the activity, after complying with all applicable laws, without going through the designation procedures required by paragraphs (a) and (b) of section 304 of the NMSA. No term of designation issued under the authority of the NMSA may take effect in Hawai'i state waters within the sanctuary if the Governor of Hawai'i certifies to the Secretary of Commerce that such term of designation is unacceptable within the review period specified in the NMSA.

Section 2. Emergencies

Where necessary to prevent or minimize the destruction of, loss of, or injury to a sanctuary resource or quality, or to minimize the imminent risk of such destruction, loss, or injury, any and all activities, including those not listed in Section 1, are subject to immediate temporary regulation, including prohibition.

Article V: Alteration of This Designation

The terms of designation, as defined under section 304(a)(4) of the NMSA, may be modified only by the same procedures by which the original designation is made, including public hearings, consultations with interested Federal, Tribal, State, regional, and local authorities and agencies, review by the appropriate Congressional committees, and approval by the Secretary of Commerce, or his or her designee.

III. Changes from Proposed to Final Regulations

Based on public comments received between March 1 and May 7, 2024, internal deliberations, consultations, engagement with cooperating agencies, and meetings with constituents, NOAA has made the following changes to the proposed rule and corresponding changes to the final EIS and sanctuary management plan.

A. Definitions

NOAA added the term “categories of hazardous cargoes” to 15 CFR 922.24, the site-specific definitions. “Categories of hazardous cargoes” is defined in PMNM regulations, 50 CFR 404.3, and is added to the final regulations for consistency with existing regulations for ship reporting. Defining “categories of hazardous cargoes” provides clarity to the public on what information must be reported when conducting passage without interruption to comply with the

ship reporting requirements, as specified in the sanctuary regulations at 15 CFR 922.243.

NOAA has made a minor revision to the term “recreational activity,” by striking “within the Midway Atoll Special Management Area” from the definition, making it consistent with the definition provided in Presidential Proclamation 8031 establishing the Monument.

B. Cooperative Management

In response to public comments, NOAA has clarified how the sanctuary will be managed in partnership with other Federal and State agencies. In the proposed rule, NOAA proposed that the sanctuary would be co-managed with the State of Hawai‘i. In the proposed regulations, NOAA identified the role that states may have in co-managing a sanctuary pursuant to the National Marine Sanctuaries Act, if all or part of the proposed sanctuary is within the territorial limits of any state. Recognition of the State of Hawai‘i as a sanctuary co-manager was not meant to exclude the other Monument co-trustees, DOI and OHA. To the contrary, partnerships with other Federal and State agencies with overlapping jurisdiction are critical to the success of the National Marine Sanctuary System and the protection of marine areas of special national significance.

In the final regulations, NOAA has renamed 15 CFR 922.242 “Cooperative Management” and added new text regarding how NOAA will manage the sanctuary in partnership with USFWS and OHA in addition to the State of Hawai‘i. In doing so, NOAA reaffirms that the existing co-management structure of the Monument is critical to the success of the sanctuary. NOAA will work in cooperation with Monument co-trustees to update the Memorandum of Agreement for Promoting Coordinated Management of Papahānaumokuākea Marine National Monument with the State of Hawai‘i, DOI, and OHA that reflects the addition of the sanctuary, and specifically addresses how the addition of a sanctuary will supplement and complement, and not supplant, the existing Monument management framework.

In the final regulations, NOAA recognizes USFWS’s management authority over Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge. NOAA also clarifies that nothing in the regulations or establishment of the national marine sanctuary shall diminish USFWS’s authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under

the National Wildlife Refuge System Administration Act, as amended, and other USFWS authorities. Where Papahānaumokuākea National Marine Sanctuary overlays Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the NMSA to provide supplemental authority to protect resources. NOAA and USFWS are developing an agreement to provide details on the execution of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge.

C. Access

In the proposed regulations, NOAA stated that a vessel may pass without interruption through the sanctuary without requiring a permit as long as the vessel does not stop, anchor, or engage in any prohibited activities. In the final regulations, NOAA has made a minor revision to 15 CFR 922.243(a)(5)(b), removing the word “anchor” from this statement. The removal of “anchor” is a technical revision because anchoring a vessel is already listed as a prohibited or otherwise regulated activity. In 15 CFR 922.243(c)(7), NOAA has added clarification on the events that would trigger “further reports,” including “pollution incidents and goods lost overboard.” This addition will help address potential threats and impacts to sanctuary resources in a timely manner from vessels transiting within the reporting area.

In the proposed regulations, NOAA stated that access is prohibited except under certain circumstances. NOAA has clarified that the prohibition on access does not restrict scientific exploration or research activities by or for the Secretary of Commerce or the Secretary of the Interior when the activity occurs within the Outer Sanctuary Zone, consistent with the exception provided in 15 CFR 922.244(f).

Finally, in 15 CFR 922.243(c), NOAA has also made technical revisions, removing the list of vessels for which the ship reporting requirements do not apply. This information is redundant of the exceptions provided in 15 CFR 922.243(a)(1) through (a)(4).

D. Prohibited or Otherwise Regulated Activities

NOAA has added a prohibition on failing to comply with vessel monitoring systems requirements in violation of 15 CFR 922.246; and a prohibition on failing to comply with ship reporting requirements in violation of 15 CFR 922.243. NOAA made these technical revisions to clarify for the public the full

scope of activities listed that are prohibited or otherwise regulated within the sanctuary.

NOAA has also made technical revisions and clarifications to the prohibition on discharging or depositing any material or other matter into the sanctuary, or discharging or depositing any material or other matter outside of the sanctuary that subsequently enters the sanctuary and injures or has the potential to injure any resources of the sanctuary. Specifically, NOAA has clarified the list of exceptions to this prohibition for consistency with Presidential Proclamation 8031, the implementing regulations at 50 CFR part 404, and other applicable law such as the Clean Water Act. For example, consistent with existing law in the Monument, NOAA has clarified that this prohibition does not apply to fish, fish parts, or chumming materials (bait) used in or resulting from lawful fishing activities, provided that such discharge or deposit is during the conduct of lawful fishing activities within the Sanctuary. In addition, NOAA has clarified that the exceptions for “discharge incidental to vessel operations,” and the discharges within Special Preservation Areas or the Midway Atoll Special Management Area may only be conducted in accordance with other applicable law, such as the Clean Water Act and its implementing regulations.

In the proposed rule, NOAA provided exceptions to vessel discharge when conducting passage without interruption under 15 CFR 922.243, but did not clarify that this exception also applies to the discharge prohibition under 15 CFR 922.244. NOAA has made these revisions in 15 CFR 922.244 to provide clarity to resource managers and the public, and consistency with existing Monument management. NOAA has made corresponding changes to the regulations at 15 CFR 922.243, removing the list of vessel discharge exceptions from this section. This revision is not substantive.

E. Exemption for Non-Commercial Fishing

In the proposed rule, NOAA proposed that eight prohibited or otherwise regulated activities in 15 CFR 922.244 would not apply to non-commercial fishing activities in the Outer Sanctuary Zone authorized by regulations promulgated pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (MSA), provided that no sale of harvested fish occurs. In response to comments of concern for this exemption, NOAA has made changes to ensure that a non-

commercial fishing permit authorized pursuant to the MSA is only exempt from a limited subset of prohibited or otherwise regulated activities in the Outer Sanctuary Zone, which may only be conducted as incidental to and necessary to conduct lawful non-commercial fishing activity.

First, NOAA has removed the exemption for “touching coral, living or dead,” as this activity is not expected to occur as incidental to a lawful non-commercial fishing activity.

Second, NOAA has removed the exemption for “discharging or depositing any material or other matter into the sanctuary, or discharging or depositing any material or other matter outside of the sanctuary that subsequently enters the sanctuary and injures or has the potential to injure any resources of the sanctuary, with exceptions.” NOAA has determined that non-commercial fishing activities authorized under the MSA do not require a broad exemption for discharge, and should be held to similar standards as other vessels. As described above, NOAA has also clarified the types of discharge that would not be regulated, including “fish, fish parts, or chumming materials (bait) used in or resulting from lawful fishing activity, provided that such discharge or deposit is during the conduct of lawful fishing activity within the Sanctuary.” This exception is consistent with Presidential Proclamation 8031, and the existing regulations for PMNM at 50 CFR 404.7.

Third, NOAA has removed the exemption for anchoring a vessel. NOAA has concluded that this activity should not occur as incidental to a lawful non-commercial fishing activity in the Outer Sanctuary Zone. Anchoring a vessel in the Outer Sanctuary Zone would not be practical given the average ocean depths within this area of the sanctuary.

NOAA has also clarified that this exemption from the sanctuary’s permitting requirements is only applicable provided that the fish harvested, either in whole or in part, are neither intended to enter commerce nor enter commerce through sale, barter, or trade, and that the resource is managed sustainably, consistent with Presidential Proclamation 9478. Moreover, consistent with the outcome of the NMSA Section 304(a)(5) process, for the exemption to apply, the fish harvested, either in whole or in part, are not intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery. Finally, NOAA has clarified that the activities under paragraph (a)(9) through (12), and (a)(14) may only be conducted as

incidental and necessary to conduct lawful non-commercial fishing activities.

F. Permit Procedures and Criteria

In the proposed regulations, NOAA proposed two new general permit categories specific to the sanctuary: (i) Native Hawaiian Practices; and (ii) Recreation. In the final regulations, NOAA maintains these two general permit categories in 15 CFR 922.30. For ease of reference, NOAA has moved the additional permit issuance criteria and requirements to the site-specific regulations for the proposed sanctuary at 15 CFR 922.245. This revision is not substantive. NOAA has also made a revision to the additional permit issuance criteria for Recreation permits. NOAA has amended the permitting criteria at 15 CFR 922.245 to clarify that a “recreational activity” may only be permitted within the Midway Atoll Special Management Area, consistent with existing regulations for the Monument.

Finally, as described below, NOAA moved the Vessel Monitoring System (VMS) requirements from 15 CFR 922.245 to a standalone section at 15 CFR 922.246. NOAA retained, with minor edits, the requirement to outfit a vessel with a NOAA Office of Law Enforcement (OLE) type-approved VMS unit, as a condition of a permit. This is consistent with the regulations implementing Presidential Proclamation 8031 at 50 CFR part 404, and specifically, the permitting findings that must be made under 50 CFR 404.11(d).

G. Vessel Monitoring System

In the proposed rule, NOAA proposed, as a part of the permit procedures and criteria under 15 CFR 922.245, that an owner or operator of a vessel that has been issued a sanctuary general permit or special use permit must ensure that such vessel has a NOAA OLE type-approved VMS on board when operating within the sanctuary. In the final regulations, NOAA has moved the VMS requirements to a standalone section at 15 CFR 922.246 for consistency with the regulations implementing Presidential Proclamation 8031 at 50 CFR part 404. NOAA also made non-substantive technical changes to the VMS requirements to more closely align with the Monument’s implementing regulations, specifically 50 CFR 404.5.

H. Sunken Military Craft

NOAA has added new text regarding the Sunken Military Craft Act acknowledging that sunken military craft in the sanctuary will continue to be

administered by the respective Secretary concerned pursuant to the Sunken Military Craft Act. NOAA will enter into a Memorandum of Agreement with the appropriate agencies regarding collaboration on implementing the Sunken Military Craft Act.

I. Emergency Regulations

NOAA has added information to Section IV of this final rule describing emergency regulations. This is a technical clarification of a regulatory provision that applies to all national marine sanctuaries, pursuant to the National Marine Sanctuary Program Regulations at 15 CFR 922 subpart A—Regulations of General Applicability. Adding this to the final rule provides clarity to the public on a supplemental authority that is provided through sanctuary designation.

J. Technical Edits

In addition to the changes discussed above, NOAA has made technical edits throughout this final rule. Many of these technical edits are necessary to conform with revisions to 15 CFR part 922 that became effective on October 16, 2024. These technical edits are not substantive. NOAA has also made two minor changes to the terms of designation that were included in the proposed rule. First, NOAA has added more detail to one sentence describing the special characteristics of the area. Second, NOAA has added “ship reporting, ship routing, and other shipping activities” to the list of activities subject to regulation in Article IV of the terms of designation to reflect the full scope of activities that may be regulated. In the draft terms of designation, NOAA only included “ship reporting.”

IV. Summary of Final Regulations

A. Adding New Subpart W

NOAA is amending 15 CFR part 922 by adding a new subpart (subpart W) that contains site-specific regulations for the sanctuary. This subpart will include the boundary, contain definitions of common terms used in the new subpart, identify prohibited activities and exceptions, and establish procedures for permitting otherwise prohibited activities. The regulations will be applied in accordance with generally recognized principles of international law and in accordance with treaties, conventions, and other agreements to which the United States is a party, consistent with sections 305(a) and 307(k) of the NMSA and the NMSA’s Regulations of General Applicability at 15 CFR 922.1(b). No regulation shall

apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States unless in accordance with generally recognized principles of international law, or applicable treaties, conventions, and other agreements.

B. Sanctuary Boundary

NOAA's designation of Papahānaumokuākea National Marine Sanctuary consists of the marine environment surrounding the Northwestern Hawaiian Islands from the shoreline of the islands and atolls seaward to 200 nautical miles, including all waters of the Monument. NOAA estimates the area encompassed in the designation is approximately 582,570 square miles (439,910 square nautical miles).

C. Definitions

This rule incorporates and adopts common terms defined in the national regulations at 15 CFR 922.11. In addition, NOAA is including 20 site-specific definitions. To the extent that a term appears at 15 CFR 922.11 and the definitions section of the final rule, the definition in the final rule would govern.

- The definitions for “Bottomfish Species” and “Pelagic Species” are adopted from regulations for Fisheries in the Western Pacific, 50 CFR 665.201 and 50 CFR 665.800.
- “Ecological integrity”, “Midway Atoll Special Management Area”, “Native Hawaiian practices”, “Pono”, “Recreational activity”, “Special Preservation Area (SPA)”, “Stowed and not available for immediate use”, “Sustenance fishing”, and “Vessel monitoring system or VMS”, are adopted from Presidential Proclamation 8031.
- “Commercial fishing” and “Non-commercial fishing” are adopted from the MSA and, in part, from regulations for Fisheries in the Western Pacific, 50 CFR 665.12.
- “Particularly Sensitive Sea Area (PSSA)” is adopted from International Maritime Organization (IMO) Resolution A.982(24), December 1, 2005.
- “Areas to be avoided (ATBA)”, “Categories of hazardous cargoes” and “Office of Law Enforcement” are adopted from Papahānaumokuākea Marine National Monument regulations, 50 CFR 404.3.
- “Outer Sanctuary Zone” refers to the area of the sanctuary that would extend from approximately 50 nautical miles from all the islands and emergent lands of the Northwestern Hawaiian Islands to the extent of the seaward limit of the United States Exclusive

Economic Zone west of 163° West Longitude. This area of the sanctuary would correspond with the area designated as a marine national monument by Presidential Proclamation 9478, referred to as the “Papahānaumokuākea Marine National Monument Expansion” or MEA. NOAA provides this definition to provide clarity to the public where there is a regulation that only applies to this area of the sanctuary, and not the entire sanctuary. Note that the MEA and the Outer Sanctuary Zone are coextensive. In this final rule, when describing the sanctuary regulations, the term “Outer Sanctuary Zone” is used, and when describing the directives of Presidential Proclamation 9478, the term “MEA” is used.

- “Reporting Area” refers to the area of the sanctuary that extends outward ten nautical miles from the PSSA boundary, as designated by the IMO, and excludes the ATBAs that fall within the PSSA boundary. The reporting area is defined by the coordinates set forth in Appendix E to the final rule. NOAA defines the “reporting area” to clarify which areas of the sanctuary apply to ship reporting requirements.
- “Scientific instrument” is a term used in Presidential Proclamation 9478, but the term was not defined. Specifically, Presidential Proclamation 9478 prohibits “drilling into, dredging, or otherwise altering the submerged lands, or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands, except for scientific instruments”. NOAA defines “scientific instrument” to clarify what activities may be conducted pursuant to a permit. NOAA defines “scientific instrument” to mean “a device, vehicle, or tool used for scientific purposes and is inclusive of structures, materials, or other matter incidental to proper use of such device, vehicle, or tool.” In defining “scientific instrument,” NOAA’s definition provides for the inclusion of “structures, materials, or other matter incidental to proper use of such device, vehicle, or tool” because, based on the type of activities previously permitted in the Monument, proper deployment and use of most scientific instruments requires more than the instrument itself. For example, there may be incidental ballast discharge associated with the use of a scientific instrument like a remotely operated vehicle, or ROV. A narrower definition of “scientific instrument” could unduly restrict NOAA’s ability to permit activities in the area of the sanctuary that overlaps with the MEA. NOAA believes a narrower definition would be inconsistent with the intent of

Presidential Proclamation 9478, which states “Undisturbed seamount communities in the adjacent area are of significant scientific interest because they provide opportunities to examine the impacts of physical, biological, and geological processes on ecosystem diversity, including understanding the impacts of climate change on these deep-sea communities. These seamounts and ridges also provide the opportunity for identification and discovery of many species not yet known to humans, with possible implications for research, medicine, and other important uses. Recent scientific research, utilizing new technology, has shown that many species identified as objects in Proclamation 8031 inhabit previously unknown geographical ranges that span beyond the existing Monument, and in some cases the adjacent area also provides important foraging habitat for these species.” These statements clearly demonstrate the significant scientific value of the MEA and underscore the opportunities for research and discovery to occur in the sanctuary.

D. Cooperative Management of the Sanctuary

Pursuant to the NMSA, states may choose to have a role in co-managing a sanctuary if all or part of the sanctuary is within the territorial limits of any state. As the sanctuary includes state waters, NOAA will co-manage the sanctuary with the State of Hawai‘i. NOAA establishes the framework for co-management in section 922.242 of the final regulations NOAA and the State of Hawai‘i may update existing agreements or develop additional agreements as necessary to provide details on the execution of sanctuary management, such as activities, programs, and permitting that can be updated to adapt to changing conditions or threats to the sanctuary resources.

NOAA and the State of Hawai‘i will manage the sanctuary in partnership with the USFWS and OHA consistent with the management of the Monument. The existing co-management structure of the Monument will be critical to the success of the sanctuary. NOAA will work in cooperation with the Monument co-trustees to update the Memorandum of Agreement for Promoting Coordinated Management of Papahānaumokuākea Marine National Monument with the State of Hawai‘i, DOI, and OHA that reflects the addition of the sanctuary, and specifically addresses how the addition of a sanctuary will supplement and complement, and not supplant, existing Monument management. This is

consistent with the existing Memorandum of Agreement, which includes a provision that states that “in the event of the designation of the Monument or any portion of the Monument as a National Marine Sanctuary under the National Marine Sanctuaries Act, nothing herein shall be construed as automatically terminating or otherwise amending this Agreement.” NOAA may enter into additional Memorandums of Agreement with the Monument co-trustees regarding this collaboration that may address, but not be limited to, sanctuary resource protection, educational programs, permitting, enforcement, research activities, development, and threats to resources. Any future proposed changes to sanctuary regulations or boundaries would be coordinated with the State and other Monument co-trustees and subject to public review as mandated by the NMSA and other Federal statutes.

The Secretary of the Interior, through the USFWS, has sole responsibility for management of the areas of the Monument that overlay the Midway Atoll National Wildlife Refuge, the Battle of Midway National Memorial, and the Hawaiian Islands National Wildlife Refuge, and exercises that responsibility in consultation with the Secretary of Commerce. Nothing in these regulations or establishment of the national marine sanctuary shall diminish USFWS’s authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act as amended, and other USFWS authorities. Where Papahānaumokuākea National Marine Sanctuary overlays Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the NMSA to provide supplemental authority to protect resources.

NOAA, in exercising its management authority under National Marine Sanctuaries Act Section 304(d), recognizes USFWS’ management authority over Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act.

The Director of the USFWS has agreed that Papahānaumokuākea National Marine Sanctuary will provide supplemental authorities where the sanctuary overlays the Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge. NOAA and USFWS are developing an agreement to memorialize this decision, and to provide details on the execution

of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, consistent with the spirit of cooperative management of the area and recognizing USFWS has sole authority in Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge pursuant to the National Wildlife Refuge System Administration Act.

Implementation of NOAA and USFWS authorities shall not enlarge or diminish the jurisdiction of the State of Hawai‘i, including the State’s responsibilities and requirements to manage Kure Atoll Wildlife Sanctuary and the State of Hawai‘i Northwestern Hawaiian Islands Marine Refuge.

E. Access

In PMNM, pursuant to Presidential Proclamation 8031, access is prohibited except under the following circumstances: (1) for emergency response and law enforcement purposes; (2) for activities and exercises of the Armed Forces; (3) for persons who have been issued Monument permits; and (4) for passage without interruption. For consistency, and to protect sanctuary resources, NOAA extends the access restrictions which apply to the area of the sanctuary that overlaps the PMNM to the area of the sanctuary that overlaps with the MEA as follows:

Access to the sanctuary is prohibited and thus unlawful except under the following circumstances: (1) for emergency response actions, law enforcement activities, and activities and exercises of the Armed Forces; (2) pursuant to a sanctuary permit; (3) when conducting non-commercial fishing activities in the Outer Sanctuary Zone authorized under the MSA in accordance with 15 CFR 922.244 (d); (4) when conducting scientific exploration or research activities by or for the Secretary of Commerce or the Secretary of the Interior when the activity occurs within the Outer Sanctuary Zone; and (5) when passing through the sanctuary without interruption.

A vessel may pass without interruption through the sanctuary without requiring a permit as long as the vessel does not stop or engage in prohibited activities within the sanctuary. A vessel passing through the sanctuary without interruption may be subject to the ship reporting system, as described below.

The access restrictions will be applied in accordance with generally recognized principles of international law and in accordance with treaties, conventions,

and other agreements to which the United States is a party, consistent with sections 305(a) and 307(k) of the NMSA and the NMSA’s Regulations of General Applicability at 15 CFR 922.1(b). No regulation shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States unless in accordance with generally recognized principles of international law, or applicable treaties, conventions, and other agreements.

F. Ship Reporting

The final rule includes regulations to implement the ship reporting system (CORAL SHIPREP) adopted by the IMO, which require entrance and exit notifications for vessels that pass without interruption through the sanctuary areas contained within a reporting area. Requiring vessels to notify NOAA immediately upon entering the reporting area will help make the vessel operators aware that they are traveling through a fragile area with potential navigational hazards, such as the extensive coral reefs found in many shallow areas of the sanctuary contained within the reporting area.

The ship reporting requirements apply to vessels that pass through the sanctuary without interruption. Conversely, the ship reporting requirements do not apply to vessels covered by an exemption at 15 CFR 922.243(a)(1) through (a)(4), or to sovereign immune vessels, which are specifically exempted from the reporting requirement in the ship reporting system adopted by the IMO. Furthermore, the ship reporting requirements will be applied in accordance with generally recognized principles of international law and in accordance with treaties, conventions, and other agreements to which the United States is a party, consistent with sections 305(a) and 307(k) of the NMSA and the NMSA’s Regulations of General Applicability at 15 CFR 922.1(b). No regulation shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States unless in accordance with generally recognized principles of international law, or applicable treaties, conventions, and other agreements.

NOAA defines the reporting area as “the area of the sanctuary that extends outward ten nautical miles from the PSSA [Particularly Sensitive Sea Area] boundary, as designated by the IMO, and excludes the ATBAs [Areas to be avoided] that fall within the PSSA boundary.” The reporting area is further defined by the coordinates set forth in Appendix E to the final rule. Appendix E includes a coordinates table for the

“Reporting Area Outer Boundary,” which contains the reporting area’s boundary surrounding the PSSA. Appendix E also includes coordinate tables for the “Inner Reporting Area Boundary” for each of the four ATBAs that fall within the PSSA, but which are not part of the reporting area.

The reporting area for the sanctuary will not include the four voluntary ATBAs adopted by the IMO that are also within the PSSA. An ATBA is an area within which either navigation is particularly hazardous or it is exceptionally important to avoid casualties. While ATBAs can be mandatory (*i.e.*, vessels are required by applicable law to avoid and operate outside of the area) most are voluntary and vessels may travel through them. Because the four ATBAs in the PSSA are voluntary, as adopted by the IMO and implemented by these regulations, the ATBAs are outside of the reporting area. Nonetheless, by virtue of entering or exiting an ATBA, vessels would also be departing or entering the reporting area, and, therefore be subject to the reporting area’s requirements four times: (1) once when it enters the reporting area; (2) once when it leaves the reporting area to enter the ATBA; (3) once when it exits the ATBA and enters the reporting area on the other side of the ATBA; and (4) once when it again leaves the reporting area. The potential burden of reporting four times is justified by the navigational hazards that exist within the ATBAs. The reporting area also includes three large areas within the PSSA that are not within the ATBAs. These breaks between the four ATBAs allow for north-south passages through the sanctuary areas contained within the reporting area that can be utilized for navigation to avoid ATBAs. Vessels passing through the sanctuary in these areas would only send email notification twice: once upon entering the reporting area, and again upon leaving the reporting area.

NOAA will implement CORAL SHIPREP’s requirements under the NMSA in keeping with the United States’ and IMO’s long-standing interest in providing additional protection to the natural, cultural, and historic resources in PMNM through ship reporting requirements. In June 2006, Presidential Proclamation 8031 directed the Secretary of Commerce and Secretary of Interior to require notification from any person passing through PMNM without interruption at least 72 hours, but no longer than 1 month, prior to the entry date, and within 12 hours of departure. Presidential Proclamation 8031 further indicated the specific types of

information that must be provided in the notification. These notification requirements were subsequently codified in 50 CFR 404.4. Presidential Proclamation 8031 also directed the Secretary of State, in consultation with the Secretary of Commerce and Secretary of Interior, to seek the cooperation of other governments and international organizations in furtherance of the purposes of the proclamation and consistent with applicable regional and multilateral arrangements for the protection and management of special marine areas.

Following Executive Order 13178 and Presidential Proclamation 8031, in April 2007 the United States proposed to the IMO that PMNM be designated as a PSSA to protect the attributes of the fragile and integrated coral reef ecosystem from potential hazards associated with international shipping activities. The U.S. noted in its proposal that the proposed PSSA and its associated protective measures would result in a minimal burden to international shipping, would significantly further increase maritime safety, would protect of the fragile environment, would preserve cultural resources and areas of cultural importance significant to Native Hawaiians, and would facilitate responses to developing maritime emergencies. On April 3, 2008, the IMO designated the PMNM as a PSSA. As part of the PSSA designation process, the IMO adopted U.S. proposals for associated protective measures. These measures included expanding and consolidating the six existing recommendatory ATBAs in the PMNM into four larger areas and enlarging the class of vessels to which they apply. In addition, the IMO adopted a ship reporting system for vessels transiting the PMNM, which is mandatory for ships 300 gross tons or greater that are entering or departing a U.S. port or place and recommended for other ships. The system requires that ships notify the U.S. shore-based authority (*i.e.*, the U.S. Coast Guard; NOAA will be receiving all messages associated with this program on behalf of the Coast Guard) at the time they begin transiting the reporting area and again when they exit. In December 2008, NOAA and the USFWS published final regulations to establish a ship reporting system for PMNM, which implemented measures adopted by the IMO requiring notification by ships passing through PMNM without interruption (73 FR 73592). These regulations modified the previous notification requirements at 50 CFR 404.4.

NOAA will implement the ship reporting system as adopted by the IMO and establish the reporting area using the boundary coordinates in Appendix E to this final rule to provide additional protection to the natural, cultural, and historic resources in the sanctuary. Accordingly, NOAA’s regulations build upon the requirements outlined in Presidential Proclamation 8031, and reflect additions made through the IMO’s adoption of a ship reporting system and the implementation of that system in 50 CFR 404.4. NOAA provides minor language changes from the process adopted by IMO Resolution MEPC.171(57) and IMO Resolution MSC.279(85) to provide clarity to the public on which vessels are required to participate in ship reporting and the type of information that should be reported.

G. Activities That Are Prohibited or Otherwise Regulated

NOAA will supplement and complement existing management of this area through prohibited or otherwise regulated activities in section 922.244. Presidential Proclamations 8031, 8112, and 9478, and regulations implementing Presidential Proclamations 8031 and 8112 at 50 CFR part 404 provide the foundation for the prohibitions. However, minor changes are made to remove discrepancies and gaps in prohibitions and regulated activities between PMNM and the MEA in order to allow for consistency in management across the sanctuary.

Within PMNM, the prohibitions in section 922.244 are already effectively in place under 50 CFR part 404, except for prohibitions 1 and 4 (detailed below). Minor changes are made to prohibitions 1 and 4 to remove discrepancies across the two zones (PMNM and MEA). Regulations implementing Presidential Proclamation 9478 have not been promulgated for the MEA. Many of the prohibitions adopted in the rule are identified in Presidential Proclamation 9478, which established the MEA. Any prohibitions for the area of the sanctuary that overlaps with the MEA that are not adopted directly from Presidential Proclamation 9478 are identified below.

1. Prohibition on Exploring for, Developing, or Producing Oil, Gas, or Minerals, or Any Energy Development Activities

Consistent with the presidential proclamations establishing the Monument, NOAA prohibits exploring for, developing, or producing oil, gas, or minerals to protect sanctuary resources and create a seamless management area

throughout the sanctuary. The addition of the prohibition on “any energy development activities” would be new for PMNM, and was added to further the underlying intent of the prohibition on oil, gas, and mineral development by accounting for technological advances in other forms of energy development.

In addition to creating consistency across the two zones, this prohibition will help advance the sanctuary’s goals and objectives by protecting sensitive marine ecosystems such as fragile coral reefs and deep-sea corals, benthic habitat, and seamounts. Prohibiting oil, gas, and mineral development reduces the risk of offshore spills, such as the Deepwater Horizon oil spill, that could significantly harm sanctuary resources. Deep seabed mining, oil and gas drilling, and other energy development activities, such as renewable energy system installation, destroys fragile benthic habitat, releases sequestered carbon, and spreads sediment plumes that can suffocate both sensitive shallow and deep-sea coral reefs, which negatively impacts nursery and foraging habitat for fish, and reduces the ecosystem’s overall resilience.

2. Prohibition on Using or Attempting To Use Poisons, Electrical Charges, or Explosives in the Collection or Harvest of a Sanctuary Resource

This prohibition is consistent with prohibitions identified in the presidential proclamations establishing the Monument.

3. Prohibition on Introducing or Otherwise Releasing an Introduced Species From Within or Into the Sanctuary

This prohibition is consistent with prohibitions identified in the presidential proclamations establishing the Monument.

4. Prohibition on Deserting a Vessel

Deserting a vessel is currently a regulated activity (allowed only with a permit) in PMNM pursuant to Presidential Proclamation 8031. Deserting a vessel is a prohibited activity in the MEA pursuant to Presidential Proclamation 9478. Based on NOAA’s experience in managing national marine sanctuaries, NOAA does not see a need to permit this activity. Prohibiting this activity will create consistency in management across the sanctuary and help to prevent desertion of a vessel following a sinking, grounding, or other incident. Prevention is much less expensive than responding to a deserted vessel and can optimally prevent impacts and damage to

sanctuary resources as well as to private property.

5. Prohibition on Anchoring on or Having a Vessel Anchored on Any Living or Dead Coral With an Anchor, Anchor Chain, or Anchor Rope

This prohibition is consistent with prohibitions identified in the presidential proclamations establishing the Monument.

6. Prohibition on Commercial Fishing or Possessing Commercial Fishing Gear Except When Stowed and Not Available for Immediate Use

Presidential Proclamation 8031 provided that commercial fishing for bottomfish and pelagic fish in PMNM that was permitted by NOAA prior to June 16, 2006 was allowed to continue for 5 years from the date of the proclamation, until June 15, 2011. After that date, Presidential Proclamation 8031 prohibited commercial fishing for bottomfish and associated pelagic species in PMNM. Presidential Proclamation 9478 also prohibits commercial fishing, as well as possessing commercial fishing gear except when stowed and not available for immediate use during passage without interruption in the MEA. With these sanctuary regulations, NOAA provides a sanctuary-wide prohibition on commercial fishing or possessing commercial fishing gear except when stowed and not available for immediate use to be consistent with the presidential proclamations establishing the Monument.

7. Prohibition on Failing To Comply With Vessel Monitoring Systems Requirements in Violation of § 922.246

This prohibition is consistent with requirements identified in Presidential Proclamation 8031. The VMS requirement for permittees operating within the areas of the sanctuary that overlap with the MEA would be a new requirement. Further discussion of the VMS requirements is included within Section IV. L. of this final rule.

8. Prohibition on Failing To Comply With Ship Reporting Requirements in Violation of § 922.243

This prohibition is consistent with the requirements of the ship reporting system (CORAL SHIPREP), as adopted by the IMO and implemented in PMNM under 50 CFR 404.4. Further discussion of the ship reporting system requirements is included within Section IV.F of this final rule.

9. Prohibition on Non-Commercial Fishing or Possessing Non-Commercial Fishing Gear Except When Stowed and Not Available for Immediate Use

The presidential proclamations establishing the Monument broadly restrict the harvest of fishery resources by prohibiting removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging any living or nonliving monument resource, as well as attempts to do the same, except as may be allowed with a permit. As noted above, Presidential Proclamations 8031 and 9478 further specify prohibitions on commercial fishing and the possession of commercial fishing gear. The presidential proclamations also identify certain types of non-commercial fishing that may be regulated (*i.e.*, allowed pursuant to a permit or incidental to a permitted activity). Presidential Proclamation 8031, for example, authorizes sustenance fishing incidental to an activity permitted in PMNM. Presidential Proclamation 9478, for example, provides that non-commercial fishing is a regulated activity (*i.e.*, allowed only with a permit) in the MEA. In the sanctuary, for consistency with the proclamations, NOAA will prohibit “non-commercial fishing” unless conducted pursuant to a sanctuary permit or, as discussed below, authorized under the MSA in the Outer Sanctuary Zone. The final rule adopts the definition of “non-commercial fishing” from the regulations for Fisheries in the Western Pacific, which is defined as “fishing that does not meet the definition of commercial fishing in the MSA, and includes, but is not limited to, sustenance, subsistence, traditional indigenous, and recreational fishing.” 50 CFR 665.12.

The final rule also provides that “possessing non-commercial fishing gear except when stowed and not available for immediate use” is prohibited unless conducted pursuant to a sanctuary permit or, as discussed below, authorized under the MSA in the Outer Sanctuary Zone. Presidential Proclamation 8031 includes “possessing fishing gear,” as a regulated activity (allowed only with a permit) in PMNM. Presidential Proclamation 9478 prohibits possessing commercial fishing gear. The final rule creates continuity between the two areas, and aims to prevent non-commercial gear from being utilized in an unauthorized manner that could lead to injury to sanctuary resources.

10. Prohibition on Drilling Into, Dredging, or Otherwise Altering the Submerged Lands; or Constructing, Placing, or Abandoning Any Structure, Material, or Other Matter on the Submerged Lands

This activity is a regulated activity (*i.e.*, allowed only with a permit) in PMNM under Presidential Proclamation 8031. In the MEA, Presidential Proclamation 9478 prohibits this type of activity, except when conducted for the use of scientific instruments, which is allowed only with a permit, subject to such terms and conditions as the Secretaries deem appropriate. In the sanctuary, these activities are prohibited unless conducted pursuant to a sanctuary permit. In the Outer Sanctuary Zone, such a permit may only be issued for scientific instruments.

11. Prohibition on Removing, Moving, Taking, Harvesting, Possessing, Injuring, Disturbing, or Damaging; or Attempting To Remove, Move, Take, Harvest, Possess, Injure, Disturb, or Damage Any Living or Nonliving Sanctuary Resource

These activities are prohibited unless conducted pursuant to a sanctuary permit, consistent with the presidential proclamations establishing the Monument.

12. Prohibition on Attracting Any Living Sanctuary Resource

This activity is prohibited unless conducted pursuant to a sanctuary permit. This prohibition is consistent with a regulated activity identified in Presidential Proclamation 8031 for PMNM. This prohibition is new in the area of sanctuary that overlaps with the MEA. Prohibiting this activity is intended to address the potential for harassment and disturbance from human interactions with living sanctuary resources.

13. Prohibition on Touching Coral, Living or Dead

This activity is prohibited unless conducted pursuant to a sanctuary permit. This prohibition is consistent with a regulated activity (*i.e.*, allowed only with a permit) identified in Presidential Proclamation 8031 for PMNM. This prohibition would be new for the area of sanctuary that overlaps with the MEA. However, prohibition 10 (above) effectively includes this activity, as touching coral is considered a disturbance which may cause injury or damage. Therefore, regulating this activity in the Outer Sanctuary Zone is primarily a technical addition which provides clarity to the public and resource managers.

14. Prohibition on Swimming, Snorkeling, or Closed or Open Circuit SCUBA Diving

These activities are prohibited unless conducted pursuant to a sanctuary permit. This prohibition is consistent with a regulated activity identified in Presidential Proclamation 8031 for any Special Preservation Area or the Midway Atoll Special Management Area. This prohibition would be new for areas of PMNM that fall outside of any Special Preservation Area or the Midway Atoll Special Management Area, and for the MEA. Expanding this regulated activity to the entire area of the proposed sanctuary allows NOAA to ensure that all in-water activities are done in compliance with the permit findings criteria and requirements, and are consistent with the care and management of sanctuary resources.

15. Prohibition on Discharging or Depositing Any Material or Other Matter Into the Sanctuary, or Discharging or Depositing Any Material or Other Matter Outside of the Sanctuary That Subsequently Enters the Sanctuary and Injures or Has the Potential To Injure Any Resources of the Sanctuary, With Exceptions

These activities are prohibited unless conducted pursuant to a sanctuary permit. This prohibition is consistent with regulated activities identified in Presidential Proclamation 8031 for PMNM. The sanctuary regulations provide an exception to this activity, for “discharge incidental to vessel operations such as approved marine sanitation device effluent, cooling water, and engine exhaust”. Within Special Preservation Areas or the Midway Atoll Special Management Area, discharge is limited to “vessel engine cooling water, weather deck runoff, and vessel engine exhaust”. The exceptions to this otherwise regulated activity must be conducted in accordance with other Federal statutes and regulations, such as section 312 of the Federal Water Pollution Control Act, as amended, (FWPCA), 33 U.S.C. 1321 *et seq.* In addition, and consistent with exceptions identified in Presidential Proclamation 8031 for PMNM, the sanctuary regulations provide an exception for “fish, fish parts, or chumming materials (bait) used in or resulting from lawful fishing activity, provided that such discharge or deposit is during the conduct of lawful fishing activity within the sanctuary”.

While this prohibition is technically new for the area of the sanctuary that overlaps with the MEA, Presidential Proclamation 9478 effectively includes

this activity. Regulating this activity for the Outer Sanctuary Zone provides clarity to the public and resource managers. Further, the prohibition on discharges within or into the sanctuary is provided in recognition that various substances can be discharged from vessels or from infrastructure or individuals along the shoreline that can harm sanctuary resources or qualities. Establishing a cohesive regulatory framework across the sanctuary would benefit sanctuary resources and sanctuary users.

16. Prohibition on Anchoring a Vessel

This activity is prohibited unless conducted pursuant to a sanctuary permit. While this activity may be permitted via a sanctuary permit, anchoring on living or dead coral may never be permitted, as noted above under prohibition 5. NOAA is regulating anchoring a vessel for consistency with a regulated activity identified in Presidential Proclamation 8031 for PMNM and because there is the potential for sanctuary resources, other than corals, to be impacted by anchoring. This prohibition is new for the area of the sanctuary that overlaps with the MEA. NOAA is including this prohibition on anchoring a vessel throughout the sanctuary to provide clarity to the public, resource managers, and enforcement personnel that all users of the sanctuary are subject to the same prohibition on anchoring a vessel unless conducted pursuant to a sanctuary permit.

H. Exemptions for Emergencies

Consistent with existing management of this area, the prohibitions for the sanctuary would not apply to any activity necessary to respond to emergencies that threaten life, property, or the environment, or to activities necessary for law enforcement purposes.

I. U.S. Armed Forces Exemption

Consistent with existing management of this area, NOAA provides a broad exemption to allow activities and exercises of the U.S. Armed Forces, including those carried out by the U.S. Coast Guard. NOAA recognizes that this broad exemption is necessary to ensure military readiness for the Department of Defense to conduct existing training, operations, and military readiness activities in the area of the sanctuary. The United States military has been able to maintain readiness and conduct training and other operations in other national marine sanctuaries based on similar broad exemptions.

All activities and exercises of the Armed Forces shall be carried out in a

manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on sanctuary resources and qualities. For any actions of the Armed Forces that are likely to destroy, cause the loss of, or injure sanctuary resources, the Armed Forces must comply with the Interagency Cooperation requirements outlined in section 304(d) of the NMSA, regardless of whether those actions are exempted from the sanctuary's prohibitions.

J. Exemption for Non-Commercial Fishing

NOAA exempts non-commercial fishing authorized under the MSA in the Outer Sanctuary Zone from needing a sanctuary permit for certain regulated activities provided under paragraph (a)(9) through (12), and (a)(14) in the final rule, provided that certain requirements are satisfied. Those requirements are that the fish harvested, either in whole or in part: (1) are not intended to enter commerce and shall not enter commerce through sale, barter, or trade, and that the resource is managed sustainably; and (2) are not intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery.

In addition, the exempted activities under paragraph (a)(9) through (12), and (a)(14) must only be conducted as incidental to and necessary to conduct lawful non-commercial fishing activity. NOAA will prepare a separate proposed rule under the MSA, which shall serve as the primary mechanism for authorizing non-commercial fishing activities in the Outer Sanctuary Zone. NOAA will periodically evaluate the effect of non-commercial fishing activities on sanctuary resources. Such evaluations would take into consideration the best scientific information available and evaluate whether additional actions are necessary for the proper care and management of sanctuary resources, including fishery resources, consistent with goals and objectives of the sanctuary. This exemption only applies to the Outer Sanctuary Zone.

K. Sanctuary Permit Procedures and Criteria

1. Sanctuary General Permits

NOAA provides the authority to issue sanctuary general permits to allow certain activities that would otherwise violate prohibitions in paragraphs (a)(9) through (15). The sanctuary permitting system was developed to allow for integration with the Monument permitting system, to ensure a

continued joint permitting system administered by Monument co-managers. NOAA may, in cooperation with the Monument co-trustees, modify the existing memorandum of agreement or develop a new memorandum of agreement to add further clarification on joint permitting.

National marine sanctuary program-wide regulations at 15 CFR 922.30 describe various purposes for which a sanctuary general permit can be issued. Three of these which would apply to this sanctuary are:

- Research—activities that constitute scientific research or scientific monitoring of a national marine sanctuary resource or quality;
- Education—activities that enhance public awareness, understanding, or appreciation of a national marine sanctuary or national marine sanctuary resource or quality; and
- Management—activities that assist in managing a national marine sanctuary.

NOAA adds two additional permit categories to 15 CFR 922.30 under which a sanctuary general permit could be issued in the sanctuary:

- Native Hawaiian Practices—activities that allow for Native Hawaiian practices within the sanctuary; and
- Recreation—recreational activities within the sanctuary, but limited to the Midway Atoll Special Management Area.

The Native Hawaiian Practices general permit category is consistent with the types of activities permitted for the PMNM. Presidential Proclamation 9478 provided Native Hawaiian practices as a regulated activity. For consistency in management across the proposed sanctuary, and to protect sanctuary resources while facilitating responsible user access, NOAA would apply this general permit category across the sanctuary.

The Recreation general permit category is consistent with the types of activities permitted for PMNM, specifically within the Midway Atoll Special Management Area. For consistency with existing Monument management, this general permit category would continue to be limited to recreational activities within the Midway Atoll Special Management Area.

The general regulations in 15 CFR part 922, subpart D relating to the permit application process, review procedures, amendments, and other permitting stipulations would apply. These national permitting regulations include a list of factors NOAA considers in deciding whether or not to issue the permit, such as whether the activity

must be conducted within the sanctuary, and whether the activity will be compatible with the primary objective of protection of sanctuary resources and qualities. NOAA will be able to impose specific terms and conditions through a permit as appropriate. The general regulations' permitting review criteria is largely consistent with the permitting findings established by Presidential Proclamation 8031 for PMNM, and implemented through 50 CFR 404.11.

In addition to permit review procedures and evaluation criteria in 15 CFR 922.33, some additional permit review criteria apply in the sanctuary, including additional criteria specific to Native Hawaiian Practices permits and Recreation permits. NOAA is providing these additional permit criteria in 15 CFR 922.245 to be consistent with the permit criteria for PMNM.

2. Special Use Permits

NOAA has the authority to issue special use permits (SUPs) in national marine sanctuaries, as established by section 310 of the NMSA (16 U.S.C. 1441) and by 15 CFR 922 subpart D. SUPs can be used to authorize specific activities in a sanctuary if such authorization is necessary to establish conditions of access to, and use of, any sanctuary resource or to promote public use and understanding of a sanctuary resource. Section 310 of the NMSA establishes four requirements for SUPs: (1) activities must be compatible with the purposes for which the sanctuary is designated and with protection of sanctuary resources; (2) SUPs shall not authorize the conduct of any activity for a period of more than five years unless otherwise renewed; (3) activities carried out under the SUP must be conducted in a manner that does not destroy, cause the loss of, or injure sanctuary resources; and (4) permittees are required to purchase and maintain comprehensive general liability insurance, or post an equivalent bond, against claims arising out of activities conducted under the SUP and to agree to hold the United States harmless against such claims. The NMSA authorizes NOAA to assess and collect fees for the conduct of any activity under a SUP, including costs incurred, or expected to be incurred, in issuing the permit and the fair market value use of sanctuary resources. Implementing regulations at 15 CFR 922.35 provide additional detail on assessment of fees for SUPs. Like with sanctuary general permits, NOAA can place conditions on SUPs specific to the activity being permitted. NOAA shall provide appropriate public notice before

identifying any category of activity subject to a special use permit.

NOAA is not adding any new SUP category as part of this designation. In evaluating applications for special use permits, NOAA will consider all applicable permitting requirements, including permitting procedures and criteria under the Monument's existing management framework. For example, certain activities may be subject to the requirements of special ocean use permits, as authorized by Presidential Proclamation 8031, and issued by Monument managers in the PMNM via 50 CFR 404.11. Special ocean use permit requirements were modeled after the NMSA's authority for SUPs, but also include a few additional requirements. For example, one of the requirements for special use permits outside Midway Atoll National Wildlife Refuge is that the activity does not involve the use of a commercial passenger vessel. For special use permits in Midway Atoll National Wildlife Refuge, an additional requirement is that the Director of the USFWS or their designee determines that the activity is compatible with the purposes for which the Midway Atoll National Wildlife Refuge was designated.

3. Sustenance Fishing

NOAA may authorize sustenance fishing outside of any Special Preservation Area as a term or condition of any sanctuary permit. Sustenance fishing in the Midway Atoll Special Management Area shall not be allowed unless the activity has been determined by the Director of the USFWS or their designee to be compatible with the purposes for which the Midway Atoll National Wildlife Refuge was established. Sustenance fishing is fishing for bottomfish or pelagic species in which all catch is consumed within the sanctuary. Sustenance Fishing is allowed incidental to an activity permitted in the PMNM under Presidential Proclamation 8031, and in regulations at 50 CFR part 404. Sustenance fishing was not specifically identified in Presidential Proclamation 9478 governing the MEA, but is allowable, consistent with proper care and management of monument objects. For consistency in management and permitting, NOAA is allowing for this activity as a term or condition of a general permit or special use permit.

L. Vessel Monitoring System

To complement existing management and provide consistency across the entirety of the sanctuary, an owner or operator of a vessel that has been issued a general permit or special use permit

under 15 CFR part 922 subpart D must ensure that such vessel has a NOAA Office of Law Enforcement (OLE)—approved Vessel Monitoring System (VMS) on board when operating within the sanctuary. Presidential Proclamation 8031 requires an owner or operator of a vessel that has been issued a permit for accessing the PMNM to have an OLE—approved VMS on board. Such a requirement was not included in Presidential Proclamation 9478. For consistency in permitting, and for the reasons identified below, NOAA implements this requirement across the sanctuary.

This requirement supports monitoring and surveillance, enforcement, and other incidental uses, consistent with the long-standing history of using vessel monitoring systems in the remote and vast area of the sanctuary, beginning with Executive Order 13178 in 2000. In directing the Secretary of Commerce to manage the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, section 5(b) of Executive Order 13178, indicated that priority management issues and actions must include enforcement and surveillance, including the use of new technologies, as well as the use of vessel monitoring systems, if warranted. The 2005 Final Reserve Operations Plan included an Enforcement Action Plan with strategies to investigate innovative technology that would be effective for enforcement and surveillance activities within this large, remote area, as well as to implement VMS.

In 2006, Presidential Proclamation 8031, as noted above, required an OLE-approved VMS on vessels with permits to access the PMNM. VMS is currently being used in the PMNM and is part of the Monument Management Plan's Enforcement Action Plan. The Monument Management Plan highlights, as an example, that when the 85-foot longliner *Swordman I*, carrying more than 6,000 gallons of diesel fuel and hydraulic oil, ran aground at Pearl and Hermes Reef in 2000, vessel monitoring system technology allowed agents to track the disaster and quickly send out equipment for an extensive cleanup. Further, the Monument Management Plan recognizes that the Monument's remote location presents unique surveillance and enforcement challenges, which a mandatory vessel monitoring system is critical to addressing.

In designating a sanctuary in the remote and vast area of the Monument and Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, NOAA recognizes the need to overcome these

natural barriers to surveillance and enforcement through the use of VMS.

M. Scientific Exploration and Research by the Department of Commerce and the Department of the Interior

Presidential Proclamation 9478, which designated the MEA, stipulates that the prohibitions required by the proclamation "shall not restrict scientific exploration or research activities by or for the Secretaries and nothing in this proclamation shall be construed to require a permit or other authorization from the other Secretary for their respective scientific activities." Presidential Proclamation 9478 further highlights the significant scientific value of the MEA and underscores the opportunities for research and discovery to occur in that area, including understanding the impacts of climate change on deep-sea communities and identifying new species. NOAA exempts the Department of Commerce's and Department of the Interior's scientific exploration or research activities from the sanctuary's prohibitions and permitting requirements within the Outer Sanctuary Zone to be consistent with Presidential Proclamation 9478. However, such activities must still comply with other Federal laws such as the NEPA, the Endangered Species Act, the National Marine Sanctuaries Act section 304(d), and the Marine Mammal Protection Act.

N. Sunken Military Craft

NOAA is also adding language regarding the Sunken Military Craft Act of 2004 (SMCA; Pub. L. 108–375, Title XIV, sections 1401 to 1408; 10 U.S.C. 113 note) that acknowledges that sunken military craft in the sanctuary will continue to be administered by the respective Secretary concerned pursuant to the SMCA. NOAA will enter into a Memorandum of Agreement with the appropriate agencies regarding collaboration on implementing the SMCA. See section VI.H for more information.

O. Emergency Regulations

NOAA is not including any sanctuary-specific regulation to allow for development of emergency regulations to address urgent threats to sanctuary resources. Rather, the emergency regulation provision included in the regulations of general applicability, which apply to all national marine sanctuaries (see 15 CFR 922.7), would also apply to Papahānaumokuākea National Marine Sanctuary. Emergency regulations are used when there is an imminent risk to sanctuary resources and a temporary regulation or

prohibition is necessary to prevent or minimize the destruction or loss of those resources, or otherwise minimize the imminent risk of such destruction, loss, or injury.

P. Other Conforming Amendments

The regulations related to National Marine Sanctuary Permitting, 15 CFR part 922, subpart D, are amended so that the regulations are accurate and up-to-date. The modified sections to conform to adding a new sanctuary are as follows:

- Section 922.30 National Marine Sanctuary general permits;
- Section 922.33 Review procedures and evaluation; and
- Section 922.37 Appeals of permitting decisions.

Notably, NOAA amends 15 CFR 922.37 “Appeals of permitting decisions,” to reflect that the general appeals process for sanctuary permits will not apply to permit applications for the sanctuary. Consistent with the current interagency permitting system that has been in place for the Monument, there would be no appeals process for the sanctuary. Should a permit applicant want NOAA and the other agencies to reconsider a permitting decision, they would need to file a new permit application.

V. Response to Comments

All comments were considered by NOAA and the State and, where appropriate, modifications were made to the final EIS, sanctuary management plan, and sanctuary rule. NOAA and the State’s responses to comments address significant issues and concerns raised by members of the public, government agencies, stakeholder groups, non-profit organizations, and Kānaka ‘Ōiwi community groups. For a full scope of all of the comments received on the draft designation documents, including the draft EIS and the draft management plan, and their responses, please review the final EIS Appendix K. This final rule includes NOAA’s responses to comments that address the significant issues raised in public comments within the scope of the proposed rule specifically, and offer additional information about why certain changes were made to the rule, the terms of designation, or the regulations. The final rule retains the numbering/naming of the comment from the final EIS Appendix K so readers can track the comments that have been included in this preamble and more efficiently find other related comments/responses in the Appendix K that have not been included in this preamble. As such,

cross-references have been retained here for completeness.

1. A–1 Comment: The majority of comments NOAA received supported the proposed sanctuary designation, including Alternative 1 (NOAA’s Preferred Alternative), and encouraged NOAA to proceed with the designation process. Commenters who support the designation cited reasons including:

- Additional regulations, protections, enforcement, and programmatic and legal benefits for Papahānaumokuākea under the National Marine Sanctuaries Act;
- Enhancing long-term protections for biological, cultural, and historical resources;
- Comprehensive and coordinated management of the marine areas of Papahānaumokuākea;
- Preserving Native Hawaiian culture, traditional practices, sacredness of waters, and connections to place for current and future generations;
- Safeguarding marine biodiversity; coral reefs, pelagic, and deep-ocean ecosystems; and endemic, threatened, and endangered species;
- Regulating, mitigating, or preventing threats such as invasive species, overfishing, illegal fishing, deep-sea mining, military activities, pollution, oil spills, marine debris, erosion, and climate change;
- Additional sources of funding to support operations, research, emergency response, citizen science, education, and outreach; and
- Opportunities for recreation and tourism;

Response: NOAA agrees that these are some of the main benefits of designating the marine areas of the Monument as a national marine sanctuary. NOAA notes that many of these comments specifically indicate a preference for Alternative 1, and NOAA has considered this in carrying Alternative 1 forward in the final EIS as the Final Agency-Preferred Alternative.

2. A–2 Comment: A minority of commenters expressed opposition to sanctuary designation, citing concerns that designating a sanctuary:

- Is an overreach by the Federal government;
- Is an act of colonialism and/or infringes on the rights of Indigenous peoples;
- Would come at a cost to Native Hawaiian, American Samoan, and/or Pacific Islander well-being, including loss of the ability to practice cultural traditions and connections to ocean resources;
- Would limit access to the ocean and resources for food, livelihood, and cultural sustenance, and limit

Indigenous rights and their ability to freely fish in local waters;

- Would decrease the amount of fishing waters across the Pacific;
- Would lead to overfishing;
- Adds unnecessary layers of bureaucracy, as the existing Monument management and protections are extensive and sufficient for the area, and that if new protections/management is needed, these should be enacted through the Monument;
- Would relinquish the Monument title and co-management framework;
- Would weaken current protections, and allow the Department of Commerce to violate protections, opening the doors to deep-sea mining and recreational tourism, and taking away human and financial resources needed to manage the area; and
- Would be redundant of current management of the Monument, and therefore unnecessary. Some commenters also expressed that they felt current Monument management to be poor, or that current management capacity is lacking; and that a sanctuary would not improve this.

Response: Through the public sanctuary designation process, and from public input received during scoping and the proposed designation stage, NOAA has determined that this action responds to the need to address threats to and discrepancies in management of nationally significant resources. NOAA has also determined that the current management regime will benefit from additional regulatory tools, as well as the first set of implementing regulations for the MEA. Chapter 2 of the final EIS and Section I.B of the final rule preamble describes the purpose and need for the sanctuary.

NOAA respects the views of the commenters, including those who expressed concern that sanctuary designation is an overreach by the Federal government; is an act of colonialism; would impact the livelihood of Pacific Islanders and/or limit Indigenous rights. NOAA seeks to support the rights of Kānaka ‘Ōiwi and Pacific Islanders, and to support biocultural conservation and restoration work by growing collective kuleana and affirming respect and reciprocity for the place and people. The sanctuary management plan (final EIS Appendix A) objectives include managing the area as a sacred site consistent with Kānaka ‘Ōiwi traditional knowledge, management concepts, and principles articulated within *Mai Ka Pō Mai*. Kānaka ‘Ōiwi culture is foundational in the co-management legacy of Papahānaumokuākea (see final EIS, sections 1.2.4 and 4.5.1), and the

designation aims to ensure ecological integrity and achieve strong, long-term protection and perpetuation of Northwestern Hawaiian Island ecosystems, Kānaka 'Ōiwi culture, and maritime heritage resources for current and future generations. Native Hawaiian access will continue under sanctuary designation. See also the responses to comments C.1, C.2, and E.7.

Regarding commenters who expressed concerns with the impact of sanctuary designation on the existing Monument, existing regulations, and or existing management of the area, see also the responses to E.1 and E.2. Regarding commenters who expressed concerns with the impact of sanctuary designation on fishing, see also the comments D.1, D.3, and D.5. NOAA also recognizes that some comments raise concerns that are outside the scope of this designation, including the ongoing process to designate a proposed national marine sanctuary in the Pacific Remote Islands. The underlying concerns of these comments were still considered in the context of Papahānaumokuākea National Marine Sanctuary. Detailed responses to specific points of concern and opposition are addressed in the subsequent responses.

3. B-1 Comment: Commenters expressed opposition to for-profit activities in the sanctuary. One commenter recommended that no human activity should be allowed in the sanctuary.

Response: The sanctuary regulations were drafted to supplement and complement existing management of the area. The existing Monument management regime allows for some for-profit activities such as professional film-making, and activities such as wildlife management, research, and Native Hawaiian practices. All are subject to permitting requirements. Consistent with the existing management of the area, NOAA will allow for regulated access to the sanctuary for these types of activities. As in the Monument, in order to receive a permit for a regulated activity, a number of findings criteria need to be met, including that the proposed activity is conducted consistent with the primary objective of protection of sanctuary resources.

4. B-2 Comment: Commenters expressed concern regarding access to Papahānaumokuākea, noting that the area can currently only be experienced by a select group of scientists, Native Hawaiian cultural practitioners, and wealthy individuals.

Response: The sanctuary regulations and permit categories were drafted to supplement and complement existing

management of the area. Consistent with the presidential proclamations designating the PMNM and MEA, and the Monument implementing regulations at 50 CFR part 404, NOAA will allow for regulated access. Anyone may apply for a permit to access the sanctuary. There are six categories of permitted activities: research, recreation, education, Native Hawaiian practices, conservation and management, and special use. In addition, a vessel may pass without interruption through the sanctuary without requiring a permit as long as the vessel does not stop or engage in prohibited activities within the sanctuary.

Additionally, the sanctuary management plan describes strategies to engage and support diverse communities who care for Papahānaumokuākea, including Indigenous and underserved communities. NOAA recognizes the constraints imposed by the vastness and remote nature of the proposed sanctuary (nearly 300 miles at its closest point from the main Hawaiian Islands), and therefore strives to provide education and outreach that brings the place to the people. Through the Mokupāpapa Discovery Center and collaborations with other interpretive centers, organizations, business agencies, and others, NOAA has expanded a network serving both local, regional, and international audiences.

5. B-3 Comment: Commenters provided recommendations that permits be easy to acquire through a streamlined process to minimize barriers and reduce redundant reviews under various authorities and regulations. One commenter suggested that the process to acquire a sanctuary or Monument Native Hawaiian practices permit, specifically, should be prioritized and streamlined.

Response: The Monument joint permitting process has been in place and permits have been issued by the co-trustees since 2007. The sanctuary includes a permitting system modeled after the existing Monument permitting system, and was developed to allow for integration with the Monument permitting system, to ensure continued joint permitting administered by Monument co-trustees. See final EIS Section 3.3.1 for an updated description of the permitting process. Through sanctuary designation, NOAA strives to conduct seamless, integrated management, such that sanctuary permits, including Native Hawaiian practices permits, will go through the same streamlined process as currently exists for the Monument.

6. B-4 Comment: Commenters expressed concerns regarding activities that take place in the Northwestern Hawaiian Islands under claims of innocent passage, and requested that all activities in the area of the proposed sanctuary comply with the United Nations Convention on the Law of the Sea, which the U.S. recognizes as customary international law, and applicable international treaties.

Response: In the preamble of the proposed rule, NOAA specified that the proposed access and ship reporting regulations would be applied in accordance with generally recognized principles of international law, in accordance with sections 305(a) and 307(k) of the NMSA and the NMSA Regulations of General Applicability at 15 CFR 922.1(b). That is, no regulation shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States unless in accordance with generally recognized principles of international law. In accordance with 15 CFR 922.1(b), NOAA has long interpreted the text of NMSA Section 305(a) as encompassing international law, including customary international law.

In the preamble of this final rule, NOAA has clarified its intention that all regulations will be applied in accordance with generally recognized principles of international law, as well as in accordance with treaties, conventions, and other agreements to which the United States is a party.

7. B-5 Comment: A commenter provided a recommendation that the IMO's designation of the Monument as a PSSA apply to the MEA. The commenter also recommended that NOAA should determine, as part of the sanctuary designation process, if additional regulatory and management controls are necessary.

Response: The IMO process for designating an area as a PSSA is outside the scope of this action. If the U.S. Government determines at a future time that designation of some or all of the Monument as a PSSA is warranted, the IMO process would remain available. Through sanctuary designation, NOAA will implement the ship reporting system (CORAL SHIPREP), which was adopted by the IMO as an associated protective measure to the designation of the Monument as a PSSA. The ship reporting system's reporting area extends outward 10 nautical miles from the PSSA boundary, as designated by the IMO, and therefore includes some portions of the MEA waters. After thorough analysis, NOAA concluded that additional regulatory measures are not necessary at this time, beyond the

sanctuary regulations for ship reporting, access, and prohibited or otherwise regulated activities. Section IV.F of this final rule preamble provides details of the ship reporting system.

8. B-6 Comment: Commenters expressed support for access for recreational activities, including snorkeling and scuba diving; and allowing opportunities for the public to interact with Papahānaumokuākea in a safe and responsible manner. Commenters stated that allowing access for recreational activities may lead to increased awareness and support for the National Marine Sanctuary System. Commenters also provided recommendations for regulating recreational activities.

Other commenters expressed concern for the potential negative impacts to resources from allowing visitation, recreation, and tourism activities in the sanctuary, specifically Midway Atoll. A few commenters opposed recreational access to the sanctuary, noting that access should be limited to research and conservation activities and/or to the Midway Atoll Special Management Area.

Response: For the sanctuary, consistent with existing regulations for PMNM, recreational activity will be defined as activities conducted for personal enjoyment that do not result in the extraction of sanctuary resources and that do not involve a fee-for-service transaction. This includes, but is not limited to, wildlife viewing, scuba diving, snorkeling, and boating. Recreation can provide significant educational opportunities, build constituencies, and provide assistance to natural resource managers. However, these activities can also lead to wildlife disturbance, habitat degradation, and pollution. It is a goal of the Monument to prevent, avoid, or minimize negative human impacts associated with recreation by allowing access only for those activities that do not threaten the natural character or biological integrity of the Monument or Native Hawaiian cultural, historic, or maritime heritage resources.

Midway Atoll Special Management Area is the only area of the Monument where recreational activities are permitted. Thus, while the sanctuary will allow for recreational activities via a permit, permits will only be issued for the Midway Atoll Special Management Area within the sanctuary, in coordination with the Monument Management Board and consistent with permitting for the existing Monument. Consistent with permit criteria for recreational activities within the Monument, recreation permits will not

be issued for activities associated with any for-hire operation or for activities that involve extractive use.

9. B-7 Comment: Commenters expressed support for allowing a fee-for-service transaction for public visitation and recreational activities at Midway Atoll National Wildlife Refuge, and pointed out the existing authority of the USFWS to charge fees for public visitation. Commenters requested that the EIS recognize the authority of the USFWS to charge fees for services.

Response: Consistent with existing permit criteria and regulations for recreational activities within the Monument, recreation permits will not be issued for activities associated with any for-hire operation, and recreational activities are defined as activities conducted for personal enjoyment that do not result in the extraction of sanctuary resources and that do not involve a fee-for-service transaction. However, NOAA acknowledges that the USFWS has the authority to charge fees for services including public visitation (50 CFR part 25 Subpart E; *Refuge Rules and Policies*). Sanctuary designation will not change this authority, and the USFWS will still be able to charge fees for services, including public visitation to Midway Atoll. See also the response to E.3.

The EIS has been revised to acknowledge that the USFWS has the authority to charge fees for services including public visitation. See sections 3.2 and 4.6.2 of the final EIS.

10. B-8 Comment: Commenters requested that the USFWS consider a visitation program at Midway Atoll; and/or expressed support for recreation and visitation to Midway Atoll. Comments also requested that the final EIS describe the sanctuary permit process for public visitation and recreational activities at Midway Atoll National Wildlife Refuge.

Response: A visitation program to Midway Atoll is outside the scope of this action. NOAA will share these comments with the USFWS, a cooperating agency for this action, who has operated a Visitor Services Program for Midway Atoll. The USFWS' Midway Atoll Comprehensive Master Plan (2022) affirms the goals, objectives, and strategies of the previous 2008 Midway Atoll Visitor Services Plan, and USFWS' intent to implement a Visitor Services Program.

11. B-9 Comment: A commenter suggested that standards for permitting should be strengthened significantly, prioritizing Native Hawaiian practices without opening the door to other types of activities.

Response: Consistent with the presidential proclamations designating PMNM and the MEA, and PMNM implementing regulations at 50 CFR part 404, NOAA will allow for regulated access to the sanctuary. The sanctuary regulations include a permitting system modeled after the existing Monument permitting system, which was developed to allow for integration with the Monument permitting system to ensure continued joint permitting administered by the Monument Management Board (MMB). The final rule adopts the same permit criteria as currently required for Monument permits, including the additional criteria for Native Hawaiian practices and recreation permits. For additional information regarding Native Hawaiian practices permitting, see the responses to B.14 and C.1.

12. B-10 Comment: Commenters recommended that NOAA hold mandatory public hearings for all permit applications, that there should be a permanent public record for all permits granted, and that there should be no multiple-year permits allowed.

Response: The sanctuary regulations include a permitting system modeled after the existing Monument permitting system, and was developed to allow for integration with the Monument permitting system to ensure continued joint permitting administered by MMB. Therefore, NOAA intends to continue with the existing public notification process for the Monument, which does not include mandatory public hearings for all permit applicants. Instead, the existing permit system for the Monument includes a *Permit Application Unified Public Notification Policy* to engage and inform the public of activities proposed to occur within the Monument. Posting of a permit application does not equate to permit approval. After posting, each application is thoroughly reviewed by the MMB. Final permitted activities may differ from the proposed activities. Some of the public notification practices for the existing Monument include:

- Within 10 calendar days of receipt of an application, a summary of an applicant's proposed activities is posted for public viewing.
- Within 40 calendar days of receipt of an application, a full permit application is posted for public viewing.
- Permit applications that include proposed activities within the Northwestern Hawaiian Islands State Marine Refuge are also posted to the Board of Land and Natural Resources (BLNR) website for seven days prior to the scheduled BLNR meeting as part of the overall BLNR submittal process. The

BLNR hearings and review process are open to the public.

All information provided in the application is reviewed by the Monument co-trustees to evaluate the potential benefits of the activity, determine whether the proposed methods will achieve the proposed results, evaluate any possible detrimental environmental impacts, and determine if issuance of a permit is appropriate. Factored in is a consideration of whether the timeframe of the proposed action is appropriate. Actions occurring within State waters are subject to a maximum permit duration of one year, while multi-year permits may only be issued outside of State waters. Therefore, consistent with existing management, multi-year permits may be granted in areas of the sanctuary that do not overlap with state waters.

Additionally, permits granted are documented within an annual permitted activities report, published by the Monument. Reports for previous years may be viewed on the Permitted Activities Annual Reports *website*.

13. B-11 Comment: Commenters recommended that independent cumulative impact assessments be required for all permit applications.

Response: Permit decisions are Federal actions which are subject to NEPA, 42 U.S.C. 4321 *et seq.* In accordance with NEPA, NOAA considers possible cumulative environmental impacts when considering Federal actions, including a decision of whether to issue a permit.

14. B-12 Comment: Commenters expressed concern that a special use permit would introduce commercial activities.

Response: In the Monument, some forms of commercial activity are currently permitted under special ocean use permits. The existing regulations at 50 CFR 404 for PMNM include permit criteria and regulations for special ocean use, which means an activity or use of the Monument that is engaged in to generate revenue or profits for one or more of the persons associated with the activity or use, and does not destroy, cause the loss of, or injure Monument resources. This includes ocean-based ecotourism and other activities such as educational and research activities that are engaged in to generate revenue, but does not include commercial fishing.

Likewise, before issuing a SUP in the sanctuary, NOAA will also ensure, among other things, that the requested activity is compatible with the purposes for which the sanctuary is designated and with protection of sanctuary resources, and is conducted in a manner

that does not destroy, cause the loss of, or injure sanctuary resources (16 U.S.C. 1441(c)). NOAA can place conditions on SUPs specific to the activity being permitted. Individual permit applications that would require a SUP are also reviewed with respect to all other pertinent regulations and statutes, including NEPA (42 U.S.C. 4321 *et seq.*), and any required consultations, permits, or authorizations. Accordingly, there are sufficient safeguards in place for any activity proposed for a SUP in the sanctuary, whether of a commercial or non-commercial nature.

In addition, NOAA is not proposing any new SUP categories as part of this designation. In order to do so, NOAA would be required to provide appropriate public notice before identifying a new category of activity subject to a SUP (16 U.S.C. 1441(b)).

15. B-13 Comment: Commenters asked why the sanctuary permit would not allow for appeals of permit decisions.

Response: The permitting system for the sanctuary is modeled after the existing Monument permitting system. The permitting system would not supplant the joint permitting system for the Monument, and was developed to ensure a continued joint permitting system administered by the MMB. The existing permit system for the Monument does not include a process to appeal a permit decision. Instead, a permit applicant may seek reconsideration of a permitting decision by filing a new permit application that redresses the issue(s) in the initial application that caused the denial. To ensure consistency with the existing permit system for the Monument, the National Marine Sanctuary Program regulations at 15 CFR 922.37 for appeals of permitting decisions will not apply to Papahānaumokuākea National Marine Sanctuary. This will ensure that permit decisions are not made solely by NOAA, but in consideration with the other Monument co-trustees. See the final EIS, Section 3.3.1 and Section IV.P of this final rule for discussion of appeals of permitting decisions.

16. B-14 Comment: A commenter stated that the proposed rule's definition of "Native Hawaiian Practices" provides a solid foundation, but is concerned that "Native Hawaiian" is not defined. The commenter requested that the definition should narrowly reference indigenous practices and only those practices of the kānaka maoli, who lived and thrived in Hawai'i prior to European and American arrival.

Response: NOAA will not define "Native Hawaiian" in the sanctuary

regulations because the issuance of Native Hawaiian practices permit is based on evaluating the activity against the permit criteria. To be consistent with the types of activities permitted for the Monument, and allow for an integrated permit process, NOAA will issue Native Hawaiian practices permits based on the same permit review procedures and additional evaluation criteria as those used for the Monument:

- The activity is non-commercial and will not involve the sale of any organism or material collected;
- The purpose and intent of the activity is appropriate and deemed necessary by traditional standards in the Native Hawaiian culture (pono), and demonstrates an understanding of, and background in, the traditional practice and its associated values and protocols;
- The activity benefits the resources of the Northwestern Hawaiian Islands and the Native Hawaiian community;
- The activity supports or advances the perpetuation of traditional knowledge and ancestral connections of Native Hawaiians to the Northwestern Hawaiian Islands; and
- Any living sanctuary resource harvested under this permit will be consumed or utilized in the sanctuary.

The permitting system for the sanctuary is modeled after the existing Monument permitting system. The permitting system will not supplant the joint permitting system for the Monument, and was developed to ensure a continued joint permitting system administered by the MMB. The existing permit system for the Monument does not define Native Hawaiian, and instead provides a specific set of findings criteria for a Native Hawaiian practice permit. The criteria for the Monument Native Hawaiian practice permit were developed following a workshop in 2004 facilitated by Kia'i Kai, a graduate program at the Kamakakuokalani Center for Hawaiian Studies at the University of Hawai'i at Mānoa, collecting input from Native Hawaiian cultural practitioners, fishermen, and others to create criteria for culturally-appropriate activities in Papahānaumokuākea. Presidential Proclamation 8031 subsequently applied these criteria in providing for additional findings for Native Hawaiian practice permits, as did the Monument's implementing regulations at 50 CFR part 404.

However, while Native Hawaiian is not defined in the regulations, the final EIS, recognizes a definition for the term Native Hawaiian per existing Federal law as important background information for the reader. See also the response to C.8.

17. *B-15 Comment:* Commenters requested that wind turbine activity, in addition to mining and exploratory activities related to energy development, be prohibited.

Response: Consistent with the presidential proclamations establishing the Monument, NOAA will prohibit exploring for, developing, or producing oil, gas, or minerals to protect sanctuary resources. NOAA will also prohibit “any energy development activities” to further the underlying intent of the prohibition on oil, gas, and mineral development by accounting for technological advances in other forms of energy development. This includes, but is not limited to, wind turbines and exploratory mining activity.

18. *B-16 Comment:* Commenters requested that submarine activity be prohibited, with several comments specifically requesting prohibitions on military submarine use.

Response: Access to the sanctuary, and therefore submarine use within the sanctuary, would be prohibited and thus unlawful except under the following circumstances: for emergency response actions, law enforcement activities, and activities and exercises of the Armed Forces; pursuant to a sanctuary permit; when conducting scientific exploration or research activities by or for the Secretary of Commerce and/or the Secretary of the Interior in the Outer Sanctuary Zone; and when passing through the sanctuary without interruption. Further, all regulations will be applied in accordance with generally recognized principles of international law, as well as in accordance with treaties, conventions, and other agreements to which the United States is a party. No regulation shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law, or applicable treaties, conventions, and other agreements.

The sanctuary regulations allow activities and exercises of the U.S. Armed Forces. This is consistent with the existing management of the Monument, as both Presidential Proclamation 8031 and Presidential Proclamation 9478 provided broad exemptions for activities of the U.S. Armed Forces. However, all activities and exercises of the Armed Forces must be carried out in a manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on sanctuary resources and qualities.

19. *B-17 Comment:* Commenters expressed concern regarding the

potential spread of invasive species and diseases from vessel transit and biofouling, and requests that the prohibition on introducing invasive species apply to all vessels, including those passing without interruption.

Response: The sanctuary regulations will prohibit introducing or otherwise releasing an introduced species from within or into the sanctuary. The sanctuary regulations would also prohibit discharging or depositing any material or other matter into the sanctuary. These prohibitions are consistent with prohibitions identified in the presidential proclamations establishing the Monument. These prohibitions would apply to all vessels, including those passing without interruption. A vessel may only pass without interruption through the sanctuary without requiring a permit, as long as the vessel does not stop or engage in prohibited activities within the sanctuary.

20. *B-18 Comment:* Commenters stated that the provisions of Presidential Proclamation 8031, 50 CFR 404, Executive Order 13178 for the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, and the State of Hawai‘i Northwestern Islands Marine Refuge should be applied to the sanctuary regulations for the Monument Expansion Area and the full sanctuary, and specifically the prohibitions regarding fishing. Commenters also stated that Presidential Proclamation 9478 is too weak and provides “loopholes.”

Response: In drafting the sanctuary regulations, NOAA reviewed the executive orders, presidential proclamations, and regulations that currently guide Monument management. NOAA adopted the management measures from these benchmarks, and, in a few areas, added to those measures to allow for consistency in regulation and management across the sanctuary. The sanctuary regulations are largely consistent with Executive Order 13178, establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve). Where the sanctuary regulations do not align with Executive Order 13178, the regulations comply with other applicable law including Presidential Proclamations 8031 and 9478 establishing PMNM and MEA, respectively, which succeeded the 2000 executive order establishing the Reserve. For example, while Executive Order 13178 sets caps on commercial fishing, the sanctuary regulations prohibit commercial fishing across the sanctuary, consistent with the presidential proclamations. In addition,

the MEA’s location outside the reserve, and other applicable law for that area such as Presidential Proclamation 9478, account for differences in management, including for non-commercial fishing.

NOAA also considered that while the Monument is managed as a unit, several State and Federal conservation areas exist within it, where specific authorities apply. For example, the State of Hawai‘i has primary responsibility for managing the State waters of the Monument, including the State of Hawai‘i Northwestern Islands Marine Refuge. These existing authorities will still remain in effect. The State of Hawai‘i also served as a cooperating agency for the EIS, allowing consideration and input into the draft documents. Further, as the sanctuary overlaps with State waters, the State will co-manage the sanctuary with NOAA, and the governor of Hawai‘i will also review NOAA’s designation documents before the sanctuary designation is final.

21. *B-19 Comment:* A commenter expressed support for the prohibition on altering the seabed by modification or placement of materials, except for scientific instruments, providing new protections for the limited and sensitive habitats of the Outer Sanctuary Zone. The commenter noted that access through permitting would allow managers to review methodologies and monitor permittees, and that while minimal user contact with the seafloor occurs or is anticipated in the Outer Sanctuary Zone, these resources are rare and extremely vulnerable to disturbance.

Response: NOAA agrees. In the MEA, Presidential Proclamation 9478 prohibits this type of activity, except for when conducted for the use of scientific instruments, which is allowed only with a permit, subject to such terms and conditions as the Secretaries of Commerce and Interior deem appropriate. Therefore, in the sanctuary, these activities are prohibited unless conducted pursuant to a sanctuary permit, and in the Outer Sanctuary Zone, such a permit may only be issued for scientific instruments.

22. *B-20 Comment:* A commenter expressed concern for the prohibition on anchoring a vessel, noting that for safety reasons, there are some scenarios when a vessel should be able to anchor.

Response: Anchoring a vessel is prohibited unless conducted pursuant to a sanctuary permit. While this activity may be permitted via a sanctuary permit, anchoring on living or dead coral may never be permitted. NOAA will regulate anchoring a vessel for consistency with a regulated activity

identified in Presidential Proclamation 8031 for PMNM and because there is the potential for sanctuary resources, other than corals, to be impacted by anchoring. This prohibition is new for the area of the sanctuary that overlaps with the MEA. NOAA recognizes that there may be scenarios where anchoring a vessel is necessary for safety. Consistent with existing management of this area, the prohibitions for the sanctuary, including the prohibitions on anchoring, will not apply to any activity necessary to respond to emergencies that threaten life, property, or the environment, or to activities necessary for law enforcement purposes.

23. B-21 Comment: Commenters expressed concerns regarding the sufficiency of enforcement in the sanctuary and the need for improved monitoring and enforcement to protect sanctuary resources. Some commenters specifically pointed out the need for increased monitoring of pollution to prevent entanglement of marine life. Suggestions and recommendations included improved or expanded monitoring and surveillance, use of technology to aid enforcement including Automatic Information Service and satellite monitoring, promulgation of strict regulations, dedicated funding, a risk assessment framework for vulnerable ecosystems, and increased collaboration with the National Environmental Satellite, Data, and Information Service and the State of Hawai'i for satellite management. Commenters also requested that enforcement be conducted by traditional vessels or new technologies to eliminate noise pollution that may impact marine life.

Response: With sanctuary designation, the NMSA provides various regulatory tools and authorities for the protection of sanctuary resources. This includes the authority to conduct enforcement activities; assess civil penalties for violations of sanctuary regulations or permits; impose liability for destruction, loss of, or injury to sanctuary resources and provide natural resource damage assessment authorities for destruction, loss of, or injury to any sanctuary resource; and issue emergency response regulations. In addition, consistent with the existing management of the Monument, the sanctuary implements regulations requiring VMS units for an owner or operator of a vessel that has been issued a permit, as well as a ship reporting system for vessels that pass without interruption through the reporting areas. Both regulatory tools are intended to increase monitoring, in order to assist enforcement activities by the U.S. Coast

Guard and NOAA's Office of Law Enforcement and further the protection of sanctuary resources. Additionally, as described in the sanctuary management plan (final EIS, Appendix A), NOAA will continue to monitor ecosystems and seek out and develop new tools and technologies for resource protection and monitoring (Strategy 1.2, Strategy 2.2, Strategy 2.3); and to work with the existing interagency Law Enforcement Coordination Team to enhance communication and coordination among enforcement personnel in order to facilitate responses to incidents and uphold sanctuary regulations and policies (Strategy 1.9).

NOAA will continue to actively work and advocate inside the ecosystem protection framework established for the Monument to minimize risks and damages to sanctuary resources. For example, ongoing research aims to identify derelict fishing gear and other marine debris through unique spectral signatures that can be visualized from space to record locations and provide that information back to partners for removal. This technology has the potential to greatly reduce the effort to locate these hazards so that they can be removed from the environment. Some broad risk assessment investigations have been conducted by the Monument co-trustees (e.g., the Papahānaumokuākea Marine National Monument Climate Change Vulnerability Analysis (2014)), however, much more remains to be done. Challenges include the vast geographic extent of ecosystems and seasonal access limitations. Conducting such assessments will require substantial time, as well as the participation of all Monument co-trustee agencies.

Regarding reducing noise pollution from vessels to minimize wildlife disturbances, uncrewed surface vehicle (USV) technology is constantly improving and NOAA is exploring ways to utilize sail drones and other vessel systems in order to maintain a physical presence in sanctuary waters without having to dedicate staffed assets. These uncrewed platforms can utilize satellites to transmit location, vessel identification, and photographic evidence back to law enforcement officials in order to expand the geographic capacity of their limited resources.

24. B-22 Comment: Commenters recommended harsh penalties for those who violate the regulations, including requests for permit violators to be banned from receiving future permits.

Response: The NMSA authorizes NOAA to assess civil penalties for violations of provisions of the NMSA,

including sanctuary regulations and permits. Each violation of the NMSA, any NMSA regulation, or any permit issued pursuant thereto, is subject to a civil penalty. Each day of a continuing violation constitutes a separate violation. The NMSA has a statutory maximum of \$216,972 per violation, per the December 27, 2023 annual adjustment for inflation (see 88 **Federal Register** 89300).

Additionally, the NMSA regulations provide a list of findings, in addition to site-specific permit review criteria, which must be made before issuing a permit, such as whether the activity will be compatible with the primary objective of protection of sanctuary resources and qualities. The NMSA regulations also provide for the denial of a permit application based on various determinations, including that the applicant has acted in violation of the terms and conditions of a permit in a sanctuary in which the proposed activity is to take place, or has acted in violation of any sanctuary regulation, or for other good cause.

25. C-1 Comment: Commenters expressed support for Native Hawaiian rights, including statements that access to the sanctuary should be allowed for Native Hawaiians to connect with ancestors and 'āina and to perpetuate cultural practices based on pilina (relationships), kuleana (responsibilities), and genealogical connections to Papahānaumokuākea. This includes voyaging, which is vital for health, well-being, and in keeping Hawaiian culture and language alive. Commenters also stated that the allowance of Native Hawaiian traditional and customary practices should not be diminished or limited through sanctuary designation.

Response: NOAA recognizes the importance of Native Hawaiians' access to the sanctuary. Consistent with the presidential proclamations designating the Monument, NOAA will allow for regulated access to the sanctuary. Access will continue through a permit process. The sanctuary includes a permitting system modeled after the existing Monument permitting system, and was developed to allow for integration with the Monument permitting system, to ensure continued joint permitting administered by the MMB. The sanctuary has adopted the same permit criteria as currently required for the Monument, including for Native Hawaiian practices permits. See also the response to B.14.

The criteria for the Monument Native Hawaiian practices permit were developed following a workshop in 2004 facilitated by Kia'i Kai, a graduate

program at the Kamakakūokalani Center for Hawaiian Studies at the University of Hawai'i at Mānoa, collecting input from Kānaka 'Ōiwi cultural practitioners, fishermen, and others to create criteria for culturally-appropriate activities in Papahānaumokuākea. For more than 20 years, the Papahānaumokuākea Native Hawaiian Cultural Working Group (CWG) has provided guidance and advice. The CWG is a group of Kānaka 'Ōiwi kūpuna (elders), researchers, cultural practitioners, educators, and community members that have deep connections and historical ties to Papahānaumokuākea through a living pilina (relationship), bound by genealogy, cultural protocols, and values building contemporary multidisciplinary research and practice. Although the group is not a formalized advisory body, the CWG and many of its members have been involved for over two decades since the establishment of the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve in 2000, and provide an important Kānaka 'Ōiwi perspective that continues to inform Monument management. Since 2007, there have been 34 Native Hawaiian practices permits issued to perpetuate cultural practices ranging from traditional voyaging navigator apprenticeship and training, Hawaiian-led archaeological and cultural resource research, integrated cultural and scientific ecosystem monitoring, resource gathering including bird feathers/bones, and subsistence harvesting of fish, algae, and invertebrates. The growing number of Native Hawaiian permits submitted and issued provides significant support for and interest in conducting Hawaiian cultural practices, with at least eight ongoing cultural initiatives occurring on 27 separate expeditions.

26. C-7 Comment: A commenter expressed concern that the findings of the Cultural Impact Assessment *E Hoi I Ke Au A Kanaloa* were not integrated in the draft EIS and the Western Pacific Regional Fishery Management Council's (WPRFMC) draft fishing regulations.

Response: Findings of the Cultural Impact Assessment *E Hoi I Ke Au A Kanaloa* relating to the sanctuary proposal were addressed in Section 2.3.2, and more extensively in Chapter 5, of the draft EIS. NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA. Therefore, development and analysis of non-commercial fishing regulations for the MEA is not part of this action and was not analyzed in the draft or final EIS. NOAA and the State encourage

commenters to participate in the future public review process for non-commercial fishing regulations in the MEA under the authority of the MSA, and any associated NEPA and/or other environmental compliance documentation.

27. C-8 Comment: A commenter expressed concern that "Native Hawaiian" is not defined. The commenter recommended the following language and definition be adopted and integrated into the final EIS: Native Hawaiian is defined as "any individual who is a descendant of the aboriginal people who, prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawai'i." The commenter also recommended the incorporation of other self-identification names, including but not limited to Kānaka Maoli, Kānaka 'Ōiwi, and indigenous peoples or indigenous Native Hawaiians.

Response: In the final EIS, NOAA recognizes a definition for the term Native Hawaiian as it is commonly defined per existing Federal law as any individual who is a descendant of the aboriginal people who, prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawai'i. See Section 1.2.4.

Throughout the EIS, NOAA also uses Kānaka 'Ōiwi and/or Kānaka Maoli as terms that refer to Native Hawaiians.

28. D-1 Comment: Commenters expressed opposition to any new fishing closures, citing reasons that included:

- Fishing becomes more difficult and expensive for fishermen, including the Hawai'i longline fishery. The small boat fishing industry will slowly go away;
- No scientific evidence that large marine reserves provide conservation benefits to fish stocks;
- Fishing areas should be managed under Magnuson-Stevens Fishery Conservation and Management Act (MSA), and closures do not support MSA Standard 1: Conservation and management measures shall prevent overfishing while achieving, on a continuing basis, the optimum yield from each fishery for the United States fishing industry;
- Fishing closures do not meet the administration's mandate for equity and justice for underserved communities;
- Fishing closures affect food security and well-being of Native Hawaiians;
- Intergenerational transmission of fishing traditions will be impeded or lost;
- Native Hawaiians should be able to fish for food; and
- Sanctuaries and fishing should be able to coexist.

Response: NOAA is not establishing any new fishing closures through sanctuary designation. The sanctuary regulations regarding commercial and non-commercial fishing are consistent with the existing Monument and its management of the area. The presidential proclamations establishing the Monument broadly restrict the harvest of fishery resources by prohibiting removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging any living or nonliving Monument resource, as well as attempts to do the same, except as may be allowed with a permit. Presidential Proclamations 8031 and 9478 further specify prohibitions on commercial fishing and the possession of commercial fishing gear. The presidential proclamations also identify certain types of non-commercial fishing that may be regulated (*i.e.*, allowed pursuant to a permit or incidental to a permitted activity). Presidential Proclamation 8031, for example, authorizes sustenance fishing incidental to an activity permitted in PMNM. Presidential Proclamation 9478, for example, provides that non-commercial fishing is a regulated activity (*i.e.*, allowed only with a permit) in the MEA.

In the sanctuary, the fishing regulations included in the final rule are consistent with Presidential Proclamation 9478 and the existing management of the area. This includes prohibiting commercial fishing and regulating non-commercial fishing pursuant to a sanctuary permit or authorized under the MSA in the Outer Sanctuary Zone. The final rule provides the first set of implementing regulation consistent with directives in Presidential Proclamation 9478, which has the force of law.

29. D-2 Comment: Commenters provided suggestions and recommendations that appropriately regulated and monitored commercial fishing, including longline fishing and trolling, should be allowed in the sanctuary, as well as the "small boat community." One commenter stated that regulated traditional small boat fisheries should have a place. One commenter also inquired whether opportunities/mechanisms for future re-evaluation and allowance of commercial fishing in the sanctuary exist. One commenter also stated that there should be fishing line limits to reduce overfishing.

Response: In the sanctuary, fishing regulations are consistent with existing applicable law in the Monument. Existing applicable law in the area of the sanctuary prohibits commercial fishing. Presidential Proclamation 8031,

and its implementing regulations at 50 CFR part 404, prohibits commercial fishing for bottomfish and associated pelagic species in the Monument after June 15, 2011. Presidential Proclamation 9478 also prohibits commercial fishing in the MEA. Therefore, any consideration of regulations allowing commercial fishing in the sanctuary would not alter existing fishing prohibitions in the area. See the response to D.1 for more detail.

30. D-3 Comment: Commenters expressed opposition to allowing commercial fishing in Papahānaumokuākea.

Response: For consistency with existing regulations and the presidential proclamations establishing the Monument, regulations include a sanctuary-wide prohibition on commercial fishing. See also the responses to D.1 and D.2.

31. D-4 Comment: Commenters requested increased support for monitoring and enforcing fishing prohibitions, and requesting that international fishing vessels be prohibited.

Response: Existing applicable law in the area of the sanctuary prohibits commercial fishing. NOAA and the State agree that monitoring and enforcement of fishing prohibitions is critical to protecting sanctuary resources. NOAA's Office of Law Enforcement and the U.S. Coast Guard support enforcement efforts across the National Marine Sanctuary System. To assist in this coordinated effort for Monument enforcement, ONMS facilitates a Monument Law Enforcement Coordination Team which is composed of law enforcement representatives from NOAA, USFWS, U.S. Coast Guard, and Hawai'i Division of Conservation and Resource Enforcement. This group meets regularly to coordinate joint enforcement efforts in the Monument.

The designation of a national marine sanctuary provides the first set of implementing regulations for the directives in Presidential Proclamation 9478, including the prohibition on commercial fishing and regulation on non-commercial fishing. By establishing these new implementing regulations, NOAA will have new tools for enforcement, including the enforcement of fishing regulations. Sanctuary designation imparts a specific set of new benefits afforded by the NMSA, including the authorization to assess civil penalties for violations of the NMSA, including sanctuary regulations and permits.

Additionally, foreign fishing has remained prohibited in U.S. waters

since the introduction of the Magnuson-Stevens Fishery Conservation and Management Act of 1976. This prohibition was enacted on February 28, 1977 and remains in effect today with limited exceptions related to international fishery agreements that predated the MSA. There are no such allowances for foreign fishing activities within the U.S. EEZ that surrounds Hawai'i.

Regarding monitoring, see also the responses to B.21 and K.2.

32. D-5 Comment: Commenters expressed opposition to allowing non-commercial fishing and to the exemption (for non-commercial fishing in the MEA) in the proposed sanctuary rule, based upon biological, cultural, or co-management considerations. Out of concern for the proposed exemption of non-commercial fishing permits, one commenter suggested that non-commercial fishing permits should only be rarely granted, and carry strict catch limits.

Response: The presidential proclamations that established the Monument (8031 and 9478) served as benchmarks for drafting regulations for the sanctuary. The presidential proclamations identify certain types of non-commercial fishing that may be regulated (*i.e.*, allowed pursuant to a permit or incidental to a permitted activity). Presidential Proclamation 8031 authorizes sustenance fishing incidental to an activity permitted in PMNM. Presidential Proclamation 9478 provides that non-commercial fishing is a regulated activity (*i.e.*, allowed only with a permit) in the MEA, provided that the fish harvested, either in whole or in part, cannot enter commerce through sale, barter, or trade, and that the resource is managed sustainably. In the sanctuary, for consistency with the proclamations, "non-commercial fishing" is prohibited unless conducted pursuant to a sanctuary permit or through an exemption for non-commercial fishing authorized under the MSA in the Outer Sanctuary Zone (the area that overlaps with the MEA).

In response to comments of concern for this exemption, NOAA has made changes to the exemption for non-commercial fishing to ensure that a non-commercial fishing permit authorized under the MSA is only exempt from a limited subset of prohibited or otherwise regulated activities, and that these exempted activities are only conducted as incidental to and necessary to a lawful non-commercial fishing activity. NOAA has also clarified that this narrow exemption from the sanctuary's permitting requirements is only applicable provided that the fish

harvested, either in whole or in part, are neither intended to enter commerce nor enter commerce through sale, barter, or trade and that the resource is managed sustainably, consistent with Presidential Proclamation 9478. Moreover, for the exemption to apply, the fish harvested, either in whole or in part, must not be intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery. Corresponding changes have been made in the final EIS Section 3.3.1.

NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, and will invite the public to provide comments on the proposed non-commercial fishing regulations for the MEA. NOAA and the State encourage commenters to participate in the future public review process for non-commercial fishing regulations in the MEA under the authority of the MSA, including on the issuance of permits and catch limits, as those are outside the scope of this action.

33. D-6 Comment: Some commenters stated that fishing should not be restricted for Native Hawaiians and Indigenous populations and/or cultural practices. One commenter emphasized that it is culturally important to be able to bring fish home to share with family.

Response: Consistent with the existing management of the Monument and the proclamations that established the Monument, NOAA would continue to allow for regulated access to the sanctuary. Kānaka 'Ōiwi and Indigenous communities may apply for a permit to fish within the sanctuary. For consistency with the proclamations that established the Monument, "non-commercial fishing" is prohibited in the Sanctuary unless conducted pursuant to a sanctuary permit or authorized under the MSA in the Outer Sanctuary Zone. See the response to D.5. In the Outer Sanctuary Zone, the sanctuary regulations will not restrict the sharing of fish from non-commercial fishing activities authorized under the MSA.

34. D-7 Comment: A commenter requested that sustenance fishing be the only form of fishing allowed in the proposed sanctuary; and that there be a requirement that fish caught be consumed within the sanctuary, and not taken outside of the sanctuary. Others requested that sustenance fishing be allowed conditionally. Suggested conditions include by location; by permit type, and by sustainability criteria: (1) the activity must be "pono;" (2) the activity must benefit the resources of the Northwestern Hawaiian Islands and the Native Hawaiian community; and (3) any resource

harvested from the Monument must be consumed in the Monument. Finally, one commenter supported defining sustenance fishing as a Native Hawaiian practice.

Response: Sustenance fishing is currently allowed incidental to an activity permitted in PMNM, pursuant to Presidential Proclamation 8031, and the implementing regulations at 50 CFR part 404. Sustenance fishing was not specifically identified in Presidential Proclamation 9478 governing the MEA, but is considered a form of non-commercial fishing which may be regulated. For consistency in management and permitting, NOAA will manage this activity as a term or condition of a general permit or special use permit for the sanctuary, outside of any special preservation area. NOAA's sanctuary permit will follow the conditions of the existing Monument permitting system, including the considerations that sustenance fishing must be conducted only for the purpose of providing sustenance in support of activities otherwise allowed under an established permit and that the harvested resource must be consumed within the Monument.

In the Outer Sanctuary Zone, other types of non-commercial fishing may be allowed, consistent with the proper care and management of sanctuary resources and monument objects. Sanctuary designation provides the first set of implementing regulations for many of the directives in Presidential Proclamation 9478, including the regulation of non-commercial fishing in the MEA. Presidential Proclamation 9478 stated that non-commercial fishing may be regulated "provided that the fish harvested, either in whole or in part, cannot enter commerce through sale, barter, or trade, and that the resource is managed sustainably." Consistent with this proclamation, some forms of non-commercial fishing beyond sustenance fishing may be allowed in the MEA/ Outer Sanctuary Zone.

NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, and will invite the public to provide comments on the proposed non-commercial fishing regulations for the MEA. NOAA and the State encourage commenters to participate during that process.

35. D-8 Comment: Some commenters suggested that only subsistence fishing be allowed in the proposed sanctuary.

Response: In State of Hawai'i waters, extending three miles seaward of any coastline (excluding Midway Atoll), Native Hawaiian subsistence fishing, as defined by the State of Hawai'i, may be

allowed. NOAA acknowledges that the Monument's managing agencies define sustenance and/or subsistence fishing in different ways. Regardless, in PMNM, all fish caught shall be consumed within the Monument. Within the sanctuary, sustenance fishing would continue to be allowed (outside of the special preservation areas) to provide sustenance in support of activities otherwise allowed under an established permit.

36. D-9 Comment: Commenters asked why regulations have not been issued for the MEA to manage non-commercial fishing.

Response: President Obama issued Presidential Proclamation 9478 on August 31, 2016, which established the MEA. On September 23, 2016, NOAA Fisheries requested that the Western Pacific Regional Fishery Management Council (WPRFMC) develop recommendations to establish fishing regulations under the MSA, including the prohibition on commercial fishing and the regulation of non-commercial fishing within the MEA. However, no further action was taken by the WPRFMC in response to Presidential Proclamation 9478 at that time. NOAA cannot speculate as to why WPRFMC decided not to take action at that time.

NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA to reflect the outcome of the WPRFMC recommendation and the NMSA Section 304(a)(5) process. Appendix C to the final EIS provides further details of this consultation process.

37. D-10 Comment: Commenters expressed concern regarding the exemption of non-commercial fishing in the MEA, and that the issuance of non-commercial fishing permits will open the door to other types of fishing in Papahānaumokuākea. Commenters also expressed concern that a sanctuary designation would remove existing protections that prohibit various forms of fishing. One commenter recommended removing the exemption of non-commercial fishing to allow for more dialogue with the Native Hawaiian community.

Response: See the responses to D.5 and F.4. Sanctuary designation does not remove any existing protections that prohibit fishing. For consistency with the presidential proclamations establishing the Monument and the regulations at 50 CFR part 404, the sanctuary regulations will authorize limited forms of fishing.

38. D-11 Comment: Commenters expressed support for allowing recreational fishing, to sustain the

community and to allow for cultural and traditional practices. One commenter recommended that recreational fishing be monitored and regulated; that recreational fishers be required to attend courses to receive permits; and that NOAA and the State of Hawai'i update methods of data collection for recreational fishing. Another commenter suggested imposing fees for recreational fishing. Other commenters requested that NOAA implement measures to prevent recreational fishers from targeting "trophy" fish, and to limit fishing in general, to stem overfishing.

Response: For consistency with the proclamations, "non-commercial fishing" is prohibited in the Sanctuary unless conducted pursuant to a sanctuary permit or, as discussed below, through an exemption for non-commercial fishing authorized under the MSA in the Outer Sanctuary Zone. The final rule adopts the definition of "non-commercial fishing" from the regulations for fisheries in the Western Pacific, which is defined as "fishing that does not meet the definition of commercial fishing in the Magnuson-Stevens Fishery Conservation and Management Act, and includes, but is not limited to, sustenance, subsistence, traditional indigenous, and recreational fishing" (50 CFR 665.12). NOAA will periodically evaluate the effect of non-commercial fishing activities on sanctuary resources. Such evaluations would take into consideration the best scientific information available and evaluate whether additional actions are necessary for the proper care and management of sanctuary resources, including fishery resources, consistent with goals and objectives of the sanctuary.

Any requirements for non-commercial fishing permits authorized by NOAA Fisheries under the MSA are outside the scope of this action. NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, and will invite the public to provide comments on the proposed non-commercial fishing regulations. NOAA and the State encourage commenters to provide input during the public review process for non-commercial fishing in the MEA.

39. D-12 Comment: A commenter expressed opposition to the issuance of permits for recreational fishing in the MEA.

Response: Please see the response to D.11. As required by Section 304(a)(5) of the NMSA, NOAA consulted with the WPRFMC to recommend any draft fishing regulations it deemed necessary to implement the sanctuary designation.

The WPRFMC determined it was necessary to develop non-commercial fishing regulations, including for recreational fishing, for the area of the proposed sanctuary that overlaps with the MEA.

40. D-13 Comment: Commenters expressed support for non-commercial fishing in the MEA proposed by WPRFMC, including allowing sale and/or cost recovery.

Response: In accordance with Section 304(a)(5) of the NMSA, NOAA provided the WPRFMC with the opportunity to recommend any draft fishing regulations it deemed necessary to implement the proposed sanctuary designation. NOAA accepted the majority of the WPRFMC's recommendation, including those parts that were found to fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation. However, the WPRFMC's recommendation providing Native Hawaiian subsistence practices fishing permit applicants the ability to request limited cost recovery by selling their catch failed to fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation (see NOAA Response Letter dated on May 31, 2023, in the final EIS Appendix C.1). NOAA is preparing a separate proposed rule under the MSA to reflect the outcome of the NMSA Section 304(a)(5) consultation process. Appendix C to the final EIS provides further details on this consultation process.

41. D-14 Comment: Commenters expressed opposition to the annual catch limits proposed by WPRFMC. Several comments expressed concern that it does not align with Native Hawaiian cultural or subsistence practices. One commenter suggested additional involvement from the Native Hawaiian community and the Office of Hawaiian Affairs (OHA) on this matter.

Response: Any requirements and conditions for non-commercial fishing permits authorized by the MSA are outside the scope of this action. NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, and will invite the public to provide comments on the proposed non-commercial fishing regulations, including the catch limits. NOAA and the State encourage commenters to participate in the future public review process for non-commercial fishing in the MEA.

42. D-15 Comment: Commenters expressed opposition to any sale, barter, or trade and the cost recovery mechanism proposed by WPRFMC. Comments also expressed concern

regarding WPRFMC's definition of "customary exchange" and that it does not align with Native Hawaiian cultural or subsistence practices.

Response: NOAA agrees with some aspects of this comment. See the response to D.13 for information on NOAA's consideration of the WPRFMC's recommended fishing regulations, and the response to D.5 for details of the exemption for non-commercial fishing. NOAA has narrowed this exemption, making it only applicable provided that the fish harvested, either in whole or in part, are neither intended to enter commerce nor enter commerce through sale, barter, or trade and that the resource is managed sustainably, consistent with Presidential Proclamation 9478. Moreover, for the exemption to apply, the fish harvested, either in whole or in part, are not intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery. See the final EIS, Section 3.3.1. The WPRFMC's final recommendation (April 23, 2023) did not include a definition of "customary exchange", and NOAA ONMS has not included a definition of customary exchange in the sanctuary regulations.

43. D-16 Comment: Commenters requested that NOAA reject the proposed non-commercial fishing regulations by NOAA Fisheries and WPRFMC.

Response: NOAA accepted the majority of the WPRFMC's recommendation as it was found to fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation. However, NOAA did reject a portion of the WPRFMC's recommendation that would have allowed sale of catch under a Native Hawaiian subsistence fishing practices permit, as it was not found to fulfill the goals and objectives of the sanctuary designation. See the response to D.13, as well as Appendix C to the final EIS, for further details of this consultation process.

44. D-17 Comment: Commenters expressed concern for a portion of the WPRFMC's recommendation on "research fishing," and definition that would include "research fishing" as a form of non-commercial fishing.

Response: NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, based on the WPRFMC's recommendations. NOAA and the State encourage commenters to provide additional input, including on research fishing, to the future public review process for non-commercial fishing regulations in the MEA.

45. D-18 Comment: A commenter expressed concern that while resources in the Monument are a co-management trust responsibility, the proposed fishing regulations for the MEA have been developed without adequate inclusion of the perspectives of the Monument co-managers.

Response: NMSA Section 304(a)(5) required NOAA to consult with the WPRFMC to recommend any draft fishing regulations it deemed necessary to implement the sanctuary designation. The State of Hawai'i maintains voting seats, and the USFWS maintains non-voting seats on the WPRFMC. The WPRFMC determined it was necessary to develop non-commercial fishing regulations under the MSA, for the area of the proposed sanctuary that overlaps with the MEA. In accordance with the Section 304(a)(5) process, NOAA accepted those parts of the WPRFMC's recommendation that fulfilled the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation, and rejected those parts that did not. Under the MSA's rulemaking process, the WPRFMC will transmit its recommendation to NOAA Fisheries, who will then prepare a proposed rule for non-commercial fishing regulations in the MEA under the MSA.

46. D-19 Comment: Commenters expressed concern regarding the separation of the NOAA Fisheries fishing regulations from the sanctuary designation process, which lacks transparency and thorough analysis of potential impacts. Commenters also requested an additional EIS and a public review of the proposed fishing regulations for the MEA. Commenters expressed concern that the proposed fishing regulations were developed in an improper sequence and there was no timeline included. Commenters also stated that impacts of WPRFMC's proposed non-commercial fishing regulations should have been analyzed within the draft EIS.

Response: NOAA acknowledges the confusion regarding the timeline of proposed fishing regulations for the MEA. NOAA Fisheries is responsible for fisheries management under the MSA and is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA. NOAA Fisheries will analyze the environmental impacts of the non-commercial fishing regulations in the MEA under the authority of the MSA in a manner consistent with NEPA. NOAA has made revisions in sections 1.4 and 3.7.2 of the final EIS to clarify this. NOAA and the State encourage commenters to participate in the future

public review process for non-commercial fishing regulations in the MEA under the authority of the MSA.

47. D-23 Comment: A commenter recommended that any activity relating to the extraction of fish be led by Native Hawaiians.

Response: The permitting system and regulations for the sanctuary is modeled after the existing Monument regulations and permitting system. The permitting system would not supplant the joint permitting system for the Monument, and was developed to ensure a continued joint permitting system administered by the MMB. While the presidential proclamations establishing the Monument broadly restrict the harvest of fishery resources, and identify certain types of non-commercial fishing that may be regulated (*i.e.*, allowed pursuant to a permit or incidental to a permitted activity), there are no restrictions as to who may apply for a permit. Sanctuary designation will not change this.

48. D-24 Comment: Commenters expressed opposition to allowing any form of fishing in the proposed sanctuary. Some associated comments stated opposition to the removal of any wildlife from the proposed sanctuary.

Response: See the response to D.1. The presidential proclamations establishing the Monument broadly restrict the harvest of fishery resources and further specify prohibitions on commercial fishing and identify certain types of non-commercial fishing that may be regulated. In the sanctuary, regulations for fishing are consistent with the proclamations and existing management of the area.

49. D-25 Comment: A commenter requested that, in the event of a natural disaster occurring with severe impacts to the food supply of Hawai'i, the proposed sanctuary should allow for sustenance fishing and sharing of fish with community.

Response: NOAA cannot speculate about how the NMSA and other authorities may or may not be used in the future scenario described by the commenter. However, in the Outer Sanctuary Zone (MEA), the sanctuary regulations will not restrict the sharing of fish from non-commercial fishing activities authorized under the MSA.

50. D-26 Comment: A commenter emphasized that new sanctuary regulations should be limited to those relating to the seafloor and islands within the MEA, as the MSA already provides for the management of fisheries in all U.S. waters.

Response: NOAA may regulate fishing under the MSA and the NMSA. See also the response to D.9. While NOAA may

regulate fishing under NMSA, and regulates fishing in the sanctuary consistent with the existing management of the area, per section 304(a)(5) of the NMSA, NOAA also provided the WPRFMC with the opportunity to recommend any draft fishing regulations it deemed necessary to implement the proposed sanctuary designation. NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA to reflect the outcome of the NMSA section 304(a)(5) process.

51. D-27 Comment: A commenter expressed opposition to any prohibitions that may affect existing community-based subsistence fishery areas, and requested that NOAA incorporate language that explicitly includes community- and cultural-based subsistence-based fishing practices as part of protected Native Hawaiian customs and practices.

Response: Community-based subsistence fishery areas are locally based, legally designated areas in the Main Hawaiian Islands where communities and the state government work together to protect and support traditional Hawaiian fishing practices. To date, there have been no community-based subsistence fishery areas established within Papahānaumokuākea. Since these areas are typically initiated at the local level by communities seeking enhanced protection of their nearshore resources, the future establishment of a community-based subsistence fishery area within Papahānaumokuākea is unlikely. As such, a discussion of such areas is beyond the scope of this action. For a description of how culturally-based subsistence fishing practices are addressed within the sanctuary, please see the response to D.8.

52. E-1 Comment: Commenters asked how a proposed sanctuary would modify the existing co-management structure for the Monument. Commenters requested articulation of roles of OHA, USFWS, and the State of Hawai'i, specifically who has jurisdiction in which areas, as well as requested that the EIS provide a detailed governance framework and a dispute resolution process for the proposed sanctuary. Commenters also stated that the draft EIS and/or draft sanctuary management plan did not clearly articulate how the sanctuary would function in coordination with the existing Monument, nor articulate how the Monument co-trustee's authorities could be used to supplement and complement NOAA authorities. One commenter suggested that NOAA

provide a graphic depicting the relationship of the proposed sanctuary with existing Monument management. Finally, some commenters questioned if there are deficiencies in the existing Monument management framework, while one commenter stated that the proposed sanctuary rule has led to confusion over the legitimacy of the Monument co-management framework.

Response: The existing Monument is jointly administered by the four co-trustees (DOC, DOI, State of Hawai'i, and OHA) through the seven-member MMB. ONMS and NOAA Fisheries collaborate to fulfill DOC's co-trustee responsibilities under the Monument, and ONMS serves on the seven-member MMB. A graphic of the existing management structure is described in the final EIS Section 3.2. Sanctuary designation will not change the existing management structure, and ONMS' role within the management framework will remain, with the added authority provided by the NMSA. Additional information has been added to the sanctuary management plan in sections 1 (About This Document) and 2 (Cooperative and Coordinated Management) and Acknowledgements to clarify this. NOAA has also made revisions to the description of the No Action Alternative in Section 3.2 of the final EIS to better articulate the existing roles of each Monument co-trustee, including their jurisdiction and authorities that guide their role in managing the Monument. Existing authorities, including management authorities of all Monument co-trustees, will remain in effect under all action alternatives.

As a result of the existing Monument management framework, of which ONMS is a critical part, the final rule and sanctuary management plan have been specifically designed to be consistent with the current management framework, and to allow for seamless operations between the Monument and sanctuary. The sanctuary will supplement and complement existing management of the Monument, and not replace or diminish the existing management of the Monument. In accordance with the NMSA, in designating a sanctuary, NOAA determines if existing authorities should be supplemented to ensure coordinated and comprehensive conservation and management of the area.

NOAA has provided additional details clarifying consistency with the management framework in Section 3.3.1 of the final EIS. Specifically, NOAA will work in cooperation with the Monument co-trustees to update the existing MOA for the Monument with

the State of Hawai'i, DOI/USFWS, and OHA to reflect the addition of the sanctuary. Further, the existing Monument MOA includes a provision that states that "in the event of the designation of the Monument or any portion of the Monument as a National Marine Sanctuary under the National Marine Sanctuaries Act, nothing herein shall be construed as automatically terminating or otherwise amending this Agreement."

53. E-2 Comment: Commenters expressed concerns regarding the exclusion of some of the Monument co-trustee agencies from co-management of the sanctuary. Commenters requested that NOAA co-manage the sanctuary with all of the Monument co-trustees (DOI, OHA, and the State of Hawai'i), and that NOAA should receive approval from and/or collaborate with the other co-trustees regarding decision making for the sanctuary. Commenters also requested that a MOA be developed to articulate the governance framework for the sanctuary, and any co-management agreement.

Response: NOAA has clarified in the final rule and the final EIS (see final EIS Section 3.3.1, final rule Section IV.D, and sanctuary management plan Section 2) how the sanctuary will be managed in partnership with USFWS and OHA. In the proposed rule, NOAA proposed that the sanctuary would be co-managed with the State of Hawai'i. Recognition of the State of Hawai'i as a co-manager was not meant to exclude the other Monument co-trustees, USFWS and OHA. To the contrary, partnerships with other Federal and State agencies with overlapping jurisdiction are critical to the success of the National Marine Sanctuary System. In the proposed regulations, NOAA was trying to explain the role that states may have in co-managing a sanctuary under the NMSA if all or part of the proposed sanctuary is within the territorial limits of any state. In the final regulations and management plan, NOAA has added new text regarding how NOAA will manage the sanctuary in partnership with the other Monument co-trustees, DOI/USFWS and OHA, as the existing co-management structure of Papahānaumokuākea Marine National Monument is critical to the success of the sanctuary.

NOAA intends to, in cooperation with the Monument co-trustees, update the existing MOA for the Monument between the State of Hawai'i, DOI/USFWS, and OHA to reflect the addition of the sanctuary. NOAA is developing an MOU with the USFWS to provide details on using supplemental authority under the NMSA to protect

resources where the sanctuary overlaps with national wildlife refuges. Finally, the sanctuary management plan was developed in consultation with the State, USFWS, and OHA to explicitly ensure concurrence of plans between the sanctuary and the Monument. Additional language has been added to the sanctuary management plan (Appendix A) to better reflect the goal of cooperative management with the Monument co-trustees.

54. E-3 Comment: Commenters requested that the final EIS should include a clear description of the permitting system for the proposed sanctuary and how it would relate to the existing Monument permitting system, including how sanctuary permits would be reviewed, approved, and conditioned. Commenters expressed that NOAA should not have sole authority over permitting for activities in the area of the sanctuary and Monument; that only one permitting system should apply to the area; that permits should be approved by all Monument co-trustees; and that the Monument permit process should be amended to include sanctuary permitting. One commenter expressed concern regarding the proposed special use permit, which allows for fee collection for permit processing. The commenter questioned how this would work alongside the Monument permit process, and asked if NOAA would keep fees internally, or divide fees received equitably amongst Monument co-managers.

Response: The Monument's joint permitting system has been in place and permits have been issued by the co-trustees since 2007. The unified Monument permitting process includes a unified Monument permit application, instructions, and template (see final EIS Section 3.2). All permitted activities in PMNM are authorized under the issuance of a single Monument permit signed by the USFWS, NOAA, and the State of Hawai'i, in cooperation with OHA. The sanctuary permitting system would complement the existing Monument permitting system, and was developed to allow for integration with the Monument permitting system, to ensure continued joint permitting administered by the MMB, which includes ONMS. The sanctuary permitting system would not supplant the joint permitting system for PMNM. The sanctuary permit categories were designed to provide the same management function and permittee interface as the current Monument permit categories. The sanctuary adopts the same permit criteria as currently required for Monument permits,

including the additional criteria for Native Hawaiian practices and recreation permits. To provide more clarity, NOAA has updated its description of the sanctuary permitting process in the final EIS, Section 3.3.1.

Prior to sanctuary designation, regulations to issue permits in the MEA had not been established and activities in the MEA have been approved via a Letter of Authorization signed by USFWS. The co-trustees agreed to implement this USFWS process as an interim measure. Sanctuary designation provides the first set of implementing regulations consistent with directives in Presidential Proclamation 9478, including regulations for permitting, in addition to governing the sanctuary.

Regarding special use permits, NOAA intends for any issuance of special use permits to be done so in coordination with the existing permit process. NOAA points out that while the Monument is jointly administered, some areas are also guided by other specific authorities. For example, USFWS has the authority to charge fees for services including public visitation (50 CFR part 25 Subpart E) in areas of the Monument that also fall within a national wildlife refuge. NOAA's authority to collect fees for special use permits provides Monument managers with a larger area, beyond the national wildlife refuges, for which permit fees may be collected for specific activities. In accordance with the NMSA, NOAA may recover administrative costs for staff time to review and take action on the permit, and for a fair market value for use of the sanctuary. While this authority may be used, the collection of fees is not required. Further, NOAA is not proposing any new category of activity subject to a special use permit as part of this designation, and due to the existing regulations for the Monument and the sanctuary, the issuance of special use permits is expected to be limited.

55. E-4 Comment: Commenters expressed concern regarding the proposed process for permitting non-commercial fishing in the MEA. Commenters specifically stated that any fishing permits should also require a consistency review by the Monument co-managers. Some commenters suggested that non-commercial fishing in the MEA should be part of a single permitting process for the sanctuary and/or Monument, and not done through a separate process, noting that any permits that authorize resource extraction should be reviewed by the MMB.

Response: NOAA's ONMS will not issue non-commercial fishing permits as part of the sanctuary regulations, but

will allow sustenance fishing as a term or condition of a permit, consistent with existing management of the Monument. In response to a recommendation for fishing regulations in the MEA by the WPRFMC, NOAA Fisheries is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, will complete the environmental compliance requirements, and will accept public comment on the proposal. NOAA and the State of Hawai'i encourage the commenter to review and participate in the future public review process for the proposed rule and any associated NEPA and/or other environmental compliance documentation for non-commercial fishing regulations in the MEA.

56. E-5 Comment: Commenters expressed concern regarding potential conflicts between the proposed sanctuary permitting process and permitting authorized by the USFWS for the Midway Atoll and Hawaiian Islands National Wildlife Refuges. One commenter stated that the USFWS has an existing process to review and issue permits to regulate use of the national wildlife refuges for research, education, management, and recreation. A commenter suggested the development of a MOU among USFWS, NOAA, and the State of Hawai'i to clarify the permit process, which should include provisions for dispute resolution and for emergency situations when actions are necessary to protect human health and safety on Midway Atoll. Commenters also expressed concern regarding the permitting of activities in the MEA, including questioning why NOAA does not recognize DOI's authority to issue permits in the MEA, and requested that any new permitting in the MEA should be done following agreement with the MMB. Finally, one commenter questioned if the USFWS would need to acquire permits from NOAA for management activities in the national wildlife refuge waters.

Response: NOAA has added additional clarification in the final rule and the final EIS (see Section 3.3.1 and Section IV.D in the preamble of the final rule) regarding how the sanctuary will be managed in partnership with other agencies. In addition to co-management with the State, NOAA will manage the sanctuary in partnership with the USFWS and OHA consistent with the management of the Monument. NOAA will work in cooperation with Monument co-trustees to update the memorandum of agreement for the Monument with the State of Hawai'i, DOI/USFWS, and OHA that reflects the addition of the sanctuary, and specifically addresses how the addition

of a sanctuary will supplement and complement, and not supplant, the existing Monument management framework. NOAA and USFWS are developing an agreement to provide details on the execution of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, and will consider if provisions are needed for dispute resolution and for emergency situations when actions are necessary to protect human health and safety on Midway Atoll.

Management of the MEA is governed by Presidential Proclamation 9478. Prior to sanctuary designation, regulations to issue permits in the MEA had not yet been established and activities in the MEA have been approved via a Letter of Authorization signed by USFWS. The co-trustees agreed to implement this USFWS process as an interim measure. Sanctuary designation provides the first set of implementing regulations, including regulations for permitting, in the MEA.

57. E-6 Comment: Commenters requested that NOAA co-manage the sanctuary specifically with the USFWS, and/or that NOAA consult with USFWS for decision making and environmental analysis in the proposed sanctuary. Some commenters also requested that NOAA recognize the authority of the USFWS, that NOAA not supersede the authority of the USFWS, and that NOAA acknowledge that the USFWS has sole authority for certain decisions in the national wildlife refuges. Some commenters expressed concern that the proposed sanctuary would give NOAA and the State of Hawai'i precedence over USFWS management of refuge waters. One commenter recommended that a MOA be developed and signed by the Secretaries of Interior and Commerce, and that a 3rd party neutral facilitator be selected to oversee implementation of the MOA. The commenter specified that the MOA should be reviewed and updated, as needed, every five years.

Response: NOAA will manage the sanctuary in partnership with the USFWS. Nothing in the establishment of the national marine sanctuary will diminish USFWS's authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act. Where Papahānaumokuākea National Marine Sanctuary overlaps Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the National Marine Sanctuaries Act to provide

supplemental authority to protect resources.

In other sanctuary sites, when there is jurisdictional overlap between NOAA and USFWS, the agencies have worked to implement their respective authorities in a manner that complements, but does not diminish or interfere with, existing authorities and strengthens existing protections and management. NOAA and USFWS are developing an agreement to provide details on the execution of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge. Any agreement developed between NOAA and the USFWS will be updated as needed, as determined by the agencies.

58. E-7 Comment: Commenters requested that NOAA co-manage the sanctuary specifically with OHA. Commenters emphasized that excluding OHA would be akin to suppressing Native Hawaiian voices and/or usurping the sovereignty of OHA. Commenters requested that NOAA consider temporarily halting sanctuary designation until Federal law allows for explicit co-management structures that include native governing bodies as equal decision-makers, and requested that NOAA work with OHA and the Native Hawaiian community to achieve the ability for Indigenous governing bodies to be eligible to be named as co-managers for marine sanctuaries under the NMSA. One commenter also pointed out that for National Marine Sanctuary of American Samoa, the American Samoa Department of Commerce has been designated as a co-manager to assist NOAA with the administration of the sanctuary, and therefore, OHA should be able to serve as a co-manager of the proposed sanctuary.

Response: NOAA will manage the sanctuary in partnership with the OHA, consistent with the management of the Monument. The existing co-management structure of the Monument and cooperation with OHA is critical to the success of the sanctuary. NOAA will work in cooperation with Monument co-trustee to update the Memorandum of Agreement for Promoting Coordinated Management of Papahānaumokuākea Marine National Monument with the State of Hawai'i, DOI/USFWS, and OHA that reflects the addition of the sanctuary, and specifically addresses how the addition of a sanctuary will supplement and complement, and not supplant, the existing Monument management framework. Under Monument management, OHA has primary responsibility for representing the interests of the Kānaka 'Ōiwi

community in the perpetuation of Hawaiian cultural resources and practices. Sanctuary designation will not change this, and NOAA intends to consult with OHA on all matters related to the perpetuation of Hawaiian cultural resources and practices.

Pursuant to the NMSA, a “state” as defined under the act, may have a role in co-managing a sanctuary if all or part of the proposed sanctuary is within the territorial limits of any state. For this reason, NOAA will co-manage the sanctuary with the State of Hawai‘i. In addition, pursuant to the NMSA, the “state” means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, the Virgin Islands, Guam, and any other commonwealth, territory, or possession of the United States. As the NMSA also defines “state” to include American Samoa, they may be a co-manager of National Marine Sanctuary of American Samoa, and the American Samoa Department of Commerce acts as the lead territorial agency.

59. E–8 Comment: Commenters requested that NOAA co-manage the sanctuary with Native Hawaiians, noting that it is critical for Native Hawaiians to be present, participatory, and empowered in all decision-making aspects regarding Papahānaumokuākea. Commenters requested that Native Hawaiians should direct and oversee plans for the sanctuary, and that NOAA should defer to opinions of Native Hawaiian groups and agencies. Some commenters suggested that management with Native Hawaiians go beyond co-management with OHA.

Response: See the response to E.7, regarding how NOAA will manage the sanctuary in partnership with OHA, but NOAA also agrees that there are opportunities for co-stewardship with the Kānaka ‘Ōiwi community beyond OHA. NOAA agrees that it is important to have Kānaka ‘Ōiwi expertise in management, including in leadership roles and that growing long-lasting partnerships with existing Kānaka ‘Ōiwi community partners is integral to management of the sanctuary (see the responses to C.2 and K.1).

NOAA has a responsibility to, and takes opportunities to work through equitable partnerships with all Indigenous Peoples. The *Imila-alpa Commitments* demonstrate ONMS’ dedication to strengthening partnerships with Indigenous governments, organizations, and communities and ensuring that ONMS’ intentions align with its actions. The commitments also state that ONMS will work to

implement White House and NOAA guidance on integrating Indigenous knowledge into processes and approaches.

60. E–9 Comment: Commenters suggested or requested that the Native Hawaiian CWG be granted authority in reviewing and approving permits to access Papahānaumokuākea and/or be granted authority to vet the permit applications. Some commenters suggested that the Native Hawaiian Cultural Working Group should be included as a fifth co-trustee of the Monument.

Response: For more than 20 years, the CWG, which advises OHA as a co-trustee of the Monument, has provided guidance and an important Native Hawaiian perspective to inform Monument management. The CWG is a group of Kānaka ‘Ōiwi kūpuna (elders), researchers, cultural practitioners, educators, and community members that have deep connections and historical ties to Papahānaumokuākea through a living pilina (relationship) bound by genealogy, cultural protocols, and values building contemporary multi-disciplinary research and practice. The CWG and many of its members have been involved since ONMS created the CWG following the establishment of the Northwest Hawaiian Islands Coral Reef Ecosystem Reserve in 2000. The CWG has a permit subcommittee that reviews Monument permits and provides input to OHA, a Monument co-trustee who also sits on the Monument permit working group. The sanctuary permitting system will complement the existing Monument permitting system, and was developed to allow for integration with the Monument permitting system, to ensure continued joint permitting administered by the MMB. Therefore, NOAA intends for the CWG to continue to provide advice and guidance on permitting for Papahānaumokuākea.

Consideration of the CWG as a co-trustee of the Monument is outside the scope of the action to designate a national marine sanctuary, because a sanctuary designation would not alter the underlying Monument management structure.

61. E–10 Comment: Commenters expressed concerns regarding NOAA being the primary manager of the proposed sanctuary, and questioned what role the State of Hawai‘i had in developing the proposed sanctuary. One commenter requested that there be a checks and balance system with the State of Hawai‘i and Native Hawaiian groups when reviewing the objectives, actions, regulations, exceptions, permits, and penalties.

Response: The NMSA provides authority for NOAA, among other things, to designate a sanctuary and promulgate regulations implementing the designation. Pursuant to the NMSA, states may choose to have a role in co-managing a sanctuary if all or part of the proposed sanctuary is within the territorial limits of any state. As the sanctuary includes state waters, NOAA will co-manage the sanctuary with the State of Hawai‘i. NOAA establishes the framework for co-management in Section 922.242 of the final rule and may update existing agreements or develop additional agreements with the State of Hawai‘i to clarify the terms of co-management. Any future proposed changes to sanctuary regulations or boundaries would be coordinated with the State and subject to public review as mandated by the NMSA and other Federal statutes.

The State of Hawai‘i also supports the sanctuary proposal. While NOAA was the lead Federal agency in the preparation of the EIS, the State of Hawai‘i served as a cooperating agency and co-developed the draft EIS and final EIS, which was also developed in accordance with the Hawai‘i Environmental Policy Act (HEPA, Chapter 343 HRS, HAR Chapter 11–200.1). The State of Hawai‘i also co-developed the sanctuary management plan.

62. F–1 Comment: Some commenters opposed the exemption for “scientific exploration or research activities by or for the Secretary of Commerce or the Secretary of the Interior when the activity occurs in the Outer Sanctuary Zone.” Commenters stated that the exemption may provide a loophole to permit large-scale take/extraction of resources. Commenters felt that the Department of Commerce and the Department of the Interior should still be required to obtain sanctuary permits.

Response: Presidential Proclamation 9478, which designated the MEA, specifically states that the prohibitions “shall not restrict scientific exploration or research activities by or for the Secretaries and nothing in this proclamation shall be construed to require a permit or other authorization from the other Secretary for their respective scientific activities.” Presidential Proclamation 9478 further highlights the significant scientific value of the MEA and underscores the opportunities for research and discovery to occur in that area, including understanding the impacts of climate change on deep-sea communities and identifying new species. NOAA is exempting scientific exploration or research activities from the sanctuary’s

prohibitions and permitting requirements for both the Department of Commerce and the Department of Interior within the Outer Sanctuary Zone, to be consistent with Presidential Proclamation 9478. However, such activities must still comply with other Federal environmental laws such as the NEPA, the Endangered Species Act, the NMSA section 304(d), and the Marine Mammal Protection Act

63. F-2 Comment: Commenters requested that Hawaiian-focused research conducted by Hawaiians be prioritized by providing an exemption for these activities.

Response: The sanctuary permitting system and the exemptions were modeled after the existing Monument permitting system. The sanctuary permitting system would not supplant the existing permitting system for the Monument and was developed to ensure a continued joint permitting system administered by the MMB. Therefore, rather than introducing a new exemption, NOAA and the State will work to prioritize Hawaiian-focused research through other practices, as described in the draft sanctuary management plan (final EIS Appendix A), including:

- supporting and facilitating Kānaka ʻŌiwi (Native Hawaiian) access and research (Strategy 2.6);
- weaving together multiple knowledge systems, values, practices, and methods, in science and research (Strategy 2.7); and
- supporting research initiatives that focus on next-generation capacity building for leadership succession of Kānaka ʻŌiwi (Native Hawaiian) and Pacific Islanders who are severely underrepresented in STEM and ocean sciences (Strategy 2.8).

64. F-3 Comment: Some commenters opposed the exemption for the activities and exercises of the U.S. Armed Forces, noting specific concern for military sonar activity.

Response: The sanctuary regulations and both Presidential Proclamations 8031 and 9478 include a broad exemption to allow activities and exercises of the U.S. Armed Forces, including those carried out by the U.S. Coast Guard. The sanctuary regulations specify that all activities and exercises of the Armed Forces shall be carried out in a manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on sanctuary resources and qualities. For any Federal agency actions, including actions of the Armed Forces that are likely to destroy, cause the loss of, or injure sanctuary resources, the Armed Forces must

comply with the consultation requirements outlined in Section 304(d) of the NMSA, regardless of whether those actions are exempted from the sanctuary's regulations.

65. F-4 Comment: Commenters expressed opposition to the exemption for non-commercial fishing activities authorized under the MSA. Commenters stated that non-commercial fishing permit holders should not have exemptions to conduct the otherwise prohibited and regulated activities of the sanctuary and that any non-commercial fishing activities should still require a separate sanctuary permit. One commenter stated that ONMS should promulgate regulations under the National Marine Sanctuaries Act as a backstop and not rely solely on the Magnuson-Stevens Fishery Conservation and Management Act application. Commenters stated that the exemption for non-commercial fishing is counter to Mai Ka Pō Mai. Commenters also requested that NOAA gather more input from the Native Hawaiian community, including the OHA and the Native Hawaiian Cultural Working Group on this topic.

Response: As required by Section 304(a)(5) of the NMSA, NOAA provided the WPRFMC with the opportunity to recommend any draft fishing regulations it deemed necessary to implement the proposed sanctuary designation. NOAA participated in six public meetings hosted by the WPRFMC on November 1st, 3rd, 4th, 5th, 8th, and 10th of 2022, which were focused on the development of fishing regulations for the area of the proposed sanctuary that overlaps with the MEA. In December 2022, the WPRFMC provided a recommendation for non-commercial fishing regulations for the area of the proposed sanctuary that overlaps with the MEA. NOAA accepted the majority of the WPRFMC's recommendations, as they were found to fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation. However, the WPRFMC's recommendation to provide Native Hawaiian subsistence practices fishing permit applicants the ability to request limited cost recovery by selling their catch in the permit application process through a statement of need for cost recovery along with expected costs, failed to fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation. Additionally, NOAA found that the allowance of "sale" under a Native Hawaiian subsistence practices fishing permit is inconsistent with the State's constitutional protection of

Native Hawaiian traditional and customary rights.

Accordingly, the sanctuary regulations proposed that prohibitions in paragraphs (a)(7) through (14) in Section 922.244 would not apply to non-commercial fishing activities in the Outer Sanctuary Zone authorized under the MSA, provided that no sale of harvested fish occurs. In response to comments of concern for this exemption, NOAA has made changes to ensure that a non-commercial fishing permit authorized under the MSA is only exempt from a limited subset of prohibited or otherwise regulated activities that may only be conducted as incidental to and necessary to a lawful non-commercial fishing activity. NOAA has also clarified that this narrow exemption from the sanctuary's permitting requirements is only applicable provided that the fish harvested, either in whole or in part, are neither intended to enter commerce nor enter commerce through sale, barter, or trade and that the resource is managed sustainably, consistent with Presidential Proclamation 9478. Moreover, consistent with the outcome of the NMSA Section 304(a)(5) process, for the exemption to apply, the fish harvested, either in whole or in part, are not intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery. See the final EIS, Section 3.3.1.

NOAA is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA, and will accept public comment on the proposal. NOAA and the State of Hawai'i encourage the commenter to participate in the future public review process for the proposed rule and any associated NEPA and/or other environmental compliance documentation for non-commercial fishing regulations in the MEA. Until a public process is conducted, and a final rule is issued for fishing regulations under the authority of the MSA, non-commercial fishing permits will not be issued for the MEA/Outer Sanctuary Zone. Consistent with existing Monument management, the sanctuary may authorize sustenance fishing outside of any special preservation area as a term or condition of any sanctuary permit.

66. F-5 Comment: Commenters requested a prohibition on mining, and/or stating opposition to mining activities, or any exemption allowing them.

Response: Consistent with the presidential proclamations establishing the Monument, NOAA will prohibit exploring for, developing, or producing

oil, gas, or minerals to protect sanctuary resources. NOAA will also prohibit “any energy development activities” to further the underlying intent of the prohibition on oil, gas, and mineral development by accounting for technological advances in other forms of energy development. Likewise, NOAA is not providing an exemption for mining activities.

67. F-6 Comment: A commenter stated that scientific or management activities undertaken by the USFWS within the Monument are not subject to any additional sanctuary requirements or authorization from NOAA.

Response: Nothing in the establishment of the national marine sanctuary will diminish USFWS’s authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act. Where Papahānaumokuākea National Marine Sanctuary overlaps Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the National Marine Sanctuaries Act to provide supplemental authority to protect resources. In other sanctuary sites when there is jurisdictional overlap between NOAA and USFWS, the agencies have worked to implement their respective authorities in a manner that complements, but does not diminish or interfere with, existing authorities and would strengthen existing protections and management. NOAA and USFWS are developing an agreement to provide details on the execution of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge.

The sanctuary permitting system was modeled after the existing Monument permitting system to ensure a single joint permitting system continues to be administered by the MMB. In addition, this final rule does not include authorization authority for the sanctuary. Consistent with Presidential Proclamation 9478, the sanctuary regulations exempt both the DOC/NOAA and the DOI/USFWS from the prohibitions, including the need to obtain a permit or authorization from the Secretary of Commerce in order to conduct scientific exploration or research activities in the MEA. NOAA has clarified the proposed framework for management and permitting in partnership with USFWS and the other Monument managers in the final EIS, Section 3.3.1.

68. G-1 Comment: Some commenters requested an extension of the public

comment period and/or additional virtual public meetings. Some commenters expressed concern that there was not adequate public education, engagement, and notification for the public comment period and meetings; that the methods for comment were not accessible for all and/or not an adequate way to gauge support or opposition; and that all communities, specifically the fishing community, were not properly engaged in the comment period. One commenter expressed concern that the public meetings did not allow for agency responses or answers to oral testimony and requested that the NOAA website provide responses to frequently asked questions from the public meetings.

Response: NOAA followed the designation processes and procedures as required pursuant to the NMSA and NEPA, both of which require broad public participation, as well as the Administrative Procedure Act’s notice requirements. The public comment period took place over the course of 68 days from March 1 to May 7, 2024. NOAA accepted public comments through the Federal eRulemaking Portal and by traditional mail. NOAA also encouraged public comments in both English and ‘Ōlelo Hawai‘i (Hawaiian language). NOAA and the State held 11 public comment meetings (nine in-person and two virtual). Additionally, prior to the public comment meetings, the State of Hawai‘i Division of Aquatic Resources held a virtual public informational meeting to engage the public. NOAA and the State of Hawai‘i provided question and answer sessions at the in-person public meetings, prior to and following the formal oral comment portion of the meeting.

NOAA also posted sanctuary designation process information and FAQs on the ONMS website in response to questions received during public meetings. NOAA believes that it has fairly engaged with and considered input from local communities, Kānaka ‘Ōiwi, government, and other stakeholders through extensive consultations, meetings, and discussions about sanctuary designation, and that draft designation documents and process steps have complied with applicable laws and policies, including the NMSA, NEPA, Administrative Procedure Act, and Section 106 of the National Historic Preservation Act. For more details regarding the public engagement process, see the final EIS, sections 1.3.1 and 1.3.2.

NOAA also specifically engaged with the fishing community and consulted with the WPRFMC as required by

Section 304(a)(5) of the NMSA. Through this consultation, NOAA provided the WPRFMC with the opportunity to recommend any draft fishing regulations it deemed necessary to implement the proposed sanctuary designation. NOAA and the State of Hawai‘i also participated in six public meetings hosted by the WPRFMC on November 1st, 3rd, 4th, 5th, 8th, and 10th of 2022, which were focused on the development of fishing regulations for the area of the proposed sanctuary that overlaps with the MEA.

69. H-2 Comment: A commenter recommended that, in describing the purposes and policies of the NMSA, and specifically, 16 U.S.C 1431 (b)(4), NOAA should define “sustainable use” as “to provide enhanced protections for pristine marine waters,” and prohibit use of the waters or marine ecosystems.

Response: The NMSA authorizes the Secretary of Commerce to designate national marine sanctuaries that meet the purposes and policies of the NMSA, including 16 U.S.C. 1431(b)(4), which focuses, in part, on the sustainable use of the marine environment. The sanctuary regulations build upon the existing protections for the Northwestern Hawaiian Islands, which provide for both restricted access to the area and responsible use subject to strict permitting terms and conditions. Given this management model, NOAA does not see a need for the sanctuary regulations to define “sustainable use” at this time.

70. I-1 Comment: Some commenters recommended that NOAA select Alternative 3, a boundary which excludes the waters of Midway Atoll and Hawaiian Islands National Wildlife Refuges. Commenters provided several reasons for supporting Alternative 3, including that the USFWS should have sole jurisdiction to manage the national wildlife refuges; that a sanctuary that overlaps with the national wildlife refuges would be inconsistent with presidential proclamations that created the Monument; that a sanctuary that overlaps with the national wildlife refuges would not comply with the National Wildlife Refuge System Administration Act; and that a sanctuary that overlaps with the national wildlife refuges may negatively impact the USFWS management of the national wildlife refuges.

Response: NOAA identified Alternative 1 (which would include the waters of Midway Atoll and Hawaiian Islands National Wildlife Refuges in the proposed sanctuary) as the Agency-Preferred Alternative based on its comparative merits. Nothing in the establishment of the national marine

sanctuary will diminish USFWS's authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act. Where Papahānaumokuākea National Marine Sanctuary overlays Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the NMSA to provide supplemental authority to protect resources. NOAA and USFWS are developing an agreement to provide details on the execution of sanctuary management where the national marine sanctuary overlaps with Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge.

In addition, the existing Monument is already jointly administered through a seven-member Monument Management Board, which includes NOAA's ONMS. ONMS and the USFWS have been cooperatively managing the area of the proposed sanctuary for nearly 20 years. As a result of the existing Monument management framework, of which ONMS is a critical part, this sanctuary rule has been specifically designed not to create any regulatory inconsistencies, and to ensure consistent management between the Monument, the national wildlife refuges, and the sanctuary.

Further, both NOAA and the State disagree that the designation is inconsistent with the directives that established the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve and the Monument. In part, the purpose of the designation is to specifically implement the provisions of Executive Order 13178, Presidential Proclamation 9478, and the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021, that directed NOAA to consider initiating the sanctuary designation process.

71. I-2 Comment: Commenters expressed opposition to any sanctuary that would include additional portions of Middle Bank, beyond the areas that are included in the Monument.

Response: NOAA considered designating a sanctuary that expanded beyond the southeastern portion of the Monument boundary to include Middle Bank. However, NOAA eliminated this alternative from detailed study, as described in the draft and final EIS, Section 3.7.

72. I-3 Comment: Commenters requested that NOAA consider including most or all of Middle Bank in the proposed sanctuary boundary, because of the scientific, ecological, and commercial benefits of the area. Commenters also requested that NOAA

consider expanding the boundary to include more area.

Response: NOAA identified Alternative 1 (which is coextensive with marine portions of the Monument) as the Agency-Preferred Alternative based on its comparative merits, and therefore does not include all of Middle Bank or any additional areas that are not part of the Monument. This is consistent with the defined purpose and need and with the provisions of Executive Order 13178, Presidential Proclamation 8031, Presidential Proclamation 9478, and the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021.

Although NOAA considered sanctuary boundary alternatives that included Middle Bank, NOAA concluded that aligning the boundary of the sanctuary with that of the Monument best fulfills the purposes and policies of the NMSA. In addition, the NMSA directs NOAA that it may designate any discrete area of the marine environment as a national marine sanctuary and promulgate regulations implementing the designation if it is determined that the area is of a size and nature that will permit comprehensive and coordinated conservation and management. NOAA concluded that any boundary alternative that expands beyond the existing boundaries of PMNM and the MEA would not be practicable in light of the need for comprehensive and coordinated management in a manner which complements the existing Monument management framework. NOAA has added these clarifications to the draft and final EIS, Section 3.7.1.

73. I-4 Comment: Commenters recommended Alternative 2, a boundary which excludes the MEA, as the preferred alternative. Some commenters expressed support for this alternative, emphasizing that excluding the MEA may allow for more fishing, including commercial fishing, in that area.

Response: NOAA identified Alternative 1 as the Agency-Preferred Alternative, which includes the MEA, based on its comparative merits. This final rule implements and is consistent with directives in Presidential Proclamation 9478, which has the force of law. Presidential Proclamation 9478, which designated the MEA, prohibits commercial fishing and provides that non-commercial fishing may be a regulated activity (*i.e.*, allowed only with a permit). Selection of Alternative 2 would not alter the directives provided in Presidential Proclamation 9478, including the prohibition on commercial fishing in the MEA.

74. I-5 Comment: A commenter requested the inclusion of a legal definition of shoreline delineation in relation to iron seawall ruins and rubble at Tern Island, and questioned if the seawall and debris would be included in the sanctuary boundary.

Response: The shoreline in the State of Hawai'i as defined by the Hawai'i Department of Land and Natural Resources is "the upper reaches of the wash of the waves, other than storm or seismic waves, at high tide during the season of the year in which the highest wash of the waves occur, usually evidenced by the edge of vegetation growth, or the upper limit of debris left by the wash of the waves" (HAR § 13-222). The Coastal Lands Program of the Hawai'i Department of Land and Natural Resources, Office of Conservation and Coastal Lands maintains the State of Hawaii Shoreline Certification Program (see Shoreline Certification Rules in HAR § 13-222). It is this program that would determine where the shoreline is delineated in the location of the iron seawall on Tern Island when necessary. Therefore, under the current definitions, any debris or rubble or portion of the Tern Island iron seawall that occurs seaward of this shoreline as defined by the State of Hawai'i will be within the sanctuary, and that which occurs upland of the shoreline will be outside the sanctuary.

75. I-6 Comment: A commenter requested that the shoreward boundary be extended to the mean high tide.

Response: NOAA considered an alternative that designated the mean high tide line as the shoreward boundary, but eliminated this alternative from detailed study (see Section 3.7.1 of the EIS). NOAA typically uses the shoreline as legally defined by the State within which the national marine sanctuary occurs, because the shoreline delineates the boundary between public and private land. The shoreline in the State of Hawai'i as defined by the Hawai'i Department of Land and Natural Resources is "the upper reaches of the wash of the waves, other than storm or seismic waves, at high tide during the season of the year in which the highest wash of the waves occur, usually evidenced by the edge of vegetation growth, or the upper limit of debris left by the wash of the waves" (HAR § 13-222). NOAA strives to designate a sanctuary which supplements and complements existing authorities, and this designation adheres to both the State's definition as well as the current landward boundary designation of the Monument.

76. *J-12 Comment:* Commenters expressed concerns regarding the lack of analysis and description on NOAA's ability to issue "emergency regulations" to prevent or minimize the loss or injury to a sanctuary resource. The commenter stated that the regulations issued jointly by NOAA and USFWS in 2006 for the original Monument contain an exemption from prohibitions for emergency actions, and that Presidential Proclamation 9478 specifically exempts from prohibitions activities "necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for law enforcement purposes." The commenters questioned why sanctuary authority to issue sanctuary regulations is necessary given existing provisions and regulations for the Monument.

Response: NOAA acknowledges that the existing management of the area includes exemptions for any activity necessary to respond to emergencies that threaten life, property, or the environment, or to activities necessary for law enforcement purposes. These exemptions are also included in the sanctuary regulations. However, NOAA's references to "emergency regulations" throughout the EIS are not referring to this exemption, but to NOAA's authority pursuant to 15 CFR 922.7, which states that "where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality, or minimize the imminent risk of such destruction, loss, or injury, any and all such activities are subject to immediate temporary regulation, including prohibition." This authority may be useful in implementing immediate temporary regulations to protect resources following incidents of resource damages, such as vessel groundings or disease. NOAA has added information regarding emergency regulations in the final rule, Section IV.O.

77. *K-6 Comment:* Commenters suggested that scientific research should not be conducted in a way that would harm resources. Commenters also expressed concerns about the use of remotely operated vehicles (ROVs) and other scientific instruments on the seafloor.

Response: The sanctuary includes a permitting system modeled after the existing Monument permitting system, such that there are sufficient safeguards in place that apply to the permit review process for all activities, including for scientific research and ROVs. The sanctuary has adopted the same permit criteria as currently required for Monument permits, including that the

proposed activity will be conducted in a manner compatible with resource protection. In addition, conditions can be placed on the permit specific to the activity being permitted and permit applications would be reviewed with respect to all other pertinent regulations and statutes, including NEPA, 42 U.S.C. 4321 *et seq.*, and any required consultations, permits, or authorizations.

78. *K-8 Comment:* A commenter suggested that NOAA leave Battle of Midway vessels and aircraft undisturbed to be respectful of the war and preserve the materials for future archaeological purposes.

Response: NOAA's management principles emphasize an *in-situ* management approach for the long-term protection of site information and integrity, as well as other preservation methods and activities outlined in the ONMS policy guidance document *Monitoring and Management of Tangible Maritime Heritage Resources*. The Sunken Military Craft Act of 2004 preserves and protects all sunken military craft that are owned by the U.S. government, as well as foreign sunken military craft that lie within U.S. waters, from unauthorized disturbances.

79. *K-10:* Commenters expressed concerns regarding the impacts of sonar activity and underwater detonations to marine mammals, fish, sea turtles, and sea invertebrates. Commenters specifically expressed concern with impacts from sonar activity and testing by the military. One commenter recommended mid-frequency active sonar as an alternative technology.

Response: Consistent with the presidential proclamations establishing the Monument, NOAA will prohibit "using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a sanctuary resource." NOAA will also prohibit, unless conducted pursuant to a permit "removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging; or attempting to remove, move, take, harvest, possess, injure, disturb, or damage any living or nonliving sanctuary resource." The use of sonar by U.S. Armed Forces is a lawful Armed Forces activity and the use has been analyzed by the U.S. Navy within prior environmental planning documents (HSTT, 2018) and is subject to other applicable laws, permits, and authorizations, including the MMPA.

NOAA provides a broad exemption to allow activities and exercises of the U.S. Armed Forces, including those carried out by the U.S. Coast Guard, to be consistent with existing management of this area, as provided for the Monument

by Presidential Proclamations 8031 and 9478. However, all activities and exercises of the Armed Forces shall be carried out in a manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on sanctuary resources and qualities. See also the F.3 response.

80. *K-11 Comment:* A commenter recommended protections for koholā (humpback whale) that are similar to the protections included in Hawaiian Islands Humpback Whale National Marine Sanctuary, including vessel rules, restrictions on sonar, and maintaining a minimum distance away from koholā.

Response: NOAA will prohibit several activities in the sanctuary that are responsive to this comment, consistent with the presidential proclamations establishing the Monument. The prohibitions most relevant for the protection of humpback whales include prohibitions on "removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging; or attempting to remove, move, take, harvest, possess, injure, disturb, or damage any living or nonliving sanctuary resource" and "attracting any living sanctuary resource." The use of sonar by the U.S. Armed Forces is a lawful activity of the Armed Forces, but is subject to other applicable laws, permits, and authorizations, including the MMPA.

81. *K-12 Comment:* A commenter requested that the Outer Sanctuary Zone be named "pu'uhonua," which means a place of safety and refuge. Another commenter asked if there would be a process for naming this area of the sanctuary.

Response: NOAA will give further consideration to this and would like to ensure an inclusive process that allows for additional input and discussion from all stakeholders and Monument co-trustees regarding a name for the Outer Sanctuary Zone. The proposed name and the process of naming this Outer Sanctuary Zone will be discussed within the Papahānaumokuākea Native Hawaiian CWG, facilitated by OHA.

82. *L-5 Comment:* A commenter requested that the rule language be revised to allow for an ongoing process for updating the sanctuary regulations. Specifically, the commenter suggested replacing the words "as may be necessary," in the Terms of Designation, Activities Subject to Regulation section, with "on an ongoing basis."

Response: The terms of designation, as defined under section 304(a)(4) of the NMSA, may be modified only by the same procedures by which the original designation is made, including public hearings, consultations with interested

Federal, Tribal, State, regional, and local authorities and agencies, review by the appropriate Congressional committees, and approval by the Secretary of Commerce, or his or her designee. Any future proposed changes to sanctuary regulations or boundaries would be subject to public review as mandated by the NMSA and other Federal statutes.

83. *L-6 Comment:* A commenter provided questions and suggestions regarding perceived data anomalies in the boundary description, including:

- “The proposed SMA and SPA boundaries do not coincide with the boundaries as described in Presidential Proclamation 8031 nor do they coincide with the proclamation’s SMA and certain SPA boundaries as charted on ENC’s that are larger scale than Band 2 (General Navigational Purpose). It appears that the coordinates of the proposed boundaries may have been derived from the SMA and SPA boundaries of the national monument as depicted on the Band 2 ENC’s.

- Appendix A to Subpart W, Points 610–662—Papahānaumokuākea National Marine Sanctuary Boundary: Points 610 through 662 form the easternmost extent of the proposed sanctuary boundary. However, these points are coincident with a portion of the Inner Reporting Area Boundary Around Nihoa ATBA. Should Points 610 through 662 be coincident with the Reporting Area Outer Boundary instead of the Inner Reporting Area Boundary?

- Pages 15302–15303, Appendix D to Subpart W—Unnamed, unnumbered table: ONMS did not designate a table number and name for the first set of coordinates that encompasses Kure Atoll.

- Pages 15306–15307, Appendix E to Subpart W, Table 1—Ship Reporting Area (Reporting Area Outer Boundary): According to FR page 15278, Column 1: “NOAA proposes to establish this reporting area, which would be defined as “the area of the proposed sanctuary that extends outward ten nautical miles from the PSSA [Particularly Sensitive Sea Area] boundary, as designated by the IMO. . . .” The coordinates for the Reporting Area Outer Boundary of Appendix E/Table 1 do not completely coincide with a 10–NM buffer (geodesic) from the PSSA boundary per the International Maritime Organization (IMO). I recommend a re-evaluation of the boundary points for the Reporting Area Outer Boundary.”

Response: The boundary discrepancies in the special management area and special preservation areas have been corrected and the updated coordinate tables, appended to this final rule, will

correspond to the coordinates as described in Presidential Proclamation 8031.

Regarding the outer boundary of the Reporting Area, NOAA will define the Reporting Area as was defined by IMO Resolution MSC.171(57) and the subsequent amendment IMO Resolution MSC.279(85) adopted in December 2008. This boundary has been corrected and is now described citing the geographic coordinates of the outer boundary of the “CORALSHIPREP” reporting area of IMO Resolution MSC.279(85).

Regarding the missing designation of a table number and name for the first set of coordinates that encompass the Kure Atoll Special Preservation Area, after investigating the issue, NOAA determined that the table did in fact have a name and number as referenced at the *web address* and therefore no corrective action was necessary.

Regarding the portion of the proposed sanctuary boundary identified as being coincident with the Inner Ship Reporting Area Boundary around the Nihoa Area to be Avoided, NOAA determined that this portion of the boundary was the same as that used for both the original and expanded marine national monument, and intends that it will also be used for this portion of the national marine sanctuary boundary. Therefore, no edits were necessary.

VI. Classification

A. National Marine Sanctuaries Act

NOAA consulted with the WPRFMC as required by section 304(a)(5) of the NMSA. Through this consultation, NOAA provided the WPRFMC with the opportunity to recommend any draft fishing regulations it deemed necessary to implement the proposed sanctuary designation. NOAA initiated the consultation on November 19, 2021. On March 22, 2022, the WPRFMC agreed to develop draft fishing regulations for the proposed sanctuary. NOAA participated in six public meetings hosted by the WPRFMC on November 1st, 3rd, 4th, 5th, 8th, and 10th of 2022, which were focused on the development of fishing regulations for the area of the proposed sanctuary that overlaps with the MEA. At its 193rd meeting in December of 2022, the WPRFMC provided a final recommendation. NOAA found that the final recommendation, in part, did not fulfill the purposes and policies of the NMSA and the goals and objectives of the proposed designation. The WPRFMC amended their recommendation during their 194th meeting in March of 2023, and submitted a revised final

recommendation to NOAA on April 14, 2023.

In May of 2023, NOAA accepted the majority of the WPRFMC’s recommendation as it fulfilled the purposes and policies of the NMSA and the goals and objectives of the proposed sanctuary designation. However, the WPRFMC’s recommendation for the disposition of Native Hawaiian Subsistence Practices Fishing catch, which would provide permit applicants the ability to request limited cost-recovery by selling their catch, was rejected by NOAA in a decision letter dated May 31, 2023. As NOAA explained in the letter, any recommendation for the allowance of “sale” is inconsistent with the goals and objectives of the proposed sanctuary designation. To reflect the outcome of the NMSA 304(a)(5) process, NOAA has prepared this final rule under the NMSA, and is preparing a separate proposed rule for regulations governing fishing in the MEA under the authority of the MSA.

Pursuant to section 304(a)(1)(C) of the NMSA, the Committee on Natural Resources of the House of Representatives, the Committee on Commerce, Science, and Transportation of the Senate, and the Governor of Hawai’i will have the opportunity to review this final action.

B. National Environmental Policy Act

As described in Section I above, NOAA and the State of Hawai’i prepared a final EIS to evaluate the impacts of designating a national marine sanctuary, which considered four alternatives for the designation of a national marine sanctuary in marine portions of the Monument. Copies of the final EIS, final management plan, and Record of Decision are available at the website listed in the **ADDRESSES** section of this final rule.

C. Executive Orders 12866: Regulatory Impact, 13563 Improving Regulation and Regulatory Review, and 14094: Modernizing Regulatory Review

The Office of Management and Budget (OMB) has determined this final rule to be significant under Executive Order 12866, “Regulatory Planning and Review,” 58 FR 190 (Oct 4, 1993), as supplemented by Executive Order 14094, “Modernizing Regulatory Review,” 88 FR 21879 (April 6, 2023). NOAA prepared an analysis of the potential costs and benefits associated with this action, which is available at <https://sanctuaries.noaa.gov/papahanaumokuakea/>.

The final rule is largely consistent with the existing management

framework for the Monument. Because the site-specific regulations finalized under the NMSA have been crafted to ensure consistency with Presidential Proclamations 8031, 8112, and 9478, the overall management framework for the area will largely remain unchanged. The designation would clarify aspects of existing Monument management and add to that management framework in ways that would have a limited effect on the public given that access to and activity within the Monument is already highly regulated and requires a permit in most instances. In most cases, permit applicants would be subject to substantially similar findings criteria and permitting requirements as currently required within the Monument. Further, the area of the sanctuary is extremely remote, nearly 300 miles at its closest point from the main Hawaiian Islands, and very few entities operate there. Limited activities are expected to continue. Therefore, the quantifiable benefits and costs associated with the site-specific regulations are limited. The primary benefits of sanctuary designation are provided by the supplemental authorities provided through the NMSA and National Marine Sanctuary Program regulations.

D. Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132 because NOAA supplements and complements State and local laws under the NMSA rather than supersedes or conflicts with them. This final rule will not have substantial direct effects on State or local governments. NOAA has coordinated closely with State partners throughout the development of this final rule and, where applicable and practicable, the final rule aligns with existing State regulations. In addition, the State of Hawai'i served as a cooperating agency and co-developed the draft EIS and final EIS, which was also developed in accordance with the Hawai'i Environmental Policy Act (HEPA, Chapter 343 HRS, HAR Chapter 11–200.1). The State of Hawai'i also co-developed the sanctuary management plan. NOAA has aimed for consistent regulations throughout sanctuary waters including those within State and Federal jurisdiction.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) requires Federal agencies to prepare an analysis of a

rule's impact on small entities whenever the agency is required to publish a rulemaking, unless the agency certifies, pursuant to 5 U.S.C. 605, that the action will not have significant economic impact on a substantial number of small entities. The RFA requires agencies to consider, but not necessarily minimize, the effects of rules on small entities. The goal of the RFA is to inform the agency and public of expected economic effects of the rule and to ensure the agency considers alternatives that minimize the expected economic effects on small entities while meeting applicable goals and objectives. Pursuant to section 605(b) of the RFA, the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule would not have a significant economic impact on a substantial number of small entities. The purpose, context, and statutory basis for this action is described above and not repeated here. The rationale for that certification was set forth in the preamble of the proposed rule (89 FR 15272, March 1, 2024), and NOAA's analysis stands.

This final rule is not expected to place a substantial number of small entities at a significant competitive disadvantage to large entities, and would not significantly reduce profits for a substantial number of small entities operating in the area of the sanctuary, as the overall management framework for the area will largely remain unchanged. The final rule would be largely consistent with the existing management framework for the Monument, which was established by Presidential Proclamation 8031 and 8112 (PMNM, 0–50 nm), and by Presidential Proclamation 9478 (MEA, 50–200 nm). The existing management framework established by these Presidential Proclamations has the force of law, and includes a permitting system, under which all entities are subject to the same reporting requirements. Further, very few entities operate in the area of the sanctuary, as the area of the sanctuary is extremely remote, nearly 300 miles at its closest point from the main Hawaiian Islands. The number of permits issued for the Monument annually ranged from 9 to 21 between 2018 and 2022.

Through this final rule, permit applicants, including applicants for activities in the area of the sanctuary that overlaps with the MEA, would be subject to substantially similar findings criteria and permitting requirements as currently required for PMNM. Based on the NOAA Monument manager's site knowledge and experience, the final

rule is not expected to result in an increase in the number of permit requests, as the majority of users operate in the area of the sanctuary that overlaps with PMNM, and do not solely operate in the area of the sanctuary that overlaps with the MEA. Therefore, these additional permitting requirements will not significantly reduce profits for a substantial number of small entities because most entities are already subject to such requirements.

NOAA does not charge a fee for review and issuance of general permits, and there are minimal, indirect costs associated with the time for an individual to complete a permit application and respond to any follow-up questions from NOAA. While NOAA may assess fees for the conduct of any activity authorized under a special use permit, fees are not required and decisions are made on a case-by-case basis. No unique professional skills are necessary to meet these reporting requirements.

Although NOAA has made minor technical changes and clarifications to the regulations from the proposed rule to the final rule, none of the changes alter the initial determination that this rule will not have a significant impact on a substantial number of small entities. NOAA also did not receive any comments relevant to the analysis or conclusions of this determination. Therefore, the determination that this rule will not have a significant economic impact on a substantial number of small entities remains unchanged. As a result, a final regulatory flexibility analysis was not required and none was prepared.

F. Paperwork Reduction Act

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, unless that collection of information displays a currently valid OMB control number. NOAA plans to use an existing collection, Papahānaumokuākea Marine National Monument Permit Applications and Reports for Permits, currently approved under OMB Control Number 0648–0548 in association with this final rule. This information collection is currently used to determine whether to approve or deny a permit application for the Papahānaumokuākea Marine National Monument. Information collected includes such items as the professional qualifications and financial ability of the applicant (as related to the requested

activity); the duration of the activity and its effects; the appropriateness of the methods and procedures proposed by the applicant for the conduct of the activity; and the extent to which the conduct of the activity may diminish or enhance the qualities for which the Monument was designated. Some of the information collected may also be used to inform management actions or decision making after a final decision has been made. Additional information regarding this collection of information—including all background materials—can be found at <https://www.reginfo.gov/public/do/PRAMain> by using the search function to enter either the title of the collection or the OMB Control Number.

NOAA believes designating a national marine sanctuary in the marine portions of the Monument will not result in a significant change to the burden, reporting, recordkeeping, and other compliance requirements as discussed in the preamble of the rule. To the extent compliance with this final rule would impose a burden on persons, including small businesses, NOAA believes this burden will be minimal. NOAA did not receive any comments in response to this determination at the proposed rule stage. Following sanctuary designation, NOAA may elect to re-visit the current collection to determine if additional changes are needed. Should NOAA, in consultation with the Department of Interior, the State of Hawaii, and the Office of Hawaiian Affairs, believe additional changes are needed to better facilitate implementation of sanctuary permitting and reporting, NOAA will publish a 60 day notice announcing potential revisions for public comment before submitting materials to OMB.

G. National Historic Preservation Act

Section 106 of the National Historic Preservation Act (NHPA, 54 U.S.C. 306108) requires Federal agencies to take into account the effects of their undertakings on historic properties and afford the Advisory Council on Historic Preservation (ACHP) the opportunity to comment with regard to the undertaking. “Historic property” means any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places maintained by the Secretary of the Interior. This term includes artifacts, records, and material remains that are related to and located within such properties, including properties of traditional religious and cultural importance to an Indigenous nation or Tribe or Native

Hawaiian organization (see 36 CFR 800.16(l)).

The regulations implementing section 106 of the NHPA (36 CFR part 800) establish a process requiring Federal agencies to: (1) determine whether the undertaking is a type of activity that could affect historic properties; (2) identify historic properties in the area of potential effects; (3) assess potential adverse effects; and (4) resolve adverse effects. The regulations require that Federal agencies consult with States, Tribes, and other interested parties when making their effect determinations.

NOAA has determined that the designation of a national marine sanctuary and related rulemaking for sanctuary-specific regulations meet the definition of an undertaking as defined at § 800.16(y). In fulfilling its responsibilities under section 106 of the NHPA, NOAA initiated consultation with the Hawai‘i State Historic Preservation Division through the Hawai‘i Cultural Resource Information System on November 21, 2021. NOAA also invited the Advisory Council on Historic Preservation (ACHP) to participate on November 21, 2021. NOAA further initiated an effort to identify consulting parties to participate in the Section 106 process through distribution of over 500 letters to individuals, organizations, and families. This included outreach to families with lineal and cultural connections to Papahānaumokuākea, cultural practitioners, Native Hawaiian Organizations, the fishing community (including subsistence, recreational, and commercial fishers), maritime heritage organizations, government agencies, and others. These letters solicited input regarding the identification of, and potential effects on, historic properties from the proposed sanctuary designation for the purpose of obtaining input for the Section 106 review and to additionally determine their interest in participating as a consulting party. Through this process NOAA identified 31 consulting parties.

NOAA subsequently hosted ten Section 106 consultation meetings with the consulting parties. Through these consultation meetings, NOAA further sought to invite consulting party and public input regarding the identification of, and potential effects on, historic properties from the proposed sanctuary designation. Subsequently, pursuant to 36 CFR 800.4(d)(1) NOAA issued a Finding of No Historic Properties Affected for this undertaking (see final EIS Appendix C). The consulting parties have been notified of the finding and the finding was provided to the Hawai‘i

State Historic Preservation Division for concurrence.

As the draft EIS was a joint Federal-State action, the State also prepared a Cultural Impact Assessment and Legal Analysis pursuant to the Hawai‘i Environmental Policy Act, Hawai‘i Revised Statutes (HRS) section 343, the corresponding Hawai‘i Administrative Rules (HAR) section 11–200.1, and the Environmental Council’s 1997 Guidelines for Assessing Cultural Impacts. Pursuant to HRS § 6E–8 and HAR § 13–275–3, the Hawai‘i Department of Land and Natural Resources (DLNR) submitted a written request to the State Historic Preservation Division (SHPD) for an agency determination letter. On June 7, 2024, SHPD concurred with DLNR’s determination of no historic properties affected. The concurrence letter from the State Historic Preservation Division is available at <https://sanctuaries.noaa.gov/papahanaumokuakea/>.

H. Sunken Military Craft Act

The Sunken Military Craft Act of 2004 (SMCA; Pub. L. 108–375, Title XIV, sections 1401 to 1408; 10 U.S.C. 113 note) preserves and protects from unauthorized disturbance all sunken military craft that are owned by the United States government, as well as foreign sunken military craft that lie within United States waters, as defined in the SMCA. Thousands of U.S. sunken military craft lie in waters around the world, many accessible to looters, treasure hunters, and others who may cause damage to them. These craft, and their associated contents, represent a collection of non-renewable and significant historical resources that often serve as war graves, carry unexploded ordnance, and contain oil and other hazardous materials. By protecting sunken military craft, the SMCA helps reduce the potential for irreversible harm to these nationally important historical and cultural resources.

Sunken military craft are administered by the respective Secretary concerned pursuant to the SMCA. The Secretary concerned is solely responsible for authorizing disturbance of sunken military craft under the SMCA, specifically for archaeological, historical, or educational purposes, and will consult with NOAA when considering permitting such activities. The Secretary concerned is also responsible for determinations of sunken military craft status and ownership, publicly disclosing the location of sunken military craft, and for determining eligibility and nominating

sunken military craft as historic properties to the National Register of Historic Places. Any agreements with foreign sovereigns regarding sunken military craft in U.S. waters are negotiated by the Secretary of Defense, the Secretary of State, and the Secretary of the Navy, according to authorities vested in each by the SMCA. The Secretary concerned, or his or her designee, and NOAA will ensure coordination and foster collaboration on any research, monitoring, and educational activities pertaining to sunken military craft located within the sanctuary system.

The 1942 Battle of Midway occurred both at Midway Atoll as well as some 100–150 nautical miles north of the atoll in the northwestern portion of Papahānaumokuākea. Aircraft carriers from the historic conflict have been located in the deep ocean, and multiple aircraft and sunken military vessels have been surveyed within the Midway Atoll Special Management Area. Hundreds of aircraft and several other aircraft carriers and destroyers from the battle remain to be discovered in Papahānaumokuākea.

K. Coastal Zone Management Act (CZMA)

Section 307 of the Coastal Zone Management Act (CZMA; 16 U.S.C. 1456) requires Federal agencies to consult with a State's coastal program on potential Federal agency activities that affect any land or water use or natural resource of the coastal zone. Because the sanctuary lies partially within State waters, NOAA submitted its Federal consistency determination to the Hawai'i Coastal Zone Management Program of the Office of Planning and Sustainable Development. NOAA's analysis found the proposed action would be undertaken in a manner consistent to the maximum extent practicable with the enforceable policies of the Hawai'i Coastal Zone Management Program. NOAA's Federal consistency determination, and the State of Hawai'i May 17, 2024 concurrence letter, are included in the final EIS Appendix C1.

L. Executive Order 12898 and 14096: Environmental Justice

Executive Order 12898 and Executive Order 14096 direct Federal agencies to identify and address disproportionately high and adverse effects of their actions on human health and the environment of communities with environmental justice concerns. Additionally, Federal agencies are directed to better protect overburdened communities from pollution and environmental harms;

strengthen engagement with communities and mobilize Federal agencies to confront existing and legacy barriers and injustices; promote the latest science, data, and research, including on cumulative impacts; increase accountability and transparency in Federal environmental justice policy; and honor and build on the foundation of ongoing environmental justice work. The designation of national marine sanctuaries by NOAA helps to ensure the enhancement of environmental quality for all populations in the United States. The sanctuary designation would not result in disproportionate negative impacts on any communities with environmental justice concerns. In addition, many of the potential impacts from designating the sanctuary would result in long-term or permanent beneficial impacts by protecting resources, which may have a positive impact on communities by providing employment and educational opportunities, and potentially result in improved ecosystem services.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure; Coastal zone; Cultural resources; Environmental; Protection; Fishing; Historic preservation; Marine protected areas; Marine resources; Natural resources; National marine sanctuaries; Penalties; Recreation and recreation areas; Reporting and recordkeeping requirements; Shipwrecks; Wildlife.

Nicole R. LeBoeuf,

Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service, National Oceanic and Atmospheric Administration.

For the reasons set forth above, NOAA amends part 922, title 15 of the Code of Federal Regulations as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

■ 2. Amend § 922.30 by:

■ a. Removing the word “and” at the end of paragraph (b)(6);

■ b. Removing the period at the end of paragraph (b)(7) and adding “;” in its place; and

■ c. Adding paragraphs (b)(8) and (9).

The additions read as follows:

§ 922.30 National Marine Sanctuary general permits

* * * * *

(b) * * *

(8) Native Hawaiian Practices—activities that allow for Native Hawaiian practices within Papahānaumokuākea National Marine Sanctuary; and

(9) Recreation—recreational activities within Papahānaumokuākea National Marine Sanctuary limited to the Midway Atoll Special Management Area.

■ 3. Amend § 922.33 by:

■ a. Removing the word “and” at the end of paragraph (a)(8);

■ b. Removing the period at the end of paragraph (a)(9) and adding “; and” in its place; and

■ c. Adding paragraph (a)(10).

The addition read as follows:

§ 922.33 Review procedures and evaluation.

(a) * * *

(10) For Papahānaumokuākea National Marine Sanctuary, there is no practicable alternative to conducting the activity within the sanctuary and the activity can be conducted with adequate safeguards for the resources and ecological integrity of the sanctuary. Further, for Native Hawaiian Practices and Recreation permits in Papahānaumokuākea National Marine Sanctuary, the activity meets the additional site-specific permit review criteria identified in § 922.245.

* * * * *

■ 4. Amend 922.37 by adding paragraph (g).

§ 922.37 Appeals of permitting decisions.

* * * * *

(g) Paragraphs (a) through (f) of this section do not apply to Papahānaumokuākea National Marine Sanctuary.

* * * * *

■ 5. Add subpart W to read as follows:

Subpart W—Papahānaumokuākea National Marine Sanctuary

Sec.

922.240 Boundary.

922.241 Definitions.

922.242 Cooperative management.

922.243 Access.

922.244 Prohibited or otherwise regulated activities.

922.245 Permit procedures and criteria.

922.246 Vessel monitoring system.

922.247 Sunken military craft.

Appendix A to Subpart W of Part 922—Papahānaumokuākea National Marine Sanctuary Boundary Description and Coordinates

Appendix B to Subpart W of Part 922—Coordinates for the Outer Sanctuary Zone

Appendix C to Subpart W of Part 922—Coordinates for the Midway Atoll Special Management Area

Appendix D to Subpart W of Part 922—
Coordinates for the Special Preservation
Areas (SPAs)

Appendix E to Subpart W of Part 922—
Coordinates for the Ship Reporting Area

Appendix F to Subpart W of Part 922—IMO
Standard Reporting Format and Data
Syntax for Ship Reporting System

§ 922.240 Boundary.

Papahānaumokuākea National Marine Sanctuary consists of an area of approximately 582,570 square miles (439,910 square nautical miles) of Pacific Ocean waters surrounding the Northwestern Hawaiian Islands and the submerged lands thereunder. The precise boundary coordinates are listed in Appendix A to this subpart. The outer seaward sanctuary boundary begins approximately 200 nautical miles SW of Kure Atoll at Point 1 and continues from this point roughly north to each successive point in numerical order to Point 232 which is approximately 204 nautical miles north of Kure Atoll. From Point 232 the sanctuary boundary continues roughly ESE to each successive point in numerical order to Point 609 which is approximately 200 nautical miles NE of Necker Island. From Point 609 the sanctuary boundary continues south to Point 610 which is approximately 90 nautical miles ENE of Necker Island. From Point 610 the sanctuary boundary continues roughly east and then SE and south to Point 635 which is approximately 50 nautical miles east of Nihoa. From Point 635 the sanctuary boundary continues roughly south and then SW and west to each successive point in numerical order to Point 662 which is approximately 71 nautical miles SW of Nihoa. From Point 662 the sanctuary boundary continues south to Point 663 which is approximately 236 nautical miles SSW of Nihoa. From Point 663 the sanctuary boundary continues roughly NW to each successive point in numerical order to Point 703 which is approximately 200 nautical miles SSE of Necker Island. From Point 703 the boundary continues roughly NW to each successive point in numerical order to Point 1128 where it ends approximately 200 nautical miles SW of Kure Atoll. The inner landward boundary of the sanctuary follows the shoreline as defined by the State of Hawai'i (HAR § 13–222).

§ 922.241 Definitions.

In addition to those definitions found at § 922.11, the following definitions apply to this subpart. To the extent that a term appears in § 922.11 and this section, the definition in this section governs.

Areas to be avoided (ATBA) means the four areas, as adopted by the International Maritime Organization, that should be avoided by vessels that are conducting passage without interruption through the sanctuary. The precise boundary coordinates for the ATBAs are listed in Appendix E to this subpart.

Bottomfish species means all species of bottomfish as defined at 50 CFR 665.201.

Categories of hazardous cargoes means goods classified in the International Maritime Dangerous Goods (IMDG) Code; substances classified in chapter 17 of the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code) and chapter 19 of the International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk (IGC Code); oils as defined in MARPOL Annex I; noxious liquid substances as defined in MARPOL Annex II; harmful substances as defined in MARPOL Annex III; and radioactive materials specified in the International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-Level Radioactive Waste on Board Ships (INF Code).

Commercial fishing means, as defined in the Magnuson-Stevens Fishery Conservation and Management Act, fishing in which the fish harvested, either in whole or in part, are intended to enter commerce or enter commerce through sale, barter, or trade.

Ecological integrity means a condition determined to be characteristic of an ecosystem that has the ability to maintain the function, structure, and abundance of natural biological communities, including rates of change in response to natural environmental variation.

Midway Atoll Special Management Area means the area of the sanctuary surrounding Midway Atoll out to a distance of 12 nautical miles. The coordinates are listed in Appendix C to this subpart.

Native Hawaiian practices means cultural activities conducted for the purposes of perpetuating traditional knowledge, caring for and protecting the environment and strengthening cultural and spiritual connections to the Northwestern Hawaiian Islands that have demonstrable benefits to the Native Hawaiian community. This may include, but is not limited to, the non-commercial use of sanctuary resources for direct personal consumption while in the sanctuary.

Non-commercial fishing means fishing that does not meet the definition

of commercial fishing in the Magnuson-Stevens Fishery Conservation and Management Act, and includes, but is not limited to, sustenance, subsistence, traditional indigenous, and recreational fishing.

Office of Law Enforcement (OLE) means NOAA, National Marine Fisheries Service, Office of Law Enforcement.

Outer Sanctuary Zone means the waters and submerged lands extending from approximately 50 nautical miles from all islands and emergent lands of the Northwestern Hawaiian Islands to the extent of the seaward limit of the United States Exclusive Economic Zone (U.S. EEZ) west of 163° West Longitude. The precise boundary coordinates for the Outer Sanctuary Zone are listed in Appendix B to this subpart.

Particularly Sensitive Sea Area (PSSA) means an area that needs special protection through action by the International Maritime Organization because of its significance for recognized ecological, socio-economic, or scientific attributes where such attributes may be vulnerable to damage by international shipping activities.

Pelagic species means Western Pacific Pelagic Management Unit Species as defined at 50 CFR 665.800.

Pono means appropriate, correct, and deemed necessary by traditional standards in Hawaiian culture.

Recreational activity means an activity conducted for personal enjoyment that does not result in the extraction of sanctuary resources and that does not involve a fee-for-service transaction. This includes, but is not limited to, wildlife viewing, SCUBA diving, snorkeling, and boating.

Reporting area means the area of the sanctuary that extends outward ten nautical miles from the Particularly Sensitive Sea Area boundary, as designated by the International Maritime Organization, and excludes the Areas to be Avoided that fall within the Particularly Sensitive Sea Area boundary. The precise boundary coordinates for the reporting area are listed in Appendix E to this subpart.

Scientific instrument means a device, vehicle, or tool used for scientific purposes and is inclusive of structures, materials, or other matter incidental to proper use of such device, vehicle, or tool.

Special Preservation Area (SPA) means discrete, biologically important areas of the sanctuary within which uses are subject to certain conditions, restrictions, and prohibitions, including but not limited to access restrictions. The coordinates are listed in Appendix D to this subpart.

Stowed and not available for immediate use means not readily accessible for immediate use, *e.g.*, by being securely covered and lashed to a deck or bulkhead, tied down, unbaited, unloaded, or partially disassembled (*e.g.*, spear shafts being kept separate from spearguns).

Sustenance fishing means fishing for bottomfish or pelagic species in which all catch is consumed within the sanctuary, and that is incidental to an activity permitted under this part.

Vessel monitoring system (VMS) means a mobile transceiver unit as described in § 922.246 and approved by NOAA's Office of Law Enforcement for use on vessels permitted to access the sanctuary, as required by this part.

§ 922.242 Cooperative management.

(a) NOAA has primary responsibility for the management of the sanctuary pursuant to the National Marine Sanctuaries Act. As the sanctuary includes State waters, NOAA will co-manage Papahānaumokuākea National Marine Sanctuary with the State of Hawai'i.

(b) NOAA will also manage the sanctuary in partnership with the U.S. Fish and Wildlife Service and the Office of Hawaiian Affairs.

(c) Nothing in these regulations or establishment of the national marine sanctuary shall diminish U.S. Fish and Wildlife Service's authority to administer Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act, as amended, and other U.S. Fish and Wildlife Service authorities. Where Papahānaumokuākea National Marine Sanctuary overlays Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge, NOAA will implement the National Marine Sanctuaries Act to provide supplemental authority to protect resources.

(d) NOAA, in exercising its management authority under National Marine Sanctuaries Act Section 304(d), recognizes U.S. Fish and Wildlife Service's management authority over Midway Atoll National Wildlife Refuge and Hawaiian Islands National Wildlife Refuge under the National Wildlife Refuge System Administration Act, as amended.

§ 922.243 Access.

(a) Access to the Sanctuary is prohibited and thus unlawful except:

(1) When conducting emergency response actions, law enforcement activities, and activities and exercises of

the Armed Forces in accordance with § 922.244(b) and (c);

(2) Pursuant to a permit issued under § 922.245;

(3) When conducting non-commercial fishing activities in the Outer Sanctuary Zone authorized under the Magnuson-Stevens Fishery Conservation and Management Act in accordance with § 922.244 (d);

(4) When conducting scientific exploration or research activities by or for the Secretary of Commerce or the Secretary of the Interior in the Outer Sanctuary Zone in accordance with § 922.244 (f).

(5) When conducting passage without interruption in accordance with paragraphs (b), (c), and (d) of this section.

(b) A vessel may pass without interruption through the sanctuary without requiring a permit as long as the vessel does not stop or engage in the prohibited activities listed in § 922.244 within the sanctuary.

(c) For areas of the sanctuary that are contained within the reporting area surrounding the Particularly Sensitive Sea Area (PSSA) designated by the International Maritime Organization (IMO), a ship reporting system (CORAL SHIPREP) specified below shall be in effect. The coordinates for the Reporting Area are listed in Appendix E to this subpart.

(1) The following vessels, except vessels entitled to sovereign immunity under international law, passing through the reporting area of the sanctuary without interruption, must participate in the ship reporting system as specified in paragraphs (c)(2) through (6) of this section:

(i) Vessels of the United States of any size;

(ii) All other ships 300 gross tonnage or greater that are entering or departing a United States port or place; and

(iii) All other ships of any size entering or departing a United States port or place and experiencing an emergency while transiting through the reporting area.

(2) All vessels passing through the reporting area of the sanctuary without interruption other than those described in paragraph (c)(1) of this section are encouraged to participate in the ship reporting system set forth in paragraphs (c)(2) through (6) of this section.

(3) Immediately upon entering the reporting area, vessels described in paragraph (c)(1) of this section must provide the following information by email sent to nwhi.notifications@noaa.gov in the IMO standard reporting format and data syntax shown in Appendix F to this subpart:

(i) Vessel name, call sign or ship station identity, flag, and IMO identification number if applicable, and either Federal documentation or State registration number if applicable;

(ii) Date, time (UTC) and month of entry;

(iii) Position;

(iv) True course;

(v) Speed in knots and tenths;

(vi) Destination and estimated time of arrival;

(vii) Intended route through the reporting area;

(viii) Vessel draft (in meters);

(ix) Categories of hazardous cargoes on board;

(x) Any vessel defects or deficiencies that restrict maneuverability or impair normal navigation;

(xi) Any pollution incident or goods lost overboard within the PSSA, the reporting area, or the U.S. EEZ;

(xii) Contact information for the vessel's agent or owner;

(xiii) Vessel size (length overall, gross tonnage) and type; and

(xiv) Total number of persons on board.

(4) Immediately upon leaving the reporting area, vessels described in paragraph (c)(1) of this section must provide the following information by email sent to nwhi.notifications@noaa.gov in the IMO standard reporting format and data syntax shown in Appendix F to this subpart:

(i) Vessel name, call sign or ship station identity, flag, and IMO identification number if applicable, and either Federal documentation or State registration number if applicable;

(ii) Date, time (UTC), and month of exit;

(iii) Position; and

(iv) Any pollution incident or goods lost overboard within the PSSA, the reporting area, or the U.S. EEZ.

(5) For vessels that are not equipped with on-board email capability, advanced notice of entrance (as outlined in paragraph (c)(3) of this section) shall be provided at least 72 hours, but not more than one month, prior to entering the reporting area. Notification of departure (as outlined in paragraph (c)(4) of this section) must be provided within 12 hours of leaving the reporting area. Notification under this paragraph may be made by email, telephone, or fax, by contacting:

(i) Email: nwhi.notifications@noaa.gov;

(ii) Telephone: 1-808-395-6944 or 1-866-478-6944; or

(iii) Fax: 1-808-455-3093.

(6) Further reports shall be made by the vessels described in paragraph (c)(1) of this section, and are encouraged for

the vessels described in paragraph (c)(2) of this section, whenever there is a change in navigation status or circumstances, particularly in relation to the intended route, defects or deficiencies, pollution incidents, or goods lost overboard.

§ 922.244 Prohibited or otherwise regulated activities.

(a) The following activities are prohibited and thus are unlawful for any person to conduct or to cause to be conducted within the sanctuary, except as specified in paragraphs (b) through (f) of this section:

(1) Exploring for, developing, or producing oil, gas, or minerals, or any energy development activities;

(2) Using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a sanctuary resource;

(3) Introducing or otherwise releasing an introduced species from within or into the sanctuary;

(4) Deserting a vessel;

(5) Anchoring on or having a vessel anchored on any living or dead coral with an anchor, anchor chain, or anchor rope;

(6) Commercial fishing, or possessing commercial fishing gear except when stowed and not available for immediate use;

(7) Failing to comply with the vessel monitoring system requirements in violation of § 922.246.

(8) Failing to comply with ship reporting requirements in violation of § 922.243.

(9) Non-commercial fishing, or possessing non-commercial fishing gear except when stowed and not available for immediate use;

(10) Drilling into, dredging, or otherwise altering the submerged lands; or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands;

(11) Removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging; or attempting to remove, move, take, harvest, possess, injure, disturb, or damage any living or nonliving sanctuary resource;

(12) Attracting any living sanctuary resource;

(13) Touching coral, living or dead;

(14) Swimming, snorkeling, or closed or open circuit SCUBA diving;

(15) Discharging or depositing any material or other matter into the sanctuary, or discharging or depositing any material or other matter outside of the sanctuary that subsequently enters the sanctuary and injures or has the potential to injure any resources of the sanctuary, except for:

(i) Fish, fish parts, or chumming materials (bait) used in or resulting from lawful fishing activity, provided that such discharge or deposit is during the conduct of lawful fishing activity within the sanctuary;

(ii) Discharge incidental to vessel operations such as approved marine sanitation device effluent, cooling water, and engine exhaust, consistent with Federal statute or regulation; and

(iii) Within Special Preservation Areas or the Midway Atoll Special Management Area, discharging or depositing material or other matter is limited to vessel engine cooling water, weather deck runoff, and vessel engine exhaust, consistent with Federal statute or regulation.

(16) Anchoring a vessel.

(b) The prohibitions in paragraph (a) of this section do not apply to activities necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for law enforcement purposes.

(c) The prohibitions in paragraph (a) of this section do not apply to activities and exercises of the U.S. Armed Forces (including those carried out by the U.S. Coast Guard). This includes the U.S. Armed Forces' response to emergencies posing an unacceptable threat to human health or safety or to the marine environment and admitting of no other feasible solution. All activities and exercises of the U.S. Armed Forces shall be carried out in a manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on sanctuary resources and qualities. These regulations shall not limit or otherwise affect the U.S. Armed Forces discretion to use, maintain, improve, manage, or control any property under their administrative control or otherwise limit the availability of such property for military mission purposes, including, but not limited to, defensive areas and airspace reservations.

(d) The prohibitions in paragraph (a)(9) through (12), and (a)(14) of this section do not apply to non-commercial fishing activities in the Outer Sanctuary Zone authorized under the Magnuson-Stevens Fishery Conservation and Management Act provided that:

(1) Fish harvested, either in whole or in part, are not intended to enter commerce and shall not enter commerce through sale, barter, or trade, and that the resource is managed sustainably;

(2) Fish harvested, either in whole or in part, are not intended to be sold and shall not be sold for any purposes, including, but not limited to, cost-recovery; and

(3) The activities under paragraph (a)(9) through (12), and (a)(14) are only conducted as incidental to and necessary to conduct lawful non-commercial fishing activity.

(e) The prohibitions in paragraphs (a)(9) through (16) of this section, do not apply to any activity conducted under and in accordance with the scope, purpose, terms, and conditions of a sanctuary general permit, or special use permit issued pursuant to subpart D of this part. In no event, may the Director issue a National Marine Sanctuary general permit or special use permit authorizing or otherwise approving activities listed in paragraph (a)(10) of this section for anything other than scientific instruments, when the activity occurs within the Outer Sanctuary Zone.

(f) The prohibitions in paragraph (a) of this section shall not restrict scientific exploration or research activities by or for the Secretary of Commerce or the Secretary of the Interior when the activity occurs within the Outer Sanctuary Zone.

§ 922.245 Permit procedures and criteria.

(a) A person may conduct an activity otherwise prohibited by § 922.244(a)(9) through (16), if such activity is specifically allowed by and conducted in accordance with the scope, purpose, terms and conditions of a permit issued under this section and subpart D of this part, and any additional permit issuance criteria and requirements in paragraphs (a)(1) and (a)(2) of this section.

(1) Native Hawaiian Practices

(i) The activity is non-commercial and will not involve the sale of any organism or material collected;

(ii) The purpose and intent of this activity is appropriate and deemed necessary by traditional standards in the Native Hawaiian culture (pono), and demonstrates an understanding of, and background in, the traditional practice, and its associated values and protocols;

(iii) The activity benefits the resources of the Northwestern Hawaiian Islands and the Native Hawaiian community;

(iv) The activity supports or advances the perpetuation of traditional knowledge and ancestral connections of Native Hawaiians to the Northwestern Hawaiian Islands; and

(v) Any living sanctuary resource harvested from the sanctuary will be consumed or utilized in the sanctuary.

(2) Recreation permits

(i) The activity is limited to the Midway Atoll Special Management Area.

(ii) The activity is for the purpose of recreational activities as defined in § 922.241;

(iii) The activity is not associated with any for-hire operation;

(iv) The activity does not involve any extractive use; and

(b) Applications for permits should be addressed to the NOAA Inouye Regional Center, Office of National Marine Sanctuaries; ATT: Permit Coordinator, Papahānaumokuākea, 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

(c) The Secretary of Commerce may authorize sustenance fishing outside of any Special Preservation Area as a term or condition of any general permit or special use permit issued under this section and subpart D of this part. Sustenance fishing in the Midway Atoll Special Management Area shall not be allowed unless the activity has been determined by the Director of the U.S. Fish and Wildlife Service or their designee to be compatible with the purposes for which the Midway Atoll National Wildlife Refuge was established. Sustenance fishing must be conducted in a manner compatible with this part, including considering the extent to which the conduct of the activity may diminish Sanctuary resources, qualities, and ecological integrity, as well as any indirect, secondary, or cumulative effects of the activity and the duration of such effects. The Secretary of Commerce may develop procedures for systematic reporting of sustenance fishing.

(d) In addition to other applicable permit issuance criteria and requirements, a permit may not be issued under this section unless the applicant's vessel has been outfitted with a VMS unit approved by OLE and the applicant complies with the requirements of § 922.246.

§ 922.246 Requirements for a vessel monitoring system.

(a) *Requirement for use.* An owner or operator of a vessel that has been issued a general permit or special use permit under § 922.245 and subpart D of this part must ensure that such vessel is operating a NOAA OLE type-approved VMS on board when operating within the sanctuary. An operating VMS includes an operating mobile transmitting unit on the vessel and a functioning communication link between the unit and OLE as provided by an OLE-approved communication service provider. As a condition of authorized access to the sanctuary, a vessel owner or operator subject to the requirements for a VMS in this section must allow OLE, the U.S. Coast Guard, and their authorized officers and designees access to the vessel's position data obtained from the VMS. NOAA may have access to, and use of,

collected data for scientific, statistical, and management purposes, and to monitor implementation of this subpart.

(b) *Installing and activating the VMS.*

(1) OLE has approval authority over the type of VMS used and the installation and operation of the VMS unit.

(2) The owner or operator of a vessel must coordinate with OLE to install and activate an approved VMS prior to operating within the sanctuary. For the purposes of this section, the following contact information applies:

(i) *OLE.* Address: 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808-725-6100; facsimile: 808-725-6199; email: pidvms@noaa.gov; business hours: Monday through Friday, except Federal holidays, 8 a.m. to 4:30 p.m., Hawaii Standard Time.

(ii) *VMS Helpdesk.* Telephone: 888-219-9228; email: ole.helpdesk@noaa.gov; business hours: Monday through Friday, except Federal holidays, 7 a.m. to 11 p.m., Eastern Time.

(c) *Interruption of operation of the VMS.* When a vessel's VMS is not operating properly within the sanctuary, the owner or operator must immediately contact OLE, and follow instructions from that office. If notified by OLE that a vessel's VMS is not operating properly, the owner and operator must follow instructions from that office. In either event, such instructions may include, but are not limited to, manually communicating a vessel's location as directed by OLE; or exiting the sanctuary until the VMS is operable.

(d) *Activities Regarding VMS For Vessels Operating in the Sanctuary.* The following activities regarding vessel monitoring systems are prohibited and thus unlawful for any person to conduct or cause to be conducted:

(1) Operating any vessel within the sanctuary without an OLE type-approved VMS;

(2) Failing to install, activate, repair, or replace a VMS prior to entering the sanctuary;

(3) Failing to operate and maintain a VMS on board the vessel;

(4) Tampering with, damaging, destroying, altering, or in any way distorting, rendering useless, inoperative, ineffective, or inaccurate the VMS, or VMS signal, or attempting any of the same;

(5) Failing to contact OLE or follow OLE instructions when automatic position reporting has been interrupted;

(6) Registering a VMS to more than one vessel permitted to operate within the sanctuary at the same time;

(7) Connecting or leaving connected additional equipment to a VMS unit without the prior approval of OLE; and

(8) Making a false statement, oral or written, to an authorized officer regarding the installation, use, operation, or maintenance of a VMS unit or communication service provider.

§ 922.247 Sunken military craft.

Sunken military craft are administered by the respective Secretary concerned pursuant to the Sunken Military Craft Act (Pub. L. 108-375, Title XIV, sections 1401 to 1408; 10 U.S.C. 113 note). The Director will enter into a Memorandum of Agreement regarding collaboration with other Federal agencies charged with implementing the Sunken Military Craft Act that may address aspects of managing and protecting sunken military craft. The Director will request approval from the Secretary concerned for any terms and conditions of ONMS permits that may involve sunken military craft.

Appendix A to Subpart W of Part 922—Papahānaumokuākea National Marine Sanctuary Boundary Description and Coordinates

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

Point No.	Longitude	Latitude
1	180.00000	25.38976
2	179.99985	25.38982
3	179.96681	25.40451
4	179.93392	25.41950
5	179.90119	25.43478
6	179.86863	25.45034
7	179.83622	25.46619
8	179.78793	25.49050
9	179.75595	25.50707
10	179.72415	25.52391
11	179.69252	25.54104
12	179.66108	25.55844
13	179.62981	25.57612
14	179.59874	25.59408
15	179.56786	25.61231
16	179.53716	25.63081
17	179.50667	25.64959
18	179.47637	25.66863
19	179.44627	25.68794
20	179.41638	25.70751
21	179.38670	25.72735
22	179.35722	25.74745
23	179.32796	25.76781
24	179.28448	25.79883
25	179.25576	25.81983
26	179.22255	25.84463
27	179.18175	25.87583
28	179.15383	25.89770
29	179.12613	25.91982
30	179.09868	25.94218
31	179.07146	25.96479
32	179.03108	25.99915
33	179.00447	26.02235
34	178.97810	26.04578
35	178.93902	26.08137
36	178.91329	26.10537
37	178.88781	26.12961
38	178.86259	26.15407

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
39	178.82525	26.19117	113	177.87543	28.90360	187	179.73411	31.34598
40	178.80068	26.21618	114	177.87967	28.93173	188	179.77707	31.36728
41	178.77639	26.24141	115	177.88514	28.96554	189	179.81095	31.38371
42	178.75236	26.26685	116	177.89133	29.00123	190	179.86214	31.40779
43	178.71683	26.30540	117	177.90063	29.05066	191	179.89652	31.42346
44	178.69349	26.33136	118	177.90735	29.08379	192	179.94844	31.44640
45	178.65901	26.37068	119	177.91806	29.13300	193	179.98329	31.46131
46	178.63637	26.39715	120	177.92567	29.16572	194	-180.00000	31.46823
47	178.61378	26.42409	121	177.93780	29.21468	195	-179.96410	31.48309
48	178.59171	26.45096	122	177.94636	29.24722	196	-179.92880	31.49722
49	178.56993	26.47801	123	177.95989	29.29590	197	-179.89333	31.51105
50	178.54844	26.50526	124	177.96959	29.32896	198	-179.83980	31.53119
51	178.52725	26.53270	125	177.97946	29.36122	199	-179.78591	31.55062
52	178.49601	26.57420	126	177.98970	29.39340	200	-179.74978	31.56318
53	178.46544	26.61611	127	178.00575	29.44148	201	-179.71350	31.57542
54	178.44544	26.64427	128	178.01692	29.47341	202	-179.65880	31.59317
55	178.41601	26.68685	129	178.03438	29.52113	203	-179.62215	31.60460
56	178.39677	26.71544	130	178.04647	29.55280	204	-179.56692	31.62114
57	178.37784	26.74421	131	178.06531	29.60012	205	-179.51138	31.63695
58	178.35922	26.77314	132	178.08497	29.64717	206	-179.47371	31.64721
59	178.34092	26.80223	133	178.09853	29.67840	207	-179.41770	31.66179
60	178.30653	26.85803	134	178.11268	29.71000	208	-179.38021	31.67109
61	178.28885	26.88744	135	178.13426	29.75642	209	-179.33210	31.68252
62	178.26294	26.93185	136	178.15665	29.80255	210	-179.28243	31.69383
63	178.24606	26.96164	137	178.17203	29.83313	211	-179.23675	31.70369
64	178.22951	26.99158	138	178.19577	29.87875	212	-179.19878	31.71149
65	178.21329	27.02166	139	178.21216	29.90921	213	-179.16071	31.71896
66	178.19632	27.05394	140	178.22879	29.93930	214	-179.10344	31.72953
67	178.17402	27.09774	141	178.25439	29.98416	215	-179.06516	31.73615
68	178.15895	27.12831	142	178.27525	30.01949	216	-179.00758	31.74546
69	178.14422	27.15901	143	178.29311	30.04905	217	-178.94983	31.75399
70	178.12274	27.20529	144	178.31861	30.09001	218	-178.90738	31.75980
71	178.10884	27.23631	145	178.34009	30.12350	219	-178.86874	31.76473
72	178.08864	27.28305	146	178.35931	30.15271	220	-178.82975	31.76934
73	178.06920	27.33006	147	178.38857	30.19588	221	-178.79099	31.77358
74	178.05667	27.36154	148	178.41018	30.22681	222	-178.75218	31.77748
75	178.03853	27.40896	149	178.43934	30.26737	223	-178.71332	31.78104
76	178.02687	27.44071	150	178.47063	30.30946	224	-178.67441	31.78425
77	178.01003	27.48851	151	178.49239	30.33792	225	-178.63547	31.78712
78	177.99924	27.52051	152	178.51400	30.36556	226	-178.59650	31.78964
79	177.98881	27.55259	153	178.54703	30.40666	227	-178.55749	31.79182
80	177.97873	27.58477	154	178.57973	30.44608	228	-178.51846	31.79366
81	177.96901	27.61703	155	178.60482	30.47552	229	-178.47941	31.79515
82	177.95509	27.66559	156	178.62805	30.50216	230	-178.43412	31.79649
83	177.94198	27.71432	157	178.65341	30.53061	231	-178.39504	31.79729
84	177.93368	27.74690	158	178.68811	30.56854	232	-178.35596	31.79775
85	177.92568	27.77984	159	178.71589	30.59815	233	-178.32396	31.79786
86	177.91811	27.81256	160	178.75298	30.63662	234	-178.28487	31.79769
87	177.90744	27.86176	161	178.77809	30.66199	235	-178.24553	31.79717
88	177.90079	27.89464	162	178.80351	30.68713	236	-178.20645	31.79631
89	177.89149	27.94406	163	178.84220	30.72443	237	-178.16738	31.79510
90	177.88574	27.97707	164	178.88157	30.76121	238	-178.12834	31.79354
91	177.88037	28.01014	165	178.90818	30.78543	239	-178.08931	31.79165
92	177.87300	28.05982	166	178.94864	30.82133	240	-178.05031	31.78940
93	177.86647	28.10959	167	178.97598	30.84496	241	-178.01134	31.78682
94	177.86258	28.14281	168	179.00360	30.86835	242	-177.97241	31.78389
95	177.85744	28.19271	169	179.04556	30.90297	243	-177.93351	31.78061
96	177.85447	28.22601	170	179.07393	30.92578	244	-177.89466	31.77699
97	177.85073	28.27600	171	179.11693	30.95947	245	-177.85585	31.77303
98	177.84871	28.30936	172	179.14594	30.98161	246	-177.81646	31.76865
99	177.84706	28.34273	173	179.18995	31.01433	247	-177.77776	31.76401
100	177.84529	28.39281	174	179.21963	31.03582	248	-177.73912	31.75902
101	177.84436	28.44291	175	179.26463	31.06757	249	-177.70055	31.75369
102	177.84422	28.47631	176	179.29516	31.08855	250	-177.66205	31.74802
103	177.84445	28.50971	177	179.34112	31.11928	251	-177.62362	31.74202
104	177.84551	28.55981	178	179.38763	31.14941	252	-177.58526	31.73567
105	177.84670	28.59348	179	179.41894	31.16915	253	-177.54140	31.72800
106	177.84844	28.63098	180	179.45050	31.18861	254	-177.50321	31.72097
107	177.85148	28.68101	181	179.49827	31.21728	255	-177.46512	31.71361
108	177.85399	28.71434	182	179.54657	31.24532	256	-177.42712	31.70592
109	177.85761	28.75561	183	179.57905	31.26365	257	-177.38921	31.69789
110	177.86197	28.79830	184	179.61792	31.28512	258	-177.35141	31.68952
111	177.86786	28.84813	185	179.65085	31.30287	259	-177.31372	31.68082
112	177.87226	28.88131	186	179.70065	31.32895	260	-177.27613	31.67179

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
261	-177.23866	31.66242	335	-174.00210	30.92545	409	-171.60049	29.12658
262	-177.20131	31.65273	336	-173.95092	30.90176	410	-171.54349	29.12439
263	-177.16094	31.64185	337	-173.91394	30.88410	411	-171.50552	29.12249
264	-177.12384	31.63149	338	-173.88027	30.86763	412	-171.45928	29.11977
265	-177.08687	31.62082	339	-173.83015	30.84236	413	-171.42136	29.11719
266	-177.04995	31.60978	340	-173.79699	30.82515	414	-171.38347	29.11427
267	-176.99406	31.60543	341	-173.74828	30.79912	415	-171.32671	29.10925
268	-176.95227	31.60174	342	-173.71286	30.77965	416	-171.28892	29.10547
269	-176.91352	31.59795	343	-173.67333	30.75735	417	-171.25118	29.10135
270	-176.87481	31.59382	344	-173.63202	30.73339	418	-171.21350	29.09689
271	-176.83616	31.58934	345	-173.60020	30.71444	419	-171.17551	29.09204
272	-176.79756	31.58453	346	-173.56860	30.69522	420	-171.13794	29.08690
273	-176.73979	31.57666	347	-173.52165	30.66586	421	-171.10043	29.08142
274	-176.70136	31.57100	348	-173.49065	30.64594	422	-171.04430	29.07256
275	-176.66300	31.56499	349	-173.45306	30.62120	423	-171.00697	29.06623
276	-176.60561	31.55534	350	-173.40817	30.59091	424	-170.96972	29.05956
277	-176.56718	31.54844	351	-173.37804	30.57004	425	-170.93255	29.05256
278	-176.52911	31.54125	352	-173.34479	30.54651	426	-170.89547	29.04522
279	-176.49114	31.53372	353	-173.30046	30.51431	427	-170.85848	29.03755
280	-176.45325	31.52586	354	-173.25673	30.48153	428	-170.82159	29.02954
281	-176.41282	31.51708	355	-173.22791	30.45935	429	-170.78479	29.02120
282	-176.37095	31.50759	356	-173.19936	30.43692	430	-170.74809	29.01253
283	-176.33338	31.49873	357	-173.15960	30.40490	431	-170.69325	28.99890
284	-176.29414	31.48910	358	-173.12000	30.37227	432	-170.65683	28.98940
285	-176.23818	31.47469	359	-173.09242	30.34897	433	-170.60242	28.97453
286	-176.20102	31.46467	360	-173.06512	30.32542	434	-170.56630	28.96421
287	-176.14552	31.44902	361	-173.02470	30.28965	435	-170.53030	28.95356
288	-176.10869	31.43818	362	-172.98494	30.25335	436	-170.49444	28.94259
289	-176.07199	31.42701	363	-172.95880	30.22886	437	-170.44089	28.92552
290	-176.03543	31.41553	364	-172.93295	30.20413	438	-170.40537	28.91374
291	-175.99902	31.40371	365	-172.89474	30.16662	439	-170.36999	28.90164
292	-175.94468	31.38539	366	-172.85721	30.12860	440	-170.33476	28.88922
293	-175.90865	31.37278	367	-172.83096	30.10131	441	-170.29968	28.87648
294	-175.87278	31.35985	368	-172.79458	30.06247	442	-170.24735	28.85678
295	-175.83644	31.34637	369	-172.77072	30.03631	443	-170.21266	28.84325
296	-175.80089	31.33281	370	-172.74717	30.00995	444	-170.16441	28.82380
297	-175.76551	31.31893	371	-172.71244	29.97001	445	-170.11868	28.81843
298	-175.72777	31.30370	372	-172.67843	29.92961	446	-170.06241	28.81110
299	-175.67361	31.30264	373	-172.65616	29.90243	447	-170.00627	28.80301
300	-175.62462	31.30118	374	-172.62336	29.86129	448	-169.95029	28.79415
301	-175.58577	31.29962	375	-172.60190	29.83362	449	-169.89448	28.78454
302	-175.56300	31.29856	376	-172.57892	29.80334	450	-169.85736	28.77770
303	-175.50480	31.29533	377	-172.55812	29.77530	451	-169.80186	28.76683
304	-175.44667	31.29132	378	-172.52756	29.73290	452	-169.74655	28.75519
305	-175.38862	31.28654	379	-172.50760	29.70441	453	-169.69147	28.74281
306	-175.33066	31.28099	380	-172.48798	29.67574	454	-169.63661	28.72968
307	-175.27281	31.27467	381	-172.46870	29.64690	455	-169.60017	28.72051
308	-175.21509	31.26757	382	-172.44976	29.61789	456	-169.54573	28.70614
309	-175.15433	31.25928	383	-172.42200	29.57406	457	-169.49155	28.69103
310	-175.10019	31.25117	384	-172.40392	29.54464	458	-169.45559	28.68055
311	-175.05021	31.24316	385	-172.37746	29.50021	459	-169.40188	28.66422
312	-174.99307	31.23327	386	-172.35178	29.45544	460	-169.34847	28.64716
313	-174.93613	31.22261	387	-172.33510	29.42540	461	-169.29538	28.62937
314	-174.87938	31.21120	388	-172.31074	29.38007	462	-169.24262	28.61087
315	-174.82112	31.19865	389	-172.29495	29.34967	463	-169.19019	28.59165
316	-174.78357	31.19012	390	-172.27193	29.30382	464	-169.13811	28.57172
317	-174.74612	31.18126	391	-172.25703	29.27308	465	-169.08640	28.55108
318	-174.69017	31.16735	392	-172.23535	29.22673	466	-169.03506	28.52974
319	-174.65301	31.15766	393	-172.22135	29.19567	467	-169.00106	28.51513
320	-174.61598	31.14764	394	-172.20103	29.14885	468	-168.95037	28.49263
321	-174.57907	31.13730	395	-172.18794	29.11749	469	-168.90010	28.46945
322	-174.54229	31.12663	396	-172.18269	29.10461	470	-168.85025	28.44559
323	-174.48737	31.11001	397	-172.14425	29.10857	471	-168.81726	28.42931
324	-174.43277	31.09266	398	-172.10644	29.11211	472	-168.76813	28.40432
325	-174.39656	31.08069	399	-172.06858	29.11531	473	-168.71946	28.37867
326	-174.36049	31.06840	400	-172.01172	29.11947	474	-168.67125	28.35237
327	-174.32457	31.05579	401	-171.95480	29.12286	475	-168.62352	28.32541
328	-174.28881	31.04287	402	-171.91682	29.12469	476	-168.58344	28.30203
329	-174.25322	31.02962	403	-171.87882	29.12618	477	-168.53902	28.30813
330	-174.21779	31.01607	404	-171.82179	29.12776	478	-168.48296	28.31510
331	-174.16782	30.99630	405	-171.78376	29.12839	479	-168.42677	28.32131
332	-174.12317	30.97807	406	-171.73360	29.12869	480	-168.37049	28.32675
333	-174.08834	30.96342	407	-171.67655	29.12830	481	-168.33291	28.32995
334	-174.03646	30.94087	408	-171.63852	29.12761	482	-168.27648	28.33411

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
483	-168.21998	28.33750	557	-165.27680	27.26746	631	-161.02266	23.15458
484	-168.16342	28.34011	558	-165.25188	27.24256	632	-161.01820	23.10217
485	-168.10683	28.34195	559	-165.21504	27.20478	633	-161.01730	23.04961
486	-168.05021	28.34302	560	-165.19085	27.17932	634	-161.01998	22.99711
487	-168.00043	28.34332	561	-165.16695	27.15365	635	-161.02620	22.94485
488	-167.94380	28.34293	562	-165.14335	27.12775	636	-161.03595	22.89307
489	-167.88718	28.34177	563	-165.12006	27.10164	637	-161.04919	22.84195
490	-167.83059	28.33983	564	-165.09707	27.07533	638	-161.06584	22.79170
491	-167.77404	28.33713	565	-165.07732	27.05226	639	-161.08586	22.74252
492	-167.73621	28.33488	566	-165.03132	27.03829	640	-161.10915	22.69460
493	-167.67976	28.33089	567	-164.99614	27.02718	641	-161.13562	22.64812
494	-167.62339	28.32613	568	-164.96109	27.01574	642	-161.16516	22.60327
495	-167.56712	28.32059	569	-164.90877	26.99799	643	-161.19766	22.56023
496	-167.51095	28.31429	570	-164.85677	26.97951	644	-161.23298	22.51916
497	-167.45490	28.30722	571	-164.82201	26.96670	645	-161.27099	22.48022
498	-167.39898	28.29939	572	-164.70700	26.92271	646	-161.31153	22.44356
499	-167.34321	28.29079	573	-164.68299	26.92268	647	-161.35444	22.40934
500	-167.30612	28.28464	574	-164.64572	26.92233	648	-161.39956	22.37767
501	-167.25063	28.27477	575	-164.58983	26.92117	649	-161.44671	22.34869
502	-167.21374	28.26778	576	-164.55259	26.91997	650	-161.49571	22.32250
503	-167.15856	28.25665	577	-164.51536	26.91843	651	-161.54635	22.29922
504	-167.10359	28.24478	578	-164.45955	26.91547	652	-161.59846	22.27892
505	-167.04884	28.23215	579	-164.40380	26.91174	653	-161.65181	22.26168
506	-166.99432	28.21878	580	-164.34813	26.90724	654	-161.70621	22.24758
507	-166.94004	28.20466	581	-164.29254	26.90197	655	-161.76145	22.23667
508	-166.88603	28.18981	582	-164.25554	26.89803	656	-161.81730	22.22899
509	-166.85017	28.17950	583	-164.21858	26.89375	657	-161.87356	22.22458
510	-166.81444	28.16886	584	-164.16325	26.88669	658	-161.93000	22.22343
511	-166.79269	28.16220	585	-164.10804	26.87887	659	-161.98641	22.22557
512	-166.76001	28.15196	586	-164.05299	26.87029	660	-162.04257	22.23099
513	-166.72461	28.14051	587	-164.01637	26.86414	661	-162.09826	22.23966
514	-166.68934	28.12874	588	-163.97983	26.85766	662	-163.00000	22.40727
515	-166.65422	28.11665	589	-163.92516	26.84731	663	-163.00000	19.23458
516	-166.61924	28.10424	590	-163.87068	26.83620	664	-163.02954	19.26137
517	-166.58441	28.09152	591	-163.81641	26.82434	665	-163.05474	19.28472
518	-166.54974	28.07847	592	-163.78034	26.81602	666	-163.07971	19.30831
519	-166.51522	28.06511	593	-163.74438	26.80737	667	-163.10443	19.33213
520	-166.48086	28.05144	594	-163.69063	26.79377	668	-163.12891	19.35619
521	-166.42964	28.03034	595	-163.63712	26.77943	669	-163.15314	19.38047
522	-166.39570	28.01589	596	-163.58387	26.76435	670	-163.18902	19.41731
523	-166.36193	28.00113	597	-163.54853	26.75389	671	-163.21262	19.44214
524	-166.31162	27.97842	598	-163.51331	26.74310	672	-163.23597	19.46720
525	-166.27830	27.96290	599	-163.46071	26.72632	673	-163.25906	19.49248
526	-166.24517	27.94707	600	-163.40842	26.70881	674	-163.28189	19.51796
527	-166.21223	27.93095	601	-163.35645	26.69058	675	-163.31564	19.55659
528	-166.17948	27.91452	602	-163.30480	26.67164	676	-163.33781	19.58261
529	-166.14693	27.89780	603	-163.27056	26.65861	677	-163.35971	19.60883
530	-166.11458	27.88078	604	-163.21948	26.63848	678	-163.38134	19.63525
531	-166.06622	27.85459	605	-163.16876	26.61765	679	-163.41328	19.67526
532	-166.03438	27.83684	606	-163.13516	26.60337	680	-163.43423	19.70218
533	-166.00275	27.81881	607	-163.08506	26.58138	681	-163.45490	19.72929
534	-165.97134	27.80048	608	-163.03536	26.55870	682	-163.47678	19.75859
535	-165.94014	27.78187	609	-163.00000	26.54202	683	-163.49689	19.78608
536	-165.90917	27.76298	610	-163.00000	24.11409	684	-163.51671	19.81376
537	-165.87842	27.74381	611	-161.74242	23.88042	685	-163.54591	19.85562
538	-165.83251	27.71439	612	-161.68679	23.86839	686	-163.56501	19.88376
539	-165.80234	27.69452	613	-161.63210	23.85316	687	-163.58383	19.91207
540	-165.77240	27.67438	614	-161.57857	23.83478	688	-163.60235	19.94056
541	-165.74243	27.65378	615	-161.52642	23.81332	689	-163.62957	19.98361
542	-165.71297	27.63310	616	-161.47586	23.78888	690	-163.64735	20.01252
543	-165.68375	27.61215	617	-161.42708	23.76155	691	-163.66483	20.04159
544	-165.65478	27.59094	618	-161.38029	23.73144	692	-163.68201	20.07083
545	-165.62607	27.56946	619	-161.33566	23.69868	693	-163.69888	20.10022
546	-165.59760	27.54773	620	-161.29337	23.66338	694	-163.71545	20.12977
547	-165.56939	27.52573	621	-161.25360	23.62570	695	-163.73841	20.17192
548	-165.54144	27.50348	622	-161.21650	23.58578	696	-163.75664	20.18197
549	-165.50001	27.46963	623	-161.18221	23.54379	697	-163.78708	20.19906
550	-165.47272	27.44675	624	-161.15087	23.49989	698	-163.81734	20.21644
551	-165.44570	27.42363	625	-161.12260	23.45425	699	-163.84743	20.23409
552	-165.41895	27.40026	626	-161.09751	23.40707	700	-163.87734	20.25202
553	-165.39248	27.37664	627	-161.07569	23.35851	701	-163.90706	20.27022
554	-165.36628	27.35279	628	-161.05724	23.30879	702	-163.93659	20.28870
555	-165.34036	27.32870	629	-161.04221	23.25809	703	-163.95588	20.30099
556	-165.30201	27.29213	630	-161.03067	23.20662	704	-163.98535	20.29532

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
705	-164.02014	20.28893	779	-167.36319	20.48344	853	-169.97718	22.19335
706	-164.07244	20.27996	780	-167.39664	20.49460	854	-170.00653	22.21103
707	-164.12487	20.27171	781	-167.44659	20.51193	855	-170.05123	22.20415
708	-164.17742	20.26419	782	-167.47975	20.52386	856	-170.08671	22.19907
709	-164.23008	20.25739	783	-167.51278	20.53610	857	-170.12225	22.19430
710	-164.28284	20.25133	784	-167.54695	20.54912	858	-170.15783	22.18987
711	-164.33569	20.24599	785	-167.57973	20.56197	859	-170.19345	22.18575
712	-164.38861	20.24139	786	-167.61238	20.57511	860	-170.22911	22.18196
713	-164.44159	20.23752	787	-167.64489	20.58856	861	-170.28268	22.17688
714	-164.49463	20.23438	788	-167.67726	20.60230	862	-170.31843	22.17390
715	-164.54771	20.23197	789	-167.70949	20.61635	863	-170.35421	22.17125
716	-164.58106	20.23084	790	-167.74158	20.63068	864	-170.39001	22.16891
717	-164.60571	20.23016	791	-167.77351	20.64532	865	-170.42584	22.16691
718	-164.65884	20.22922	792	-167.80530	20.66024	866	-170.46169	22.16523
719	-164.71217	20.22902	793	-167.83694	20.67546	867	-170.51548	22.16332
720	-164.74760	20.22929	794	-167.86841	20.69097	868	-170.55136	22.16245
721	-164.78302	20.22990	795	-167.91533	20.71478	869	-170.58725	22.16191
722	-164.83614	20.23141	796	-167.94640	20.73101	870	-170.62314	22.16170
723	-164.88922	20.23366	797	-167.97731	20.74752	871	-170.65929	22.16181
724	-164.92459	20.23557	798	-168.00804	20.76432	872	-170.69518	22.16224
725	-164.97761	20.23904	799	-168.03861	20.78140	873	-170.73106	22.16301
726	-165.01292	20.24176	800	-168.08412	20.80755	874	-170.76693	22.16410
727	-165.04914	20.24489	801	-168.11424	20.82533	875	-170.80279	22.16551
728	-165.10201	20.25007	802	-168.14417	20.84338	876	-170.83863	22.16725
729	-165.13720	20.25393	803	-168.17392	20.86172	877	-170.89236	22.17047
730	-165.18992	20.26033	804	-168.20348	20.88032	878	-170.92815	22.17302
731	-165.24253	20.26745	805	-168.24746	20.90873	879	-170.96391	22.17590
732	-165.27754	20.27261	806	-168.27653	20.92801	880	-170.99964	22.17910
733	-165.31250	20.27808	807	-168.31977	20.95743	881	-171.03533	22.18262
734	-165.36483	20.28690	808	-168.36255	20.98744	882	-171.07099	22.18647
735	-165.41702	20.29644	809	-168.40487	21.01804	883	-171.12440	22.19286
736	-165.45173	20.30321	810	-168.43282	21.03877	884	-171.15995	22.19751
737	-165.50401	20.31402	811	-168.47433	21.07033	885	-171.19545	22.20249
738	-165.54798	20.32372	812	-168.50174	21.09169	886	-171.23089	22.20780
739	-165.60124	20.31609	813	-168.54244	21.12420	887	-171.28396	22.21635
740	-165.65391	20.30930	814	-168.58263	21.15727	888	-171.33689	22.22563
741	-165.70669	20.30323	815	-168.62230	21.19089	889	-171.38967	22.23563
742	-165.75955	20.29790	816	-168.66145	21.22506	890	-171.42477	22.24269
743	-165.81249	20.29329	817	-168.68726	21.24813	891	-171.47727	22.25389
744	-165.86549	20.28942	818	-168.71283	21.27145	892	-171.52961	22.26579
745	-165.91855	20.28628	819	-168.75073	21.30685	893	-171.58175	22.27841
746	-165.97164	20.28388	820	-168.77569	21.33074	894	-171.63370	22.29174
747	-166.02477	20.28221	821	-168.81266	21.36701	895	-171.68543	22.30577
748	-166.07792	20.28127	822	-168.83700	21.39147	896	-171.73694	22.32050
749	-166.13108	20.28107	823	-168.87302	21.42858	897	-171.78823	22.33594
750	-166.18423	20.28161	824	-168.90847	21.46618	898	-171.83927	22.35207
751	-166.23737	20.28287	825	-168.93178	21.49152	899	-171.89005	22.36889
752	-166.29049	20.28488	826	-168.96624	21.52992	900	-171.94057	22.38641
753	-166.34357	20.28762	827	-168.99177	21.55913	901	-171.99082	22.40461
754	-166.36478	20.28892	828	-169.02276	21.59546	902	-172.03998	22.42318
755	-166.39682	20.29110	829	-169.04473	21.62184	903	-172.09233	22.42751
756	-166.43214	20.29382	830	-169.07716	21.66178	904	-172.12811	22.43088
757	-166.48507	20.29852	831	-169.09844	21.68866	905	-172.18170	22.43653
758	-166.52032	20.30205	832	-169.12982	21.72934	906	-172.21738	22.44070
759	-166.57311	20.30796	833	-169.15039	21.75669	907	-172.25302	22.44519
760	-166.61798	20.31350	834	-169.18071	21.79808	908	-172.28861	22.45001
761	-166.65308	20.31816	835	-169.20232	21.82840	909	-172.32414	22.45515
762	-166.70563	20.32577	836	-169.21703	21.84743	910	-172.37735	22.46346
763	-166.74060	20.33125	837	-169.23883	21.85466	911	-172.41274	22.46941
764	-166.77552	20.33705	838	-169.27247	21.86611	912	-172.46572	22.47892
765	-166.82777	20.34635	839	-169.32272	21.88387	913	-172.50095	22.48566
766	-166.87988	20.35637	840	-169.37269	21.90231	914	-172.55367	22.49638
767	-166.91453	20.36345	841	-169.42237	21.92143	915	-172.58872	22.50392
768	-166.94911	20.37085	842	-169.47175	21.94123	916	-172.64114	22.51582
769	-166.99267	20.38061	843	-169.52083	21.96170	917	-172.67599	22.52415
770	-167.02709	20.38865	844	-169.56958	21.98284	918	-172.71075	22.53279
771	-167.07857	20.40130	845	-169.61800	22.00464	919	-172.76272	22.54635
772	-167.11278	20.41012	846	-169.66608	22.02710	920	-172.79725	22.55578
773	-167.14689	20.41926	847	-169.71382	22.05022	921	-172.83168	22.56552
774	-167.19433	20.43226	848	-169.76119	22.07399	922	-172.86601	22.57558
775	-167.22830	20.44187	849	-169.80819	22.09840	923	-172.90023	22.58594
776	-167.26218	20.45180	850	-169.85481	22.12345	924	-172.95136	22.60207
777	-167.29596	20.46203	851	-169.90103	22.14914	925	-172.98531	22.61320
778	-167.32963	20.47258	852	-169.94686	22.17546	926	-173.03602	22.63048

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
927	-173.08645	22.64845	1001	-175.70591	23.07887	1075	-177.83690	24.87185
928	-173.11992	22.66081	1002	-175.73795	23.09434	1076	-177.88667	24.87745
929	-173.15325	22.67347	1003	-175.76982	23.11009	1077	-177.94111	24.88429
930	-173.18646	22.68643	1004	-175.81731	23.13426	1078	-177.97195	24.88850
931	-173.23601	22.70643	1005	-175.84877	23.15073	1079	-177.99642	24.89200
932	-173.26888	22.72014	1006	-175.88005	23.16748	1080	-178.05062	24.90028
933	-173.30160	22.73415	1007	-175.91116	23.18451	1081	-178.10469	24.90929
934	-173.34556	22.75354	1008	-175.94209	23.20183	1082	-178.14066	24.91569
935	-173.37723	22.74830	1009	-175.98815	23.22832	1083	-178.16577	24.92034
936	-173.41276	22.74274	1010	-176.01862	23.24633	1084	-178.21953	24.93078
937	-173.44836	22.73750	1011	-176.04891	23.26461	1085	-178.27313	24.94194
938	-173.48400	22.73258	1012	-176.09398	23.29254	1086	-178.32655	24.95380
939	-173.51970	22.72798	1013	-176.12379	23.31150	1087	-178.37978	24.96637
940	-173.55544	22.72371	1014	-176.15339	23.33073	1088	-178.43281	24.97965
941	-173.59122	22.71976	1015	-176.18280	23.35022	1089	-178.48563	24.99363
942	-173.62704	22.71613	1016	-176.21200	23.36998	1090	-178.53822	25.00832
943	-173.66290	22.71283	1017	-176.25542	23.40011	1091	-178.59058	25.02370
944	-173.69879	22.70985	1018	-176.28410	23.42052	1092	-178.61445	25.03096
945	-173.73471	22.70720	1019	-176.31256	23.44119	1093	-178.64360	25.04005
946	-173.77065	22.70487	1020	-176.35486	23.47268	1094	-178.67821	25.05115
947	-173.80661	22.70286	1021	-176.38278	23.49399	1095	-178.70077	25.05859
948	-173.84260	22.70118	1022	-176.41048	23.51554	1096	-178.72148	25.06052
949	-173.87860	22.69983	1023	-176.43795	23.53735	1097	-178.75794	25.06420
950	-173.91461	22.69880	1024	-176.46520	23.55940	1098	-178.81257	25.07031
951	-173.95063	22.69810	1025	-176.50563	23.59294	1099	-178.86732	25.07718
952	-173.98666	22.69772	1026	-176.53229	23.61560	1100	-178.90360	25.08214
953	-174.02268	22.69767	1027	-176.55872	23.63850	1101	-178.93984	25.08742
954	-174.05871	22.69794	1028	-176.59790	23.67330	1102	-178.98140	25.09383
955	-174.09473	22.69854	1029	-176.62372	23.69679	1103	-179.01755	25.09959
956	-174.13075	22.69947	1030	-176.66199	23.73246	1104	-179.07166	25.10883
957	-174.16675	22.70072	1031	-176.68719	23.75653	1105	-179.10765	25.11539
958	-174.20274	22.70229	1032	-176.71213	23.78082	1106	-179.14357	25.12227
959	-174.23871	22.70419	1033	-176.73682	23.80534	1107	-179.19731	25.13318
960	-174.27466	22.70642	1034	-176.76125	23.83007	1108	-179.25088	25.14480
961	-174.31059	22.70897	1035	-176.78542	23.85503	1109	-179.28649	25.15295
962	-174.34649	22.71185	1036	-176.80933	23.88021	1110	-179.32201	25.16141
963	-174.38235	22.71504	1037	-176.83297	23.90559	1111	-179.35744	25.17018
964	-174.41819	22.71857	1038	-176.85635	23.93119	1112	-179.38198	25.17642
965	-174.45398	22.72242	1039	-176.87945	23.95700	1113	-179.43515	25.19048
966	-174.48974	22.72659	1040	-176.90229	23.98302	1114	-179.47030	25.20018
967	-174.52545	22.73108	1041	-176.93602	24.02243	1115	-179.50534	25.21020
968	-174.56111	22.73589	1042	-176.96913	24.06229	1116	-179.55771	25.22581
969	-174.59672	22.74103	1043	-176.99085	24.08911	1117	-179.60982	25.24211
970	-174.63227	22.74649	1044	-177.01229	24.11613	1118	-179.66167	25.25910
971	-174.66777	22.75227	1045	-177.03344	24.14334	1119	-179.69609	25.27081
972	-174.70321	22.75837	1046	-177.06462	24.18450	1120	-179.73039	25.28283
973	-174.73859	22.76479	1047	-177.08505	24.21218	1121	-179.76456	25.29514
974	-174.77389	22.77153	1048	-177.10518	24.24004	1122	-179.79860	25.30776
975	-174.82672	22.78224	1049	-177.12502	24.26808	1123	-179.83251	25.32068
976	-174.86184	22.78978	1050	-177.14456	24.29630	1124	-179.86628	25.33389
977	-174.89689	22.79763	1051	-177.17331	24.33895	1125	-179.89991	25.34741
978	-174.93185	22.80580	1052	-177.19210	24.36760	1126	-179.93340	25.36122
979	-174.96673	22.81429	1053	-177.21058	24.39642	1127	-179.96674	25.37533
980	-175.00151	22.82309	1054	-177.22875	24.42540	1128	-180.00000	25.38976
981	-175.03621	22.83220	1055	-177.25544	24.46918			
982	-175.07081	22.84163	1056	-177.27284	24.49856			
983	-175.10531	22.85136	1057	-177.28992	24.52810			
984	-175.13972	22.86141	1058	-177.30670	24.55779			
985	-175.17401	22.87177	1059	-177.32315	24.58763			
986	-175.20820	22.88244	1060	-177.33929	24.61762			
987	-175.24228	22.89342	1061	-177.36249	24.66210			
988	-175.27624	22.90471	1062	-177.38606	24.67081			
989	-175.31009	22.91630	1063	-177.41985	24.68359			
990	-175.34381	22.92820	1064	-177.45352	24.69667			
991	-175.37741	22.94040	1065	-177.48704	24.71005			
992	-175.41089	22.95290	1066	-177.53706	24.73067			
993	-175.44423	22.96571	1067	-177.57023	24.74479			
994	-175.47744	22.97882	1068	-177.60325	24.75920			
995	-175.51051	22.99222	1069	-177.63612	24.77391			
996	-175.54345	23.00593	1070	-177.66883	24.78890			
997	-175.57624	23.01993	1071	-177.71760	24.81194			
998	-175.60888	23.03422	1072	-177.74992	24.82767			
999	-175.64138	23.04881	1073	-177.78207	24.84367			
1000	-175.67372	23.06370	1074	-177.81404	24.85997			

Appendix B to Subpart W of Part 922— Coordinates for the Outer Sanctuary Zone

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

The boundaries for the areas listed in this appendix, unless otherwise described in this rule, begin at Point 1 as indicated in the particular area's coordinate table and continue to each successive point in numerical order until ending at the last point in the table.

Point No.	Longitude	Latitude
1	180.00000	25.38976
2	179.99985	25.38982

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
3	179.96681	25.40451	77	178.01003	27.48851	151	178.49239	30.33792
4	179.93392	25.41950	78	177.99924	27.52051	152	178.51400	30.36556
5	179.90119	25.43477	79	177.98881	27.55259	153	178.54703	30.40666
6	179.86863	25.45034	80	177.97873	27.58477	154	178.57973	30.44608
7	179.83622	25.46619	81	177.96901	27.61703	155	178.60482	30.47552
8	179.78793	25.49050	82	177.95509	27.66559	156	178.62805	30.50217
9	179.75595	25.50707	83	177.94198	27.71432	157	178.65341	30.53062
10	179.72415	25.52391	84	177.93368	27.74690	158	178.68811	30.56854
11	179.69252	25.54104	85	177.92568	27.77984	159	178.71589	30.59815
12	179.66108	25.55844	86	177.91811	27.81256	160	178.75298	30.63662
13	179.62981	25.57612	87	177.90744	27.86176	161	178.77809	30.66199
14	179.59874	25.59408	88	177.90079	27.89464	162	178.80351	30.68714
15	179.56786	25.61231	89	177.89149	27.94406	163	178.84220	30.72443
16	179.53716	25.63081	90	177.88574	27.97707	164	178.88157	30.76121
17	179.50667	25.64959	91	177.88037	28.01014	165	178.90818	30.78543
18	179.47637	25.66863	92	177.87300	28.05982	166	178.94864	30.82133
19	179.44627	25.68794	93	177.86647	28.10958	167	178.97598	30.84496
20	179.41638	25.70751	94	177.86258	28.14281	168	179.00360	30.86835
21	179.38670	25.72735	95	177.85744	28.19271	169	179.04556	30.90298
22	179.35722	25.74745	96	177.85448	28.22601	170	179.07393	30.92578
23	179.32796	25.76781	97	177.85073	28.27601	171	179.11693	30.95947
24	179.28448	25.79883	98	177.84871	28.30936	172	179.14594	30.98161
25	179.25576	25.81983	99	177.84706	28.34273	173	179.18995	31.01433
26	179.22255	25.84463	100	177.84529	28.39281	174	179.21963	31.03582
27	179.18175	25.87583	101	177.84437	28.44291	175	179.26462	31.06757
28	179.15383	25.89770	102	177.84422	28.47631	176	179.29516	31.08855
29	179.12613	25.91982	103	177.84445	28.50971	177	179.34112	31.11929
30	179.09868	25.94218	104	177.84551	28.55981	178	179.38763	31.14941
31	179.07146	25.96479	105	177.84670	28.59348	179	179.41894	31.16915
32	179.03108	25.99915	106	177.84844	28.63098	180	179.45050	31.18861
33	179.00447	26.02235	107	177.85148	28.68101	181	179.49827	31.21728
34	178.97810	26.04578	108	177.85399	28.71434	182	179.54657	31.24532
35	178.93902	26.08137	109	177.85761	28.75561	183	179.57905	31.26365
36	178.91329	26.10537	110	177.86197	28.79830	184	179.61792	31.28512
37	178.88781	26.12961	111	177.86786	28.84813	185	179.65085	31.30287
38	178.86259	26.15407	112	177.87226	28.88131	186	179.70065	31.32895
39	178.82525	26.19117	113	177.87543	28.90359	187	179.73411	31.34597
40	178.80068	26.21618	114	177.87967	28.93174	188	179.77707	31.36728
41	178.77639	26.24141	115	177.88514	28.96554	189	179.81095	31.38371
42	178.75236	26.26685	116	177.89133	29.00123	190	179.86214	31.40779
43	178.71684	26.30540	117	177.90063	29.05066	191	179.89652	31.42346
44	178.69349	26.33136	118	177.90735	29.08379	192	179.94844	31.44640
45	178.65901	26.37068	119	177.91806	29.13300	193	179.98329	31.46131
46	178.63637	26.39715	120	177.92568	29.16572	194	180.00000	31.46823
47	178.61378	26.42409	121	177.93780	29.21468	195	179.96410	31.48309
48	178.59171	26.45096	122	177.94636	29.24723	196	179.92880	31.49723
49	178.56993	26.47801	123	177.95989	29.29590	197	179.89333	31.51105
50	178.54844	26.50526	124	177.96959	29.32896	198	179.83980	31.53119
51	178.52724	26.53270	125	177.97946	29.36123	199	179.78591	31.55062
52	178.49600	26.57420	126	177.98970	29.39340	200	179.74978	31.56318
53	178.46544	26.61611	127	178.00575	29.44148	201	179.71350	31.57542
54	178.44544	26.64427	128	178.01692	29.47341	202	179.65880	31.59317
55	178.41601	26.68685	129	178.03438	29.52113	203	179.62215	31.60460
56	178.39677	26.71544	130	178.04647	29.55280	204	179.56691	31.62114
57	178.37784	26.74421	131	178.06531	29.60012	205	179.51138	31.63695
58	178.35922	26.77314	132	178.08497	29.64717	206	179.47371	31.64721
59	178.34092	26.80223	133	178.09853	29.67840	207	179.41770	31.66178
60	178.30653	26.85803	134	178.11268	29.71000	208	179.38021	31.67109
61	178.28885	26.88744	135	178.13426	29.75642	209	179.33210	31.68252
62	178.26293	26.93184	136	178.15665	29.80255	210	179.28243	31.69383
63	178.24606	26.96164	137	178.17203	29.83313	211	179.23675	31.70369
64	178.22951	26.99158	138	178.19577	29.87875	212	179.19878	31.71149
65	178.21329	27.02166	139	178.21216	29.90921	213	179.16071	31.71896
66	178.19632	27.05394	140	178.22879	29.93930	214	179.10344	31.72953
67	178.17402	27.09775	141	178.25439	29.98416	215	179.06516	31.73615
68	178.15895	27.12831	142	178.27525	30.01949	216	179.00758	31.74546
69	178.14422	27.15901	143	178.29311	30.04905	217	178.94983	31.75399
70	178.12274	27.20530	144	178.31861	30.09002	218	178.90738	31.75980
71	178.10884	27.23631	145	178.34009	30.12350	219	178.86874	31.76473
72	178.08864	27.28305	146	178.35931	30.15271	220	178.82975	31.76934
73	178.06920	27.33006	147	178.38857	30.19588	221	178.79099	31.77358
74	178.05667	27.36154	148	178.41018	30.22681	222	178.75218	31.77748
75	178.03853	27.40896	149	178.43934	30.26737	223	178.71331	31.78104
76	178.02687	27.44071	150	178.47063	30.30946	224	178.67441	31.78425

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
225	-178.63547	31.78712	299	-175.67361	31.30264	373	-172.65616	29.90243
226	-178.59650	31.78964	300	-175.62462	31.30118	374	-172.62336	29.86129
227	-178.55749	31.79182	301	-175.58577	31.29962	375	-172.60190	29.83362
228	-178.51846	31.79366	302	-175.56300	31.29856	376	-172.57892	29.80334
229	-178.47941	31.79515	303	-175.50480	31.29533	377	-172.55812	29.77530
230	-178.43412	31.79649	304	-175.44667	31.29132	378	-172.52756	29.73290
231	-178.39504	31.79729	305	-175.38861	31.28654	379	-172.50760	29.70441
232	-178.35596	31.79775	306	-175.33066	31.28099	380	-172.48798	29.67574
233	-178.32396	31.79786	307	-175.27281	31.27467	381	-172.46870	29.64690
234	-178.28487	31.79769	308	-175.21509	31.26757	382	-172.44976	29.61789
235	-178.24552	31.79717	309	-175.15434	31.25928	383	-172.42200	29.57406
236	-178.20645	31.79631	310	-175.10019	31.25117	384	-172.40392	29.54464
237	-178.16738	31.79510	311	-175.05021	31.24316	385	-172.37746	29.50021
238	-178.12834	31.79355	312	-174.99307	31.23327	386	-172.35178	29.45544
239	-178.08931	31.79165	313	-174.93613	31.22261	387	-172.33510	29.42540
240	-178.05031	31.78940	314	-174.87938	31.21120	388	-172.31074	29.38007
241	-178.01134	31.78682	315	-174.82112	31.19865	389	-172.29495	29.34967
242	-177.97241	31.78389	316	-174.78357	31.19012	390	-172.27193	29.30382
243	-177.93351	31.78061	317	-174.74613	31.18126	391	-172.25702	29.27308
244	-177.89466	31.77699	318	-174.69017	31.16735	392	-172.23535	29.22673
245	-177.85585	31.77303	319	-174.65301	31.15766	393	-172.22135	29.19567
246	-177.81646	31.76865	320	-174.61598	31.14765	394	-172.20103	29.14885
247	-177.77776	31.76401	321	-174.57907	31.13730	395	-172.18794	29.11749
248	-177.73912	31.75902	322	-174.54229	31.12663	396	-172.18269	29.10461
249	-177.70055	31.75369	323	-174.48737	31.11001	397	-172.14425	29.10857
250	-177.66205	31.74802	324	-174.43277	31.09266	398	-172.10644	29.11211
251	-177.62362	31.74202	325	-174.39656	31.08069	399	-172.06858	29.11531
252	-177.58526	31.73567	326	-174.36049	31.06840	400	-172.01172	29.11948
253	-177.54140	31.72800	327	-174.32457	31.05579	401	-171.95480	29.12286
254	-177.50321	31.72097	328	-174.28881	31.04287	402	-171.91682	29.12469
255	-177.46512	31.71361	329	-174.25322	31.02962	403	-171.87882	29.12618
256	-177.42712	31.70592	330	-174.21779	31.01607	404	-171.82179	29.12776
257	-177.38921	31.69788	331	-174.16782	30.99630	405	-171.78376	29.12839
258	-177.35141	31.68952	332	-174.12317	30.97807	406	-171.73360	29.12869
259	-177.31372	31.68082	333	-174.08835	30.96342	407	-171.67655	29.12830
260	-177.27613	31.67179	334	-174.03646	30.94087	408	-171.63852	29.12761
261	-177.23866	31.66242	335	-174.00210	30.92545	409	-171.60049	29.12658
262	-177.20131	31.65273	336	-173.95092	30.90176	410	-171.54349	29.12439
263	-177.16094	31.64185	337	-173.91394	30.88410	411	-171.50552	29.12250
264	-177.12384	31.63150	338	-173.88027	30.86763	412	-171.45928	29.11977
265	-177.08687	31.62082	339	-173.83014	30.84236	413	-171.42136	29.11719
266	-177.04995	31.60978	340	-173.79699	30.82515	414	-171.38347	29.11427
267	-176.99406	31.60543	341	-173.74828	30.79912	415	-171.32671	29.10925
268	-176.95227	31.60174	342	-173.71286	30.77965	416	-171.28892	29.10547
269	-176.91351	31.59795	343	-173.67333	30.75735	417	-171.25118	29.10135
270	-176.87481	31.59382	344	-173.63202	30.73338	418	-171.21350	29.09689
271	-176.83616	31.58934	345	-173.60020	30.71444	419	-171.17551	29.09204
272	-176.79756	31.58453	346	-173.56860	30.69522	420	-171.13794	29.08690
273	-176.73979	31.57666	347	-173.52165	30.66586	421	-171.10043	29.08142
274	-176.70136	31.57100	348	-173.49065	30.64594	422	-171.04430	29.07256
275	-176.66300	31.56499	349	-173.45306	30.62120	423	-171.00697	29.06623
276	-176.60561	31.55534	350	-173.40817	30.59091	424	-170.96972	29.05956
277	-176.56718	31.54844	351	-173.37804	30.57004	425	-170.93255	29.05256
278	-176.52911	31.54125	352	-173.34479	30.54651	426	-170.89547	29.04522
279	-176.49114	31.53372	353	-173.30046	30.51431	427	-170.85848	29.03755
280	-176.45325	31.52586	354	-173.25673	30.48153	428	-170.82159	29.02954
281	-176.41282	31.51708	355	-173.22791	30.45935	429	-170.78479	29.02120
282	-176.37095	31.50759	356	-173.19936	30.43692	430	-170.74809	29.01253
283	-176.33338	31.49873	357	-173.15960	30.40490	431	-170.69325	28.99890
284	-176.29414	31.48910	358	-173.12000	30.37227	432	-170.65683	28.98940
285	-176.23818	31.47469	359	-173.09241	30.34897	433	-170.60242	28.97453
286	-176.20102	31.46467	360	-173.06512	30.32542	434	-170.56630	28.96421
287	-176.14552	31.44902	361	-173.02470	30.28965	435	-170.53030	28.95356
288	-176.10869	31.43818	362	-172.98494	30.25335	436	-170.49444	28.94259
289	-176.07199	31.42701	363	-172.95880	30.22886	437	-170.44089	28.92552
290	-176.03543	31.41553	364	-172.93295	30.20413	438	-170.40537	28.91374
291	-175.99902	31.40371	365	-172.89474	30.16662	439	-170.36999	28.90164
292	-175.94468	31.38539	366	-172.85721	30.12860	440	-170.33476	28.88922
293	-175.90865	31.37278	367	-172.83096	30.10131	441	-170.29968	28.87648
294	-175.87278	31.35985	368	-172.79458	30.06247	442	-170.24735	28.85678
295	-175.83644	31.34637	369	-172.77072	30.03631	443	-170.21266	28.84325
296	-175.80089	31.33281	370	-172.74717	30.00995	444	-170.16441	28.82380
297	-175.76551	31.31893	371	-172.71244	29.97001	445	-170.11868	28.81843
298	-175.72777	31.30370	372	-172.67843	29.92961	446	-170.06241	28.81110

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
447	-170.00627	28.80301	521	-166.42964	28.03034	595	-163.63712	26.77943
448	-169.95029	28.79415	522	-166.39570	28.01589	596	-163.58387	26.76435
449	-169.89448	28.78454	523	-166.36193	28.00113	597	-163.54853	26.75389
450	-169.85736	28.77770	524	-166.31162	27.97842	598	-163.51331	26.74311
451	-169.80186	28.76683	525	-166.27830	27.96290	599	-163.46071	26.72632
452	-169.74655	28.75519	526	-166.24517	27.94707	600	-163.40842	26.70881
453	-169.69147	28.74281	527	-166.21223	27.93095	601	-163.35645	26.69058
454	-169.63661	28.72968	528	-166.17948	27.91452	602	-163.30480	26.67164
455	-169.60017	28.72051	529	-166.14693	27.89780	603	-163.27056	26.65861
456	-169.54573	28.70614	530	-166.11458	27.88078	604	-163.21948	26.63848
457	-169.49155	28.69103	531	-166.06622	27.85459	605	-163.16876	26.61765
458	-169.45559	28.68055	532	-166.03438	27.83684	606	-163.13516	26.60338
459	-169.40188	28.66422	533	-166.00275	27.81881	607	-163.08506	26.58138
460	-169.34847	28.64716	534	-165.97134	27.80048	608	-163.03536	26.55870
461	-169.29538	28.62937	535	-165.94014	27.78187	609	-163.00000	26.54202
462	-169.24262	28.61087	536	-165.90917	27.76298	610	-163.00000	24.11409
463	-169.19019	28.59165	537	-165.87842	27.74381	611	-164.53740	24.39976
464	-169.13811	28.57172	538	-165.83251	27.71439	612	-165.58333	24.59413
465	-169.08640	28.55108	539	-165.80234	27.69452	613	-166.05600	24.68197
466	-169.03506	28.52974	540	-165.77240	27.67438	614	-166.75000	25.17393
467	-169.00106	28.51513	541	-165.74242	27.65378	615	-167.32998	25.58506
468	-168.95037	28.49264	542	-165.71296	27.63310	616	-167.44143	25.66407
469	-168.90010	28.46945	543	-165.68375	27.61215	617	-167.61200	25.78498
470	-168.85025	28.44559	544	-165.65478	27.59094	618	-167.80596	25.81664
471	-168.81726	28.42931	545	-165.62607	27.56946	619	-167.96475	25.84257
472	-168.76813	28.40432	546	-165.59760	27.54773	620	-170.38404	26.23759
473	-168.71946	28.37867	547	-165.56939	27.52573	621	-171.41934	26.55588
474	-168.67125	28.35237	548	-165.54144	27.50348	622	-171.45849	26.56791
475	-168.62352	28.32541	549	-165.50001	27.46963	623	-171.51400	26.58498
476	-168.58344	28.30203	550	-165.47272	27.44675	624	-171.56405	26.59157
477	-168.53902	28.30813	551	-165.44570	27.42363	625	-171.62846	26.60005
478	-168.48296	28.31510	552	-165.41895	27.40026	626	-173.51320	26.84822
479	-168.42677	28.32131	553	-165.39248	27.37664	627	-175.00000	28.26784
480	-168.37049	28.32675	554	-165.36628	27.35279	628	-175.17766	28.43748
481	-168.33291	28.32995	555	-165.34036	27.32870	629	-175.32900	28.58198
482	-168.27648	28.33411	556	-165.30201	27.29213	630	-175.57260	28.64457
483	-168.21998	28.33750	557	-165.27680	27.26746	631	-175.59127	28.64937
484	-168.16342	28.34011	558	-165.25188	27.24255	632	-177.12157	29.04257
485	-168.10683	28.34195	559	-165.21504	27.20478	633	-177.20130	29.05797
486	-168.05021	28.34302	560	-165.19085	27.17932	634	-178.14636	29.24060
487	-168.00043	28.34332	561	-165.16695	27.15365	635	-178.20545	29.24908
488	-167.94380	28.34293	562	-165.14335	27.12775	636	-178.26503	29.25427
489	-167.88718	28.34177	563	-165.12006	27.10165	637	-178.32487	29.25614
490	-167.83059	28.33984	564	-165.09707	27.07533	638	-178.38473	29.25468
491	-167.77404	28.33713	565	-165.07732	27.05226	639	-178.44436	29.24991
492	-167.73621	28.33489	566	-165.03132	27.03829	640	-178.50352	29.24183
493	-167.67976	28.33089	567	-164.99614	27.02718	641	-178.56197	29.23049
494	-167.62339	28.32613	568	-164.96109	27.01574	642	-178.61949	29.21593
495	-167.56712	28.32059	569	-164.90877	26.99799	643	-178.67583	29.19820
496	-167.51095	28.31429	570	-164.85677	26.97951	644	-178.73077	29.17738
497	-167.45490	28.30722	571	-164.82201	26.96670	645	-178.78409	29.15356
498	-167.39898	28.29939	572	-164.70700	26.92271	646	-178.83557	29.12682
499	-167.34321	28.29079	573	-164.68299	26.92268	647	-178.88501	29.09728
500	-167.30612	28.28464	574	-164.64572	26.92233	648	-178.93222	29.06506
501	-167.25063	28.27477	575	-164.58983	26.92118	649	-178.97700	29.03028
502	-167.21374	28.26778	576	-164.55259	26.91997	650	-179.01917	28.99308
503	-167.15856	28.25665	577	-164.51536	26.91843	651	-179.05858	28.95361
504	-167.10359	28.24478	578	-164.45955	26.91547	652	-179.09506	28.91204
505	-167.04883	28.23215	579	-164.40380	26.91174	653	-179.12848	28.86852
506	-166.99432	28.21878	580	-164.34813	26.90724	654	-179.15870	28.82324
507	-166.94004	28.20466	581	-164.29254	26.90197	655	-179.18560	28.77636
508	-166.88603	28.18981	582	-164.25554	26.89803	656	-179.20909	28.72809
509	-166.85017	28.17950	583	-164.21858	26.89375	657	-179.22907	28.67861
510	-166.81444	28.16886	584	-164.16325	26.88669	658	-179.24548	28.62811
511	-166.79269	28.16221	585	-164.10804	26.87887	659	-179.25824	28.57681
512	-166.76001	28.15196	586	-164.05299	26.87029	660	-179.26732	28.52490
513	-166.72461	28.14051	587	-164.01637	26.86414	661	-179.27269	28.47258
514	-166.68934	28.12874	588	-163.97983	26.85766	662	-179.27400	28.43037
515	-166.65422	28.11665	589	-163.92516	26.84731	663	-179.27432	28.42008
516	-166.61924	28.10424	590	-163.87068	26.83620	664	-179.27400	28.41208
517	-166.58441	28.09152	591	-163.81641	26.82434	665	-179.27222	28.36758
518	-166.54974	28.07847	592	-163.76034	26.81602	666	-179.26640	28.31530
519	-166.51522	28.06511	593	-163.74438	26.80737	667	-179.25689	28.26345
520	-166.48086	28.05144	594	-163.69063	26.79377	668	-179.24374	28.21223

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
669	-179.22699	28.16184	743	-163.84743	20.23409	817	-167.14689	20.41926
670	-179.20673	28.11247	744	-163.87734	20.25202	818	-167.19433	20.43226
671	-179.18302	28.06433	745	-163.90706	20.27023	819	-167.22831	20.44187
672	-179.15598	28.01760	746	-163.93659	20.28870	820	-167.26218	20.45180
673	-179.12572	27.97246	747	-163.95588	20.30099	821	-167.29596	20.46203
674	-179.09234	27.92909	748	-163.98535	20.29532	822	-167.32963	20.47258
675	-179.05599	27.88765	749	-164.02014	20.28893	823	-167.36319	20.48344
676	-179.01681	27.84832	750	-164.07244	20.27996	824	-167.39664	20.49460
677	-178.97496	27.81123	751	-164.12487	20.27171	825	-167.44659	20.51193
678	-178.93061	27.77654	752	-164.17742	20.26419	826	-167.47975	20.52386
679	-178.88391	27.74438	753	-164.23008	20.25739	827	-167.51278	20.53610
680	-178.83507	27.71488	754	-164.28284	20.25133	828	-167.54695	20.54913
681	-178.78427	27.68814	755	-164.33569	20.24599	829	-167.57973	20.56197
682	-178.73170	27.66428	756	-164.38861	20.24139	830	-167.61238	20.57511
683	-178.67758	27.64338	757	-164.44159	20.23752	831	-167.64489	20.58856
684	-178.62211	27.62552	758	-164.49463	20.23438	832	-167.67726	20.60230
685	-178.56551	27.61078	759	-164.54771	20.23197	833	-167.70949	20.61634
686	-178.49843	27.59784	760	-164.58106	20.23084	834	-167.74158	20.63068
687	-177.55523	27.41586	761	-164.60571	20.23016	835	-167.77351	20.64532
688	-176.49794	27.24611	762	-164.65884	20.22922	836	-167.80530	20.66024
689	-175.00000	25.83069	763	-164.71217	20.22902	837	-167.83694	20.67546
690	-174.41400	25.27697	764	-164.74760	20.22930	838	-167.86841	20.69097
691	-171.83651	24.93729	765	-164.78302	20.22990	839	-167.91533	20.71478
692	-170.86958	24.62936	766	-164.83614	20.23141	840	-167.94640	20.73101
693	-170.83964	24.61983	767	-164.88922	20.23366	841	-167.97731	20.74752
694	-170.79300	24.60497	768	-164.92459	20.23557	842	-168.00804	20.76432
695	-170.73999	24.59633	769	-164.97761	20.23904	843	-168.03861	20.78140
696	-168.38105	24.21167	770	-165.01292	20.24176	844	-168.08412	20.80755
697	-168.38083	24.21163	771	-165.04914	20.24489	845	-168.11424	20.82533
698	-168.38072	24.21155	772	-165.10200	20.25007	846	-168.14417	20.84338
699	-166.79085	23.09144	773	-165.13720	20.25393	847	-168.17392	20.86172
700	-166.75000	23.06265	774	-165.18992	20.26033	848	-168.20348	20.88032
701	-166.60000	22.95697	775	-165.24253	20.26745	849	-168.24746	20.90873
702	-166.38872	22.93221	776	-165.27754	20.27261	850	-168.27653	20.92801
703	-166.32723	22.92501	777	-165.31250	20.27808	851	-168.31977	20.95743
704	-165.58333	22.83782	778	-165.36483	20.28690	852	-168.36255	20.98744
705	-164.86038	22.75309	779	-165.41702	20.29644	853	-168.40487	21.01804
706	-163.00000	22.40727	780	-165.45173	20.30321	854	-168.43282	21.03877
707	-163.00000	19.23458	781	-165.50401	20.31402	855	-168.47433	21.07033
708	-163.02954	19.26137	782	-165.54798	20.32372	856	-168.50174	21.09169
709	-163.05474	19.28472	783	-165.60124	20.31609	857	-168.54244	21.12420
710	-163.07970	19.30831	784	-165.65391	20.30930	858	-168.58263	21.15727
711	-163.10443	19.33213	785	-165.70669	20.30323	859	-168.62230	21.19089
712	-163.12891	19.35619	786	-165.75955	20.29790	860	-168.66145	21.22506
713	-163.15314	19.38047	787	-165.81249	20.29329	861	-168.68726	21.24813
714	-163.18902	19.41731	788	-165.86549	20.28942	862	-168.71283	21.27145
715	-163.21262	19.44214	789	-165.91855	20.28628	863	-168.75073	21.30685
716	-163.23597	19.46720	790	-165.97164	20.28388	864	-168.77569	21.33075
717	-163.25906	19.49247	791	-166.02477	20.28221	865	-168.81266	21.36701
718	-163.28189	19.51796	792	-166.07792	20.28127	866	-168.83700	21.39147
719	-163.31564	19.55659	793	-166.13108	20.28107	867	-168.87302	21.42858
720	-163.33781	19.58261	794	-166.18423	20.28160	868	-168.90847	21.46618
721	-163.35971	19.60883	795	-166.23737	20.28288	869	-168.93178	21.49152
722	-163.38134	19.63525	796	-166.29049	20.28488	870	-168.96624	21.52992
723	-163.41328	19.67526	797	-166.34357	20.28762	871	-168.99177	21.55913
724	-163.43423	19.70218	798	-166.36478	20.28892	872	-169.02276	21.59546
725	-163.45489	19.72929	799	-166.39682	20.29110	873	-169.04473	21.62184
726	-163.47678	19.75859	800	-166.43214	20.29382	874	-169.07716	21.66178
727	-163.49689	19.78608	801	-166.48507	20.29852	875	-169.09844	21.68866
728	-163.51671	19.81376	802	-166.52032	20.30205	876	-169.12982	21.72934
729	-163.54591	19.85563	803	-166.57311	20.30796	877	-169.15039	21.75669
730	-163.56501	19.88376	804	-166.61798	20.31350	878	-169.18071	21.79808
731	-163.58383	19.91207	805	-166.65308	20.31816	879	-169.20233	21.82840
732	-163.60235	19.94056	806	-166.70563	20.32577	880	-169.21703	21.84743
733	-163.62957	19.98361	807	-166.74060	20.33125	881	-169.23883	21.85466
734	-163.64735	20.01252	808	-166.77552	20.33705	882	-169.27247	21.86611
735	-163.66483	20.04159	809	-166.82777	20.34635	883	-169.32272	21.88387
736	-163.68201	20.07082	810	-166.87988	20.35637	884	-169.37269	21.90231
737	-163.69888	20.10022	811	-166.91453	20.36345	885	-169.42237	21.92143
738	-163.71545	20.12977	812	-166.94911	20.37085	886	-169.47175	21.94122
739	-163.73841	20.17193	813	-166.99267	20.38061	887	-169.52083	21.96170
740	-163.75664	20.18197	814	-167.02709	20.38865	888	-169.56958	21.98284
741	-163.78708	20.19906	815	-167.07857	20.40130	889	-169.61800	22.00464
742	-163.81734	20.21644	816	-167.11278	20.41012	890	-169.66609	22.02710

Point No.	Longitude	Latitude	Point No.	Longitude	Latitude	Point No.	Longitude	Latitude
891	-169.71382	22.05022	965	-172.83168	22.56552	1039	-175.51051	22.99222
892	-169.76119	22.07399	966	-172.86601	22.57558	1040	-175.54345	23.00593
893	-169.80819	22.09840	967	-172.90023	22.58594	1041	-175.57624	23.01993
894	-169.85481	22.12345	968	-172.95136	22.60207	1042	-175.60888	23.03422
895	-169.90103	22.14914	969	-172.98531	22.61320	1043	-175.64138	23.04881
896	-169.94686	22.17546	970	-173.03602	22.63048	1044	-175.67372	23.06370
897	-169.97718	22.19335	971	-173.08645	22.64845	1045	-175.70591	23.07887
898	-170.00653	22.21103	972	-173.11992	22.66081	1046	-175.73795	23.09434
899	-170.05123	22.20415	973	-173.15325	22.67347	1047	-175.76982	23.11009
900	-170.08671	22.19907	974	-173.18646	22.68643	1048	-175.81731	23.13426
901	-170.12224	22.19431	975	-173.23601	22.70643	1049	-175.84877	23.15073
902	-170.15783	22.18987	976	-173.26888	22.72014	1050	-175.88005	23.16748
903	-170.19345	22.18575	977	-173.30160	22.73415	1051	-175.91116	23.18451
904	-170.22911	22.18196	978	-173.34556	22.75354	1052	-175.94209	23.20183
905	-170.28268	22.17688	979	-173.37723	22.74830	1053	-175.98815	23.22832
906	-170.31843	22.17390	980	-173.41277	22.74274	1054	-176.01862	23.24633
907	-170.35421	22.17125	981	-173.44836	22.73750	1055	-176.04891	23.26461
908	-170.39002	22.16891	982	-173.48400	22.73258	1056	-176.09398	23.29254
909	-170.42584	22.16691	983	-173.51970	22.72798	1057	-176.12379	23.31150
910	-170.46169	22.16523	984	-173.55544	22.72371	1058	-176.15339	23.33073
911	-170.51549	22.16332	985	-173.59122	22.71976	1059	-176.18280	23.35022
912	-170.55136	22.16245	986	-173.62704	22.71613	1060	-176.21200	23.36998
913	-170.58725	22.16191	987	-173.66290	22.71283	1061	-176.25542	23.40011
914	-170.62314	22.16170	988	-173.69879	22.70985	1062	-176.28410	23.42053
915	-170.65929	22.16181	989	-173.73470	22.70720	1063	-176.31256	23.44120
916	-170.69518	22.16224	990	-173.77065	22.70487	1064	-176.35486	23.47268
917	-170.73106	22.16301	991	-173.80661	22.70286	1065	-176.38278	23.49399
918	-170.76693	22.16410	992	-173.84260	22.70118	1066	-176.41048	23.51554
919	-170.80279	22.16551	993	-173.87860	22.69983	1067	-176.43795	23.53735
920	-170.83863	22.16725	994	-173.91461	22.69880	1068	-176.46520	23.55940
921	-170.89236	22.17047	995	-173.95063	22.69810	1069	-176.50563	23.59294
922	-170.92815	22.17302	996	-173.98666	22.69772	1070	-176.53229	23.61560
923	-170.96391	22.17590	997	-174.02268	22.69767	1071	-176.55872	23.63850
924	-170.99964	22.17910	998	-174.05871	22.69794	1072	-176.59790	23.67330
925	-171.03533	22.18263	999	-174.09473	22.69854	1073	-176.62372	23.69679
926	-171.07099	22.18648	1000	-174.13075	22.69947	1074	-176.66199	23.73246
927	-171.12440	22.19286	1001	-174.16675	22.70072	1075	-176.68719	23.75653
928	-171.15995	22.19751	1002	-174.20274	22.70229	1076	-176.71213	23.78082
929	-171.19545	22.20249	1003	-174.23871	22.70419	1077	-176.73682	23.80534
930	-171.23089	22.20780	1004	-174.27466	22.70642	1078	-176.76125	23.83007
931	-171.28396	22.21635	1005	-174.31059	22.70897	1079	-176.78542	23.85503
932	-171.33689	22.22563	1006	-174.34649	22.71185	1080	-176.80933	23.88021
933	-171.38967	22.23563	1007	-174.38235	22.71505	1081	-176.83297	23.90559
934	-171.42477	22.24269	1008	-174.41819	22.71857	1082	-176.85635	23.93119
935	-171.47727	22.25389	1009	-174.45398	22.72242	1083	-176.87945	23.95700
936	-171.52961	22.26579	1010	-174.48974	22.72659	1084	-176.90229	23.98302
937	-171.58175	22.27841	1011	-174.52545	22.73108	1085	-176.93602	24.02243
938	-171.63369	22.29174	1012	-174.56111	22.73589	1086	-176.96913	24.06229
939	-171.68543	22.30577	1013	-174.59672	22.74103	1087	-176.99085	24.08911
940	-171.73694	22.32050	1014	-174.63227	22.74649	1088	-177.01229	24.11613
941	-171.78823	22.33594	1015	-174.66777	22.75227	1089	-177.03344	24.14334
942	-171.83927	22.35207	1016	-174.70321	22.75837	1090	-177.06462	24.18451
943	-171.89005	22.36889	1017	-174.73859	22.76479	1091	-177.08505	24.21218
944	-171.94057	22.38641	1018	-174.77389	22.77154	1092	-177.10518	24.24004
945	-171.99082	22.40461	1019	-174.82672	22.78224	1093	-177.12502	24.26808
946	-172.03998	22.42318	1020	-174.86184	22.78978	1094	-177.14456	24.29630
947	-172.09233	22.42751	1021	-174.89689	22.79763	1095	-177.17331	24.33895
948	-172.12811	22.43088	1022	-174.93185	22.80580	1096	-177.19209	24.36760
949	-172.18170	22.43653	1023	-174.96673	22.81429	1097	-177.21058	24.39642
950	-172.21738	22.44070	1024	-175.00151	22.82308	1098	-177.22875	24.42540
951	-172.25302	22.44519	1025	-175.03621	22.83220	1099	-177.25544	24.46918
952	-172.28861	22.45001	1026	-175.07081	22.84163	1100	-177.27284	24.49856
953	-172.32414	22.45515	1027	-175.10531	22.85136	1101	-177.28992	24.52810
954	-172.37735	22.46346	1028	-175.13972	22.86141	1102	-177.30670	24.55779
955	-172.41274	22.46941	1029	-175.17401	22.87178	1103	-177.32315	24.58763
956	-172.46572	22.47892	1030	-175.20820	22.88244	1104	-177.33929	24.61762
957	-172.50095	22.48567	1031	-175.24228	22.89342	1105	-177.36249	24.66210
958	-172.55366	22.49638	1032	-175.27624	22.90471	1106	-177.38606	24.67081
959	-172.58872	22.50392	1033	-175.31009	22.91630	1107	-177.41985	24.68359
960	-172.64114	22.51582	1034	-175.34381	22.92820	1108	-177.45352	24.69667
961	-172.67599	22.52415	1035	-175.37741	22.94040	1109	-177.48704	24.71005
962	-172.71075	22.53279	1036	-175.41089	22.95290	1110	-177.53706	24.73067
963	-172.76272	22.54635	1037	-175.44423	22.96571	1111	-177.57023	24.74479
964	-172.79725	22.55578	1038	-175.47744	22.97882	1112	-177.60325	24.75920

Point No.	Longitude	Latitude
1113	– 177.63612	24.77391
1114	– 177.66883	24.78891
1115	– 177.71760	24.81195
1116	– 177.74992	24.82767
1117	– 177.78206	24.84367
1118	– 177.81404	24.85996
1119	– 177.83690	24.87185
1120	– 177.88667	24.87745
1121	– 177.94111	24.88429
1122	– 177.97195	24.88850
1123	– 177.99642	24.89200
1124	– 178.05062	24.90028
1125	– 178.10469	24.90929
1126	– 178.14066	24.91569
1127	– 178.16577	24.92034
1128	– 178.21953	24.93078
1129	– 178.27313	24.94194
1130	– 178.32655	24.95380
1131	– 178.37978	24.96637
1132	– 178.43281	24.97965
1133	– 178.48563	24.99363
1134	– 178.53822	25.00832
1135	– 178.59058	25.02370
1136	– 178.61445	25.03096
1137	– 178.64360	25.04005
1138	– 178.67821	25.05115
1139	– 178.70077	25.05859
1140	– 178.72148	25.06052
1141	– 178.75794	25.06420
1142	– 178.81257	25.07031
1143	– 178.86732	25.07718
1144	– 178.90360	25.08214
1145	– 178.93984	25.08742
1146	– 178.98140	25.09382
1147	– 179.01755	25.09959
1148	– 179.07166	25.10883
1149	– 179.10765	25.11539
1150	– 179.14357	25.12227
1151	– 179.19731	25.13318
1152	– 179.25088	25.14480
1153	– 179.28649	25.15295
1154	– 179.32201	25.16140
1155	– 179.35744	25.17018
1156	– 179.38198	25.17642
1157	– 179.43516	25.19048
1158	– 179.47030	25.20018
1159	– 179.50534	25.21020
1160	– 179.55770	25.22581
1161	– 179.60982	25.24211
1162	– 179.66168	25.25911
1163	– 179.69610	25.27081
1164	– 179.73039	25.28283
1165	– 179.76456	25.29514
1166	– 179.79860	25.30776
1167	– 179.83251	25.32068
1168	– 179.86628	25.33389
1169	– 179.89991	25.34741
1170	– 179.93340	25.36122
1171	– 179.96674	25.37533
1172	– 180.00000	25.38976

**Appendix C to Subpart W of Part 922—
Coordinates for the Midway Atoll
Special Management Area**

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

The boundaries for the areas listed in this appendix, unless otherwise described in this rule, begin at Point 1 as indicated in the particular area's coordinate table and continue to each successive point in numerical order until ending at the last point in the table.

Point No.	Longitude	Latitude
1	– 177.31267	27.99792
2	– 177.36342	27.99124
3	– 177.41762	27.99216
4	– 177.47082	27.99962
5	– 177.51875	28.01516
6	– 177.55393	28.03661
7	– 177.59424	28.06817
8	– 177.62036	28.10572
9	– 177.64395	28.14862
10	– 177.65507	28.20134
11	– 177.65600	28.21430
12	– 177.65028	28.23674
13	– 177.65187	28.25877
14	– 177.63704	28.29735
15	– 177.62519	28.31624
16	– 177.60768	28.33804
17	– 177.59529	28.36997
18	– 177.56544	28.40418
19	– 177.52661	28.43628
20	– 177.49013	28.46044
21	– 177.44568	28.47591
22	– 177.42409	28.48231
23	– 177.37872	28.48480
24	– 177.32412	28.48128
25	– 177.26570	28.46492
26	– 177.21865	28.44274
27	– 177.17255	28.41268
28	– 177.13782	28.37680
29	– 177.11574	28.33244
30	– 177.08945	28.26879
31	– 177.08725	28.21427
32	– 177.08489	28.17927
33	– 177.09363	28.15669
34	– 177.10914	28.12595
35	– 177.12481	28.09780
36	– 177.15060	28.06781
37	– 177.18677	28.03986
38	– 177.22207	28.02105
39	– 177.26492	28.00572
40	– 177.31267	27.99792

**Appendix D to Subpart W of Part 922—
Coordinates for the Special
Preservation Areas (SPAs)**

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

The boundaries for the areas listed in this appendix, unless otherwise described in this rule, begin at Point 1 as indicated in the particular area's coordinate table and continue to each successive point in numerical order until ending at the last point in the table.

**TABLE 1—COORDINATES FOR
HÖLANIKŪ (KURE ATOLL) SPA**

Point No.	Longitude	Latitude
1	– 178.42982	28.39284
2	– 178.43641	28.39991
3	– 178.44628	28.41516
4	– 178.44829	28.43220
5	– 178.44120	28.45537
6	– 178.43083	28.47814
7	– 178.41324	28.49646
8	– 178.40698	28.50082
9	– 178.39886	28.50648
10	– 178.38081	28.51486
11	– 178.35703	28.51998
12	– 178.33482	28.52195

**TABLE 1—COORDINATES FOR
HÖLANIKŪ (KURE ATOLL) SPA—
Continued**

Point No.	Longitude	Latitude
13	– 178.33480	28.52195
14	– 178.33096	28.52588
15	– 178.32267	28.52960
16	– 178.30753	28.54606
17	– 178.29651	28.54402
18	– 178.28574	28.52279
19	– 178.28205	28.50290
20	– 178.28203	28.50289
21	– 178.27634	28.49938
22	– 178.26090	28.48707
23	– 178.25026	28.47569
24	– 178.24590	28.47103
25	– 178.23869	28.45022
26	– 178.23126	28.41686
27	– 178.23242	28.39706
28	– 178.23826	28.37827
29	– 178.24572	28.36305
30	– 178.24663	28.36228
31	– 178.24665	28.36227
32	– 178.23880	28.35166
33	– 178.22857	28.34386
34	– 178.21418	28.34135
35	– 178.21125	28.32830
36	– 178.21580	28.32098
37	– 178.22682	28.31875
38	– 178.23360	28.32678
39	– 178.26169	28.33216
40	– 178.26256	28.34256
41	– 178.26685	28.34603
42	– 178.26983	28.34386
43	– 178.28608	28.33631
44	– 178.31541	28.33530
45	– 178.36386	28.34022
46	– 178.38109	28.34407
47	– 178.40622	28.32394
48	– 178.42837	28.32125
49	– 178.43274	28.36763
50	– 178.42982	28.39284

**TABLE 2—COORDINATES FOR
MANAWAI (PEARL AND HERMES
ATOLL) SPA**

Point No.	Longitude	Latitude
1	– 176.03652	27.75775
2	– 176.04088	27.76832
3	– 176.04088	27.76832
4	– 176.04830	27.77010
5	– 176.06549	27.78232
6	– 176.03704	27.84094
7	– 176.03441	27.85558
8	– 176.03489	27.87411
9	– 176.02724	27.89274
10	– 176.01285	27.89991
11	– 175.98350	27.91077
12	– 175.98347	27.91080
13	– 175.97662	27.91971
14	– 175.96741	27.92798
15	– 175.95689	27.93510
16	– 175.94636	27.93942
17	– 175.93781	27.94332
18	– 175.92692	27.95035
19	– 175.90613	27.96355
20	– 175.88894	27.97471
21	– 175.87548	27.98165
22	– 175.86046	27.98780
23	– 175.83952	27.99711

TABLE 2—COORDINATES FOR
MANAWAI (PEARL AND HERMES
ATOLL) SPA—Continued

Point No.	Longitude	Latitude
24	–175.82333	28.00466
25	–175.81383	28.00844
26	–175.80379	28.01098
27	–175.79318	28.01152
28	–175.78174	28.01106
29	–175.77016	28.01031
30	–175.76421	28.00935
31	–175.76418	28.00935
32	–175.76189	28.01111
33	–175.73451	28.02165
34	–175.71502	28.00762
35	–175.70865	27.98973
36	–175.70863	27.98971
37	–175.69833	27.98219
38	–175.69171	27.97663
39	–175.68857	27.97399
40	–175.68160	27.96778
41	–175.67658	27.96256
42	–175.67240	27.95558
43	–175.66795	27.94587
44	–175.66433	27.93515
45	–175.66239	27.92393
46	–175.66156	27.91419
47	–175.66186	27.89972
48	–175.66410	27.88349
49	–175.66915	27.86916
50	–175.67268	27.85916
51	–175.67530	27.84825
52	–175.67894	27.83626
53	–175.68258	27.82801
54	–175.68899	27.81801
55	–175.69097	27.81125
56	–175.69321	27.80550
57	–175.69331	27.80524
58	–175.69713	27.79526
59	–175.70412	27.78375
60	–175.70943	27.77649
61	–175.71351	27.77101
62	–175.71352	27.77099
63	–175.71049	27.76347
64	–175.71993	27.75551
65	–175.72502	27.75516
66	–175.72955	27.74921
67	–175.73541	27.74444
68	–175.74364	27.73989
69	–175.75468	27.73513
70	–175.76640	27.73259
71	–175.77924	27.73129
72	–175.79543	27.73023
73	–175.81639	27.73105
74	–175.82556	27.73236
75	–175.83310	27.73358
76	–175.83756	27.73456
77	–175.84175	27.73504
78	–175.84594	27.73228
79	–175.85277	27.72748
80	–175.86185	27.72274
81	–175.87480	27.71713
82	–175.89491	27.70934
83	–175.91378	27.70257
84	–175.92997	27.69926
85	–175.94532	27.69745
86	–175.95649	27.69766
87	–175.96681	27.69937
88	–175.97685	27.70332
89	–175.98968	27.71026
90	–176.00334	27.72044
91	–176.01701	27.73237
92	–176.02593	27.74182
93	–176.02997	27.74680

TABLE 2—COORDINATES FOR
MANAWAI (PEARL AND HERMES
ATOLL) SPA—Continued

Point No.	Longitude	Latitude
94	–176.03178	27.74903
95	–176.03652	27.75775

TABLE 3—COORDINATES FOR KAPOU
(LISIANSKI ISLAND) SPA

Point No.	Longitude	Latitude
1	–173.79069	25.94039
2	–173.79506	25.91077
3	–173.79506	25.91077
4	–173.85089	25.87148
5	–173.89161	25.87949
6	–173.94399	25.87998
7	–174.10879	25.96371
8	–174.12000	25.97958
9	–174.14257	26.00021
10	–174.15729	26.04055
11	–174.15482	26.12273
12	–174.13333	26.17497
13	–174.08554	26.21215
14	–174.05059	26.21724
15	–173.98290	26.21243
16	–173.93333	26.18331
17	–173.89656	26.14220
18	–173.86186	26.11938
19	–173.82229	26.08560
20	–173.79999	26.04164
21	–173.76666	26.00831
22	–173.75210	25.98825
23	–173.75283	25.97102
24	–173.79069	25.94039

TABLE 4—COORDINATES FOR KAMOLE
(LAYSAN ISLAND) SPA

Point No.	Longitude	Latitude
1	–171.65000	25.71667
2	–171.66667	25.70000
3	–171.70000	25.69167
4	–171.70833	25.70000
5	–171.73333	25.70000
6	–171.75000	25.69167
7	–171.78333	25.69167
8	–171.81667	25.70833
9	–171.85000	25.75833
10	–171.86667	25.79167
11	–171.87500	25.83333
12	–171.85000	25.86667
13	–171.83333	25.88333
14	–171.80000	25.90000
15	–171.76667	25.90000
16	–171.67500	25.88333
17	–171.62500	25.86667
18	–171.60000	25.83333
19	–171.59167	25.79167
20	–171.60000	25.76667
21	–171.61667	25.74167
22	–171.63333	25.72500
23	–171.65000	25.71667

TABLE 5—COORDINATES FOR
KAMOKUOKAMOHOALI'Ī (MARO REEF)
SPA

Point No.	Longitude	Latitude
1	–170.51714	25.56669
2	–170.40880	25.46669
3	–170.35047	25.37502
4	–170.40880	25.25835
5	–170.42547	25.25002
6	–170.54214	25.25835
7	–170.59214	25.28335
8	–170.65047	25.30002
9	–170.76714	25.31669
10	–170.80047	25.33335
11	–170.80880	25.35835
12	–170.86714	25.39169
13	–170.89214	25.45002
14	–170.90047	25.52502
15	–170.90047	25.55002
16	–170.87547	25.58335
17	–170.80881	25.62502
18	–170.77547	25.63335
19	–170.70880	25.63335
20	–170.68381	25.61669
21	–170.57547	25.59169
22	–170.51714	25.56669

TABLE 6—COORDINATES FOR 'ŌNŪNUI
AND 'ŌNUIKI (GARDNER PINNACLES)
SPA

Point No.	Longitude	Latitude
1	–167.93207	25.06955
2	–167.92506	25.04175
3	–167.94165	25.01326
4	–167.94166	24.94164
5	–167.92273	24.90603
6	–167.90123	24.88174
7	–167.89166	24.84997
8	–167.89766	24.74763
9	–167.87266	24.62908
10	–167.87360	24.59072
11	–167.86659	24.56315
12	–167.87500	24.49164
13	–167.89063	24.44829
14	–167.90184	24.42844
15	–167.95440	24.41115
16	–167.98968	24.41979
17	–168.00369	24.43801
18	–168.01666	24.50831
19	–168.05000	24.57498
20	–168.08333	24.59164
21	–168.12500	24.69997
22	–168.13333	24.77497
23	–168.15000	24.81664
24	–168.15000	24.88331
25	–168.22500	24.94997
26	–168.26666	25.00831
27	–168.27799	25.06540
28	–168.26794	25.09301
29	–168.25089	25.10375
30	–168.22575	25.16587
31	–168.19632	25.18175
32	–168.14166	25.19164
33	–168.08636	25.19273
34	–168.04128	25.17404
35	–167.98333	25.12498
36	–167.93207	25.06955

TABLE 7—COORDINATES FOR LALO
(FRENCH FRIGATE SHOALS) SPA

Point No.	Longitude	Latitude
1	– 165.58333	23.99997
2	– 165.58333	23.49997
3	– 166.75000	23.66664
4	– 166.92817	23.68779
5	– 166.92756	23.74082
6	– 166.92417	24.03651
7	– 166.75227	24.03400
8	– 166.75000	24.16664
9	– 165.58333	23.99997

TABLE 8—COORDINATES FOR
MOKUMANAMANA (NECKER) SPA

Point No.	Longitude	Latitude
1	– 164.55178	23.64216
2	– 164.53515	23.61324
3	– 164.53018	23.58826
4	– 164.52734	23.55099
5	– 164.50977	23.52283
6	– 164.45148	23.49085
7	– 164.44165	23.48045
8	– 164.39327	23.46288
9	– 164.36812	23.46322
10	– 164.32711	23.44904
11	– 164.30462	23.43128
12	– 164.28233	23.39686
13	– 164.27062	23.35708
14	– 164.25021	23.30870
15	– 164.25676	23.28970
16	– 164.26716	23.27912
17	– 164.27585	23.25682
18	– 164.29815	23.23537
19	– 164.33671	23.23253
20	– 164.36910	23.23801
21	– 164.39560	23.25619
22	– 164.45702	23.26300
23	– 164.47063	23.27037
24	– 164.48333	23.29164
25	– 164.52500	23.30831
26	– 164.59613	23.30887
27	– 164.63036	23.29942
28	– 164.64112	23.30040
29	– 164.63917	23.31377
30	– 164.62971	23.32387
31	– 164.61895	23.32681
32	– 164.62156	23.34246
33	– 164.60917	23.35387
34	– 164.58863	23.40643
35	– 164.57950	23.44490
36	– 164.60558	23.45599
37	– 164.60917	23.46675
38	– 164.62260	23.47995
39	– 164.65117	23.49002
40	– 164.69597	23.49691
41	– 164.73352	23.49654
42	– 164.76980	23.48444
43	– 164.78209	23.50277
44	– 164.79929	23.50920
45	– 164.81081	23.52337
46	– 164.83255	23.53736
47	– 164.84703	23.56743
48	– 164.83436	23.60088
49	– 164.81981	23.61619
50	– 164.80110	23.62243
51	– 164.76840	23.62148
52	– 164.73854	23.63112
53	– 164.68789	23.65058
54	– 164.62458	23.66325
55	– 164.57582	23.65644

TABLE 8—COORDINATES FOR
MOKUMANAMANA (NECKER) SPA—
Continued

Point No.	Longitude	Latitude
56	– 164.55178	23.64216

TABLE 9—COORDINATES FOR NIHOA
ISLAND SPA

Point No.	Longitude	Latitude
1	– 161.97131	23.09961
2	– 161.97057	23.10037
3	– 161.96981	23.10112
4	– 161.96904	23.10185
5	– 161.96825	23.10258
6	– 161.96745	23.10329
7	– 161.96663	23.10399
8	– 161.96580	23.10468
9	– 161.96495	23.10535
10	– 161.96409	23.10602
11	– 161.96322	23.10667
12	– 161.96234	23.10731
13	– 161.96144	23.10793
14	– 161.96053	23.10854
15	– 161.95961	23.10914
16	– 161.95867	23.10972
17	– 161.95773	23.11029
18	– 161.95677	23.11085
19	– 161.95580	23.11139
20	– 161.95482	23.11191
21	– 161.95383	23.11242
22	– 161.95283	23.11292
23	– 161.95182	23.11340
24	– 161.95080	23.11387
25	– 161.94977	23.11432
26	– 161.94874	23.11475
27	– 161.94769	23.11517
28	– 161.94664	23.11558
29	– 161.94557	23.11597
30	– 161.94450	23.11634
31	– 161.94342	23.11670
32	– 161.94234	23.11704
33	– 161.94125	23.11736
34	– 161.94015	23.11767
35	– 161.93905	23.11796
36	– 161.93794	23.11824
37	– 161.93682	23.11850
38	– 161.93570	23.11874
39	– 161.93458	23.11897
40	– 161.93345	23.11917
41	– 161.93232	23.11937
42	– 161.93118	23.11954
43	– 161.93004	23.11970
44	– 161.92890	23.11984
45	– 161.92775	23.11996
46	– 161.92661	23.12007
47	– 161.92546	23.12016
48	– 161.92431	23.12023
49	– 161.92315	23.12029
50	– 161.92200	23.12032
51	– 161.92085	23.12035
52	– 161.91969	23.12035
53	– 161.91854	23.12034
54	– 161.91739	23.12030
55	– 161.91624	23.12026
56	– 161.91509	23.12019
57	– 161.91394	23.12011
58	– 161.91279	23.12001
59	– 161.91164	23.11989
60	– 161.91050	23.11976
61	– 161.90936	23.11961

TABLE 9—COORDINATES FOR NIHOA
ISLAND SPA—Continued

Point No.	Longitude	Latitude
62	– 161.90823	23.11944
63	– 161.90709	23.11925
64	– 161.90597	23.11905
65	– 161.90484	23.11883
66	– 161.90372	23.11860
67	– 161.90261	23.11835
68	– 161.90150	23.11808
69	– 161.90040	23.11779
70	– 161.89930	23.11749
71	– 161.89821	23.11717
72	– 161.89713	23.11684
73	– 161.89605	23.11649
74	– 161.89520	23.11619
75	– 161.89498	23.11612
76	– 161.89401	23.11577
77	– 161.89392	23.11574
78	– 161.89287	23.11534
79	– 161.89182	23.11493
80	– 161.89079	23.11450
81	– 161.88976	23.11405
82	– 161.88874	23.11359
83	– 161.88774	23.11311
84	– 161.88674	23.11262
85	– 161.88575	23.11212
86	– 161.88477	23.11160
87	– 161.88381	23.11107
88	– 161.88285	23.11052
89	– 161.88191	23.10995
90	– 161.88097	23.10938
91	– 161.88005	23.10878
92	– 161.87915	23.10818
93	– 161.87825	23.10756
94	– 161.87737	23.10693
95	– 161.87650	23.10628
96	– 161.87564	23.10563
97	– 161.87480	23.10495
98	– 161.87397	23.10427
99	– 161.87316	23.10358
100	– 161.87236	23.10287
101	– 161.87157	23.10215
102	– 161.87080	23.10142
103	– 161.87004	23.10067
104	– 161.86930	23.09992
105	– 161.86858	23.09916
106	– 161.86787	23.09838
107	– 161.86750	23.09796
108	– 161.86718	23.09759
109	– 161.86650	23.09679
110	– 161.86584	23.09599
111	– 161.86520	23.09517
112	– 161.86457	23.09435
113	– 161.86396	23.09351
114	– 161.86337	23.09267
115	– 161.86279	23.09181
116	– 161.86224	23.09095
117	– 161.86170	23.09008
118	– 161.86117	23.08920
119	– 161.86067	23.08832
120	– 161.86018	23.08742
121	– 161.85972	23.08653
122	– 161.85927	23.08562
123	– 161.85884	23.08470
124	– 161.85842	23.08378
125	– 161.85803	23.08286
126	– 161.85766	23.08193
127	– 161.85730	23.08099
128	– 161.85697	23.08004
129	– 161.85665	23.07910
130	– 161.85635	23.07814
131	– 161.85608	23.07719
132	– 161.85582	23.07622

TABLE 9—COORDINATES FOR NIHOA
ISLAND SPA—Continued

Point No.	Longitude	Latitude
133	– 161.85558	23.07526
134	– 161.85536	23.07429
135	– 161.85516	23.07332
136	– 161.85499	23.07235
137	– 161.85483	23.07137
138	– 161.85469	23.07039
139	– 161.85457	23.06941
140	– 161.85447	23.06843
141	– 161.85439	23.06744
142	– 161.85433	23.06645
143	– 161.85429	23.06547
144	– 161.85428	23.06448
145	– 161.85428	23.06349
146	– 161.85430	23.06251
147	– 161.85434	23.06152
148	– 161.85440	23.06053
149	– 161.85449	23.05955
150	– 161.85459	23.05857
151	– 161.85471	23.05758
152	– 161.85485	23.05660
153	– 161.85502	23.05563
154	– 161.85520	23.05465
155	– 161.85540	23.05367
156	– 161.85562	23.05271
157	– 161.85586	23.05174
158	– 161.85612	23.05078
159	– 161.85641	23.04982
160	– 161.85671	23.04887
161	– 161.85703	23.04791
162	– 161.85736	23.04697
163	– 161.85772	23.04603
164	– 161.85810	23.04510
165	– 161.85850	23.04417
166	– 161.85891	23.04324
167	– 161.85935	23.04233
168	– 161.85980	23.04142
169	– 161.86027	23.04051
170	– 161.86076	23.03962
171	– 161.86126	23.03873
172	– 161.86179	23.03785
173	– 161.86233	23.03698
174	– 161.86289	23.03611
175	– 161.86347	23.03525
176	– 161.86407	23.03440
177	– 161.86468	23.03357
178	– 161.86531	23.03274
179	– 161.86596	23.03191
180	– 161.86662	23.03110
181	– 161.86730	23.03031
182	– 161.86800	23.02951
183	– 161.86871	23.02873
184	– 161.86943	23.02796
185	– 161.87018	23.02720
186	– 161.87094	23.02646
187	– 161.87171	23.02572
188	– 161.87250	23.02500
189	– 161.87330	23.02428
190	– 161.87412	23.02358
191	– 161.87495	23.02290
192	– 161.87579	23.02222
193	– 161.87665	23.02156
194	– 161.87752	23.02091
195	– 161.87841	23.02027
196	– 161.87931	23.01965
197	– 161.88022	23.01903
198	– 161.88114	23.01844
199	– 161.88207	23.01786
200	– 161.88302	23.01729
201	– 161.88398	23.01673
202	– 161.88494	23.01619
203	– 161.88592	23.01567

TABLE 9—COORDINATES FOR NIHOA
ISLAND SPA—Continued

Point No.	Longitude	Latitude
204	– 161.88691	23.01515
205	– 161.88791	23.01466
206	– 161.88892	23.01417
207	– 161.88994	23.01371
208	– 161.89097	23.01326
209	– 161.89201	23.01282
210	– 161.89306	23.01240
211	– 161.89411	23.01200
212	– 161.89517	23.01161
213	– 161.89624	23.01123
214	– 161.89732	23.01088
215	– 161.89841	23.01054
216	– 161.89950	23.01021
217	– 161.90059	23.00990
218	– 161.90170	23.00961
219	– 161.90281	23.00934
220	– 161.90392	23.00908
221	– 161.90504	23.00884
222	– 161.90617	23.00861
223	– 161.90730	23.00840
224	– 161.90843	23.00821
225	– 161.90875	23.00816
226	– 161.90956	23.00803
227	– 161.91070	23.00788
228	– 161.91185	23.00774
229	– 161.91299	23.00761
230	– 161.91366	23.00755
231	– 161.91414	23.00751
232	– 161.91529	23.00742
233	– 161.91644	23.00734
234	– 161.91759	23.00729
235	– 161.91874	23.00725
236	– 161.91990	23.00723
237	– 161.92105	23.00723
238	– 161.92221	23.00724
239	– 161.92336	23.00727
240	– 161.92336	23.00727
241	– 161.92451	23.00732
242	– 161.92566	23.00738
243	– 161.92681	23.00747
244	– 161.92796	23.00757
245	– 161.92910	23.00768
246	– 161.93024	23.00782
247	– 161.93138	23.00797
248	– 161.93252	23.00814
249	– 161.93365	23.00832
250	– 161.93478	23.00852
251	– 161.93590	23.00874
252	– 161.93702	23.00898
253	– 161.93814	23.00923
254	– 161.93924	23.00950
255	– 161.94035	23.00978
256	– 161.94144	23.01008
257	– 161.94253	23.01040
258	– 161.94362	23.01074
259	– 161.94469	23.01109
260	– 161.94576	23.01146
261	– 161.94682	23.01184
262	– 161.94788	23.01224
263	– 161.94892	23.01265
264	– 161.94996	23.01308
265	– 161.95098	23.01352
266	– 161.95200	23.01399
267	– 161.95301	23.01446
268	– 161.95401	23.01495
269	– 161.95500	23.01546
270	– 161.95597	23.01598
271	– 161.95694	23.01651
272	– 161.95790	23.01706
273	– 161.95884	23.01762
274	– 161.95977	23.01820

TABLE 9—COORDINATES FOR NIHOA
ISLAND SPA—Continued

Point No.	Longitude	Latitude
275	– 161.96069	23.01879
276	– 161.96160	23.01940
277	– 161.96172	23.01948
278	– 161.96189	23.01960
279	– 161.96250	23.02001
280	– 161.96338	23.02065
281	– 161.96425	23.02129
282	– 161.96510	23.02195
283	– 161.96595	23.02262
284	– 161.96677	23.02330
285	– 161.96759	23.02400
286	– 161.96839	23.02471
287	– 161.96917	23.02543
288	– 161.96995	23.02616
289	– 161.97070	23.02690
290	– 161.97144	23.02765
291	– 161.97217	23.02842
292	– 161.97287	23.02920
293	– 161.97357	23.02998
294	– 161.97424	23.03078
295	– 161.97490	23.03159
296	– 161.97555	23.03240
297	– 161.97617	23.03323
298	– 161.97678	23.03406
299	– 161.97738	23.03491
300	– 161.97795	23.03576
301	– 161.97851	23.03662
302	– 161.97905	23.03749
303	– 161.97957	23.03837
304	– 161.98008	23.03926
305	– 161.98056	23.04015
306	– 161.98103	23.04105
307	– 161.98148	23.04196
308	– 161.98191	23.04287
309	– 161.98232	23.04379
310	– 161.98271	23.04472
311	– 161.98309	23.04565
312	– 161.98344	23.04659
313	– 161.98378	23.04753
314	– 161.98409	23.04848
315	– 161.98439	23.04943
316	– 161.98467	23.05039
317	– 161.98493	23.05135
318	– 161.98516	23.05232
319	– 161.98538	23.05329
320	– 161.98558	23.05426
321	– 161.98576	23.05523
322	– 161.98592	23.05621
323	– 161.98606	23.05719
324	– 161.98618	23.05817
325	– 161.98628	23.05915
326	– 161.98635	23.06013
327	– 161.98641	23.06112
328	– 161.98645	23.06211
329	– 161.98647	23.06309
330	– 161.98647	23.06408
331	– 161.98645	23.06507
332	– 161.98640	23.06606
333	– 161.98634	23.06704
334	– 161.98626	23.06803
335	– 161.98616	23.06901
336	– 161.98603	23.06999
337	– 161.98589	23.07097
338	– 161.98573	23.07195
339	– 161.98555	23.07293
340	– 161.98535	23.07390
341	– 161.98512	23.07487
342	– 161.98488	23.07583
343	– 161.98462	23.07680
344	– 161.98434	23.07776
345	– 161.98404	23.07871

TABLE 9—COORDINATES FOR NIHOA ISLAND SPA—Continued

Point No.	Longitude	Latitude
346	– 161.98372	23.07966
347	– 161.98338	23.08061
348	– 161.98302	23.08155
349	– 161.98265	23.08248
350	– 161.98225	23.08341
351	– 161.98183	23.08433
352	– 161.98140	23.08525
353	– 161.98095	23.08616
354	– 161.98048	23.08706
355	– 161.97999	23.08796
356	– 161.97948	23.08885
357	– 161.97896	23.08973
358	– 161.97841	23.09060
359	– 161.97785	23.09147
360	– 161.97727	23.09232
361	– 161.97668	23.09317
362	– 161.97606	23.09401
363	– 161.97543	23.09484
364	– 161.97479	23.09566
365	– 161.97413	23.09647
366	– 161.97345	23.09727
367	– 161.97275	23.09806
368	– 161.97204	23.09884
369	– 161.97131	23.09961

Appendix E to Subpart W of Part 922—Coordinates for the Ship Reporting Area

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

The Reporting Area Outer Boundary is defined by the following geographic coordinates and description as outlined in IMO Resolution MSC.279(85) Appendix 1—Outer Boundary adopted on 1 December 2008 that superseded and amended IMO Resolution MEPC.171(57) adopted on 4 April 2008.

The outer boundary of the CORALSHIPREP reporting area consists of lines connecting the following geographical positions:

- Starting at (1) 29° 24′.21 N, 178° 06′.45 W;
- A rhumb line to (2) 29° 12′.16 N, 177° 04′.25 W;
- Then a rhumb line to (3) 28° 43′.78 N, 175° 13′.76 W;
- Then a rhumb line to (4) 27° 00′.28 N, 173° 25′.37 W;
- Then a rhumb line to (5) 26° 44′.85 N, 171° 28′.22 W;
- Then a rhumb line to (6) 26° 23′.95 N, 170° 20′.25 W;
- Then a rhumb line to (7) 25° 56′.49 N, 167° 32′.03 W;
- Then a rhumb line to (8) 24° 50′.23 N, 165° 58′.56 W;
- Then a rhumb line to (9) 24° 02′.61 N, 161° 42′.30 W;
- Then an arc with a 60.25 nm radius centered at (21) 23° 03′.61 N, 161° 55′.22 W;
- To a point (10) 22° 04′.59 N, 162° 08′.14 W;
- Then a rhumb line to (11) 22° 35′.32 N, 164° 53′.46 W;
- Then a rhumb line to (12) 22° 47′.86 N, 166° 40′.44 W;
- Then a rhumb line to (13) 24° 03′.30 N, 168° 27′.53 W;

Then a rhumb line to (14) 24° 26′.59 N, 170° 50′.37 W;

Then a rhumb line to (15) 24° 46′.49 N, 171° 52′.87 W;

Then a rhumb line to (16) 25° 07′.23 N, 174° 30′.23 W;

Then a rhumb line to (17) 27° 05′.50 N, 176° 35′.40 W;

Then a rhumb line to (18) 27° 15′.11 N, 177° 35′.26 W;

Then a rhumb line to (19) 27° 26′.10 N, 178° 32′.23 W;

Then an arc with a 60.17 nm radius centered at (20) 28° 25′.23 N, 178° 19′.51 W;

Then to point (1) 29° 24′.21 N, 178° 06′.45 W.

The boundaries for the Inner Reporting Areas listed in this appendix, unless otherwise described in this rule, begin at Point 1 as indicated in the particular area's coordinate table and continue to each successive point in numerical order until ending at the last point in the table.

TABLE 1—COORDINATES OF THE INNER REPORTING AREA BOUNDARY AROUND HŌLANIKŪ (KURE ATOLL), KUAHELANI (MIDWAY ATOLL), MANAWAI (PEARL AND HERMES ATOLL) AREA TO BE AVOIDED (ATBA)

Point No.	Longitude	Latitude
1	– 175.78700	27.01217
2	– 175.87900	27.01133
3	– 175.96933	27.01817
4	– 176.05883	27.03317
5	– 176.14683	27.05567
6	– 176.23183	27.08533
7	– 176.31317	27.12283
8	– 176.39000	27.16633
9	– 176.46233	27.21700
10	– 176.47833	27.22950
11	– 176.49783	27.24600
12	– 177.55517	27.41583
13	– 178.49833	27.59783
14	– 178.56550	27.61067
15	– 178.62200	27.62550
16	– 178.67750	27.64333
17	– 178.73167	27.66417
18	– 178.78417	27.68800
19	– 178.83500	27.71483
20	– 178.88383	27.74433
21	– 178.93050	27.77650
22	– 178.97483	27.81117
23	– 179.01667	27.84817
24	– 179.05650	27.88700
25	– 179.09350	27.92817
26	– 179.12683	27.97150
27	– 179.15783	28.01683
28	– 179.18500	28.06350
29	– 179.20883	28.11183
30	– 179.22917	28.16117
31	– 179.24583	28.21167
32	– 179.25900	28.26300
33	– 179.26850	28.31517
34	– 179.27417	28.36733
35	– 179.27600	28.41200
36	– 179.27617	28.42000
37	– 179.27600	28.43017
38	– 179.27400	28.47250
39	– 179.26833	28.52483
40	– 179.25900	28.57683
41	– 179.24583	28.62817

TABLE 1—COORDINATES OF THE INNER REPORTING AREA BOUNDARY AROUND HŌLANIKŪ (KURE ATOLL), KUAHELANI (MIDWAY ATOLL), MANAWAI (PEARL AND HERMES ATOLL) AREA TO BE AVOIDED (ATBA)—Continued

Point No.	Longitude	Latitude
42	– 179.22900	28.67850
43	– 179.20900	28.72800
44	– 179.18550	28.77633
45	– 179.15867	28.82317
46	– 179.12833	28.86850
47	– 179.09500	28.91200
48	– 179.05850	28.95350
49	– 179.01917	28.99300
50	– 178.97700	29.03017
51	– 178.93217	29.06500
52	– 178.88500	29.09717
53	– 178.83550	29.12667
54	– 178.78400	29.15350
55	– 178.73067	29.17733
56	– 178.67567	29.19817
57	– 178.61933	29.21583
58	– 178.56183	29.23033
59	– 178.50350	29.24167
60	– 178.44433	29.24983
61	– 178.38467	29.25467
62	– 178.32483	29.25600
63	– 178.26500	29.25417
64	– 178.20533	29.24900
65	– 178.14633	29.24050
66	– 177.20117	29.05783
67	– 177.12150	29.04250
68	– 175.59117	28.64933
69	– 175.57250	28.64450
70	– 175.32900	28.58183
71	– 175.17750	28.43733
72	– 175.14917	28.41017
73	– 175.15067	28.40883
74	– 175.08183	28.33483
75	– 175.03200	28.26750
76	– 174.98883	28.19633
77	– 174.95383	28.12150
78	– 174.92800	28.04383
79	– 174.91033	27.96400
80	– 174.90083	27.88350
81	– 174.90083	27.80200
82	– 174.91033	27.72133
83	– 174.92850	27.64133
84	– 174.95533	27.56350
85	– 174.99050	27.48833
86	– 175.03383	27.41667
87	– 175.08450	27.34883
88	– 175.14317	27.28633
89	– 175.20783	27.22883
90	– 175.27783	27.17650
91	– 175.35417	27.13133
92	– 175.43483	27.09283
93	– 175.51917	27.06100
94	– 175.60667	27.03700
95	– 175.69633	27.02150
96	– 175.78700	27.01217

TABLE 2—COORDINATES FOR THE INNER REPORTING AREA BOUNDARY AROUND 'ŌNŪNUI AND 'ŌNUIKI (GARDNER PINNACLES), LALO (FRENCH FRIGATE SHOALS), MOKUMANAMANA (NECKER) ATBA

Point No.	Longitude	Latitude
1	– 168.00150	25.83633
2	– 167.87767	25.82733
3	– 167.87750	25.82833
4	– 167.80583	25.81650
5	– 167.61200	25.78483
6	– 167.44133	25.66400
7	– 167.32983	25.58500
8	– 166.75000	25.17383
9	– 166.05600	24.68183
10	– 165.58317	24.59400
11	– 164.51867	24.39633
12	– 164.51900	24.39317
13	– 164.49567	24.38850
14	– 164.40867	24.36417
15	– 164.32317	24.33500
16	– 164.24267	24.29583
17	– 164.16617	24.24983
18	– 164.09483	24.19767
19	– 164.03000	24.13833
20	– 163.97050	24.07467
21	– 163.92033	24.00450
22	– 163.87650	23.93083
23	– 163.84267	23.85283
24	– 163.81633	23.77217
25	– 163.79983	23.68950
26	– 163.79267	23.60567
27	– 163.79333	23.52117
28	– 163.80467	23.43783
29	– 163.82500	23.35567
30	– 163.85233	23.27550
31	– 163.89117	23.19933
32	– 163.93583	23.12567
33	– 163.98967	23.05767
34	– 164.05017	22.99417
35	– 164.11833	22.93783
36	– 164.19150	22.88700
37	– 164.26967	22.84333
38	– 164.35267	22.80800
39	– 164.43800	22.77883
40	– 164.52667	22.75817
41	– 164.61717	22.74717
42	– 164.70850	22.74417
43	– 164.79983	22.74867
44	– 164.82533	22.75183
45	– 164.85800	22.75650
46	– 164.85883	22.75283
47	– 165.58317	22.83767
48	– 166.32717	22.92500
49	– 166.38867	22.93217
50	– 166.60000	22.95683
51	– 166.75000	23.06250
52	– 166.79083	23.09133
53	– 168.38100	24.21167
54	– 168.37967	24.21467
55	– 168.45467	24.26750
56	– 168.52767	24.31917
57	– 168.59917	24.37117
58	– 168.66567	24.42850
59	– 168.72583	24.49183
60	– 168.77717	24.56117
61	– 168.82150	24.63433
62	– 168.85767	24.71133
63	– 168.88533	24.79083
64	– 168.90467	24.87233
65	– 168.91367	24.95533
66	– 168.91583	25.03867

TABLE 2—COORDINATES FOR THE INNER REPORTING AREA BOUNDARY AROUND 'ŌNŪNUI AND 'ŌNUIKI (GARDNER PINNACLES), LALO (FRENCH FRIGATE SHOALS), MOKUMANAMANA (NECKER) ATBA—Continued

Point No.	Longitude	Latitude
67	– 168.90717	25.12167
68	– 168.88867	25.20317
69	– 168.86267	25.28317
70	– 168.82667	25.35950
71	– 168.78217	25.43233
72	– 168.73100	25.50150
73	– 168.67367	25.56483
74	– 168.60867	25.62283
75	– 168.53733	25.67483
76	– 168.46133	25.72067
77	– 168.38033	25.75950
78	– 168.29600	25.79050
79	– 168.20783	25.81317
80	– 168.11817	25.82867
81	– 168.02700	25.83517
82	– 168.00150	25.83633

TABLE 3—COORDINATES FOR INNER REPORTING AREA BOUNDARY AROUND THE KAPOU (LISIANSKI ISLAND), KAMOLE (LAYSAN ISLAND), KAMOKUOKAMOHOALI'I (MARO REEF), RAITA BANK ATBA

Point No.	Longitude	Latitude
1	– 173.56150	26.85217
2	– 173.51450	26.84583
3	– 173.51317	26.84817
4	– 171.62833	26.60000
5	– 171.56400	26.59150
6	– 171.51400	26.58500
7	– 171.45833	26.56783
8	– 171.41933	26.55583
9	– 170.38400	26.23767
10	– 169.81600	26.14483
11	– 169.81717	26.13933
12	– 169.76383	26.12700
13	– 169.67617	26.10050
14	– 169.59400	26.06617
15	– 169.51517	26.02517
16	– 169.44083	25.97750
17	– 169.37233	25.92200
18	– 169.31000	25.86117
19	– 169.25317	25.79633
20	– 169.20567	25.72567
21	– 169.16550	25.65083
22	– 169.13467	25.57283
23	– 169.11267	25.49233
24	– 169.09883	25.41017
25	– 169.09400	25.32717
26	– 169.09883	25.24417
27	– 169.11100	25.16150
28	– 169.13367	25.08083
29	– 169.16600	25.00283
30	– 169.20583	24.92767
31	– 169.25233	24.85583
32	– 169.30800	24.78950
33	– 169.37033	24.72817
34	– 169.43850	24.67233
35	– 169.51300	24.62367
36	– 169.59400	24.58333
37	– 169.67767	24.55033

TABLE 3—COORDINATES FOR INNER REPORTING AREA BOUNDARY AROUND THE KAPOU (LISIANSKI ISLAND), KAMOLE (LAYSAN ISLAND), KAMOKUOKAMOHOALI'I (MARO REEF), RAITA BANK ATBA—Continued

Point No.	Longitude	Latitude
38	– 169.76467	24.52233
39	– 169.85133	24.50517
40	– 169.94217	24.49467
41	– 170.03017	24.49267
42	– 170.07617	24.49350
43	– 170.73983	24.59617
44	– 170.79300	24.60483
45	– 170.83950	24.61967
46	– 170.86950	24.62933
47	– 171.83650	24.93717
48	– 174.41400	25.27683
49	– 174.64083	25.49267
50	– 174.70050	25.55467
51	– 174.75333	25.62217
52	– 174.79733	25.69467
53	– 174.83417	25.77050
54	– 174.86283	25.84883
55	– 174.88183	25.93000
56	– 174.89117	26.01183
57	– 174.89350	26.09450
58	– 174.88450	26.17650
59	– 174.86800	26.25767
60	– 174.84283	26.33667
61	– 174.80733	26.41250
62	– 174.76567	26.48583
63	– 174.71600	26.55433
64	– 174.65817	26.61850
65	– 174.59383	26.67667
66	– 174.52383	26.72917
67	– 174.44783	26.77483
68	– 174.36817	26.81500
69	– 174.28383	26.84650
70	– 174.19650	26.87000
71	– 174.10717	26.88683
72	– 174.01633	26.89567
73	– 173.92467	26.89567
74	– 173.83367	26.88817
75	– 173.74300	26.87600
76	– 173.65233	26.86417
77	– 173.56150	26.85217

TABLE 4—COORDINATES FOR THE INNER REPORTING AREA BOUNDARY AROUND NIHOA ATBA

Point No.	Longitude	Latitude
1	– 161.78483	23.88033
2	– 161.74450	23.87317
3	– 161.74233	23.88033
4	– 161.68667	23.86833
5	– 161.63200	23.85300
6	– 161.57850	23.83467
7	– 161.52633	23.81317
8	– 161.47583	23.78883
9	– 161.42700	23.76150
10	– 161.38017	23.73133
11	– 161.33550	23.69867
12	– 161.29333	23.66333
13	– 161.25350	23.62567
14	– 161.21650	23.58567
15	– 161.18217	23.54367
16	– 161.15083	23.49983

TABLE 4—COORDINATES FOR THE
INNER REPORTING AREA BOUNDARY
AROUND NIHOA ATBA—Continued

Point No.	Longitude	Latitude
17	– 161.12250	23.45417
18	– 161.09750	23.40700
19	– 161.07567	23.35850
20	– 161.05717	23.30867
21	– 161.04217	23.25800
22	– 161.03067	23.20650
23	– 161.02250	23.15450
24	– 161.01817	23.10217
25	– 161.01717	23.04950
26	– 161.01983	22.99700
27	– 161.02617	22.94483
28	– 161.03583	22.89300
29	– 161.04917	22.84183
30	– 161.06583	22.79167
31	– 161.08583	22.74250
32	– 161.10900	22.69450
33	– 161.13550	22.64800
34	– 161.16500	22.60317
35	– 161.19750	22.56017
36	– 161.23283	22.51900
37	– 161.27083	22.48017
38	– 161.31150	22.44350
39	– 161.35433	22.40933
40	– 161.39950	22.37767
41	– 161.44667	22.34867

TABLE 4—COORDINATES FOR THE
INNER REPORTING AREA BOUNDARY
AROUND NIHOA ATBA—Continued

Point No.	Longitude	Latitude
42	– 161.49567	22.32250
43	– 161.54633	22.29917
44	– 161.59833	22.27883
45	– 161.65167	22.26167
46	– 161.70617	22.24750
47	– 161.76133	22.23667
48	– 161.81717	22.22883
49	– 161.87350	22.22450
50	– 161.93000	22.22333
51	– 161.98633	22.22500
52	– 162.04250	22.23083
53	– 162.09083	22.23850
54	– 162.09817	22.23950
55	– 162.11467	22.24317
56	– 162.20300	22.26450
57	– 162.28850	22.29500
58	– 162.37000	22.33283
59	– 162.44733	22.37883
60	– 162.51917	22.43133
61	– 162.58483	22.49017
62	– 162.64350	22.55467
63	– 162.69533	22.62450
64	– 162.73900	22.69883
65	– 162.77450	22.77717
66	– 162.80083	22.85800

TABLE 4—COORDINATES FOR THE
INNER REPORTING AREA BOUNDARY
AROUND NIHOA ATBA—Continued

Point No.	Longitude	Latitude
67	– 162.81817	22.94100
68	– 162.82633	23.02500
69	– 162.82483	23.10967
70	– 162.81483	23.19350
71	– 162.79500	23.27617
72	– 162.76633	23.35600
73	– 162.72917	23.43367
74	– 162.68350	23.50667
75	– 162.63050	23.57517
76	– 162.56967	23.63767
77	– 162.50300	23.69483
78	– 162.42983	23.74533
79	– 162.35183	23.78933
80	– 162.26933	23.82583
81	– 162.18317	23.85400
82	– 162.09383	23.87400
83	– 162.00417	23.88567
84	– 161.91250	23.88933
85	– 161.82133	23.88483
86	– 161.78483	23.88033

**Appendix F to Subpart W of Part 922—
IMO Standard Reporting Format and
Data Syntax for Ship Reporting System**

Telegraphy	Function	Information required	Example field text
	System identifier	CORAL SHIPREP //	CORAL SHIPREP //
A	Ship	Vessel name/call sign/flag/IMO number/Federal documentation or State registration number if applicable //	A/OCEAN VOYAGER/C5FU8/
B	Date, time (UTC), and month of entry.	A 6-digit group giving day of month (first two digits), hours and minutes (last four digits) in coordinated universal time, suffixed by the letter Z (indicating time in UTC), and three letters indicating month //	BAHAMAS/IMO 9359165/ B/271107Z DEC//.
C	Position	A 4-digit group giving latitude in degrees and minutes, suffixed with the letter N (indicating north), followed by a single /, and a five-digit group giving longitude in degrees and minutes, suffixed with the letter W (indicating west) // [Report in the World Geodetic System 1984 Datum (WGS–84)].	C/2728N/17356W//.
E	True course	3-digit number indicating true course //	E/180//.
F	Speed in knots and tenths	3-digit group indicating knots decimal tenths //	F/20.5//.
I	Destination and estimated time of arrival.	Name of port city/country/estimated arrival date and time group expressed as in (B) //	I/SEATTLE/USA/311230Z DEC//.
L	Intended route through the reporting area.	Route information should be reported as a direct rhumbline (RL) course through the reporting area and intended speed (expressed as in E and F) or a series of waypoints (WP). Each waypoint entry should be reported as latitude and longitude, expressed as in (C), and intended speed between waypoints (as in F) // (Note: As many “L” lines as needed may be used to describe the vessel’s intended route.).	L/RL/215/20.5// -OR- L/WP/2734N/17352W/20.5// L/WP/2641N/17413W/20.5// L/WP/2605N/17530W/20.5//.
O	Vessel draft in meters	Maximum present static draft reported in meters decimal centimeters //	O/11.50//.
P	Categories of Hazardous Cargoes*.	Classification Code (e.g., IMDG, IBC, IGC, INF) / and all corresponding Categories of Hazardous Cargoes (delimited by commas) // Note: If necessary, use a separate “P” line for each type of Classification Code.	P/IMDG/1.4G,2.1,2.2,2.3, 3.4.1,6.1,8,9//.
Q	Defects or deficiencies**	Brief details of defects, damage, deficiencies or limitations that restrict maneuverability or impair normal navigation // (If none, enter the number zero.).	Q/Include details as required//.
R	Pollution incident or goods lost overboard**.	Description of pollution incident or goods lost overboard within the Monument, the Reporting Area, or the U.S. Exclusive Economic Zone// (If none, enter the number zero.).	R/0//.
T	Contact information of ship’s agent or owner.	Name/address/and phone number of ship’s agent or owner // ..	T/JOHN DOE/GENERIC SHIP- PING COMPANY INC, 6101 ACME ROAD, ROOM 123, CITY, STATE, COUNTRY 12345/123–123–1234//.

Telegraphy	Function	Information required	Example field text
	System identifier	CORAL SHIPREP //	CORAL SHIPREP //
U	Ship size (length overall and gross tonnage) and type.	Length overall reported in meters decimal centimeters/number of gross tons/type of ship (e.g., bulk carrier, chemical tanker, oil tanker, gas tanker, container, general cargo, fishing vessel, research, passenger, OBO, RORO) //.	U/294.14/54592/CONTAINER SHIP//.
W	Persons	Total number of persons on board //	W/15//.

Table Notes:

* Categories of hazardous cargoes means goods classified in the International Maritime Dangerous Goods (IMDG) Code; substances classified in chapter 17 of the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code) and chapter 19 of the International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk (IGC Code); oils as defined in MARPOL Annex I; noxious liquid substances as defined in MARPOL Annex II; harmful substances as defined in MARPOL Annex III; and radioactive materials specified in the Code for the Safe Carriage of the Irradiated Nuclear Fuel, Plutonium and High-Level Radioactive Wastes in Flasks on Board Ships (INF Code).

** In accordance with the provisions of the MARPOL Convention, ships must report information relating to defects, damage, deficiencies or other limitations as well as, if necessary, information relating to pollution incidents or loss of cargo. Safety related reports must be provided to CORAL SHIPREP without delay should a ship suffer damage, failure or breakdown affecting the safety of the ship (Item Q), or if a ship makes a marked deviation from a route, course or speed previously advised (Item L). Pollution or cargo lost overboard must be reported without delay (Item R).

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Threatened Species
Status With Section 4(d) Rule for Clear Lake Hitch; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2024-0161;
FXES1111090FEDR-256-FF09E21000]

RIN 1018-BH84

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Clear Lake Hitch

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Clear Lake hitch (*Lavinia exilicauda chi*), a freshwater fish subspecies in the North American minnow family that is restricted to the Clear Lake watershed in Lake County, California, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the Clear Lake hitch. After a review of the best available scientific and commercial information, we find that listing the Clear Lake hitch is warranted. Accordingly, we propose to list the Clear Lake hitch as a threatened species with protective regulations issued under section 4(d) of the Act ("4(d) rule"). If we finalize this rule as proposed, it would add the Clear Lake hitch to the List of Endangered and Threatened Wildlife and extend the Act's protections to this subspecies.

DATES: We will accept comments received or postmarked on or before March 17, 2025. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by March 3, 2025.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter FWS-R8-ES-2024-0161, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment."

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R8-ES-2024-0161, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Supporting materials, such as the species status assessment report, are available at <https://www.regulations.gov> at Docket No. FWS-R8-ES-2024-0161.

FOR FURTHER INFORMATION CONTACT:

Michael Fris, Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Sacramento, CA 95825; telephone 916-414-6700. 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. Please see Docket No. FWS-R8-ES-2024-0161 on <https://www.regulations.gov> for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range).

If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that the Clear Lake hitch meets the Act's definition of a threatened species; therefore, we are proposing to list it as such. Listing a species as an endangered or threatened species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. We propose to list the Clear Lake hitch as

a threatened species with a rule issued under section 4(d) of the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the Clear Lake hitch meets the definition of a threatened species due to the following threats: habitat loss, degradation, and modifications (Factor A), predation (Factor C), competition (Factor E), and the effects of climate change (Factor E).

Section 4(a)(3) of the Act requires that the Secretary of the Interior (Secretary), to the maximum extent prudent and determinable, concurrently with listing designate critical habitat for the species. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat. At this time, critical habitat for the Clear Lake hitch is not determinable.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Clear Lake hitch's biology, range, and population trends, including:
(a) Biological or ecological requirements of the subspecies,

including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns and the locations of any additional areas occupied by the subspecies;

(d) Historical and current population levels, and current and projected trends; and

Past and ongoing conservation measures for the subspecies, its habitat, or both.

(2) Threats and conservation actions affecting the subspecies, including:

(a) Factors that may be affecting the continued existence of the subspecies, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors;

(b) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this subspecies; and

(c) Existing regulations or conservation actions that may be addressing threats to this subspecies.

(3) Additional information concerning the historical and current status of this subspecies.

(4) Information to assist with applying or issuing protective regulations under section 4(d) of the Act that may be necessary and advisable to provide for the conservation of the Clear Lake hitch. In particular, we seek information concerning:

(a) The extent to which we should include any of the section 9 prohibitions in the 4(d) rule; or

(b) Whether we should consider any additional exceptions from the prohibitions in the 4(d) rule.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on <https://www.regulations.gov>. Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after this proposal. Based on the new information we receive (and, if relevant, any comments on that new information), we may conclude that the Clear Lake hitch is endangered instead of threatened, or we may conclude that the subspecies does not warrant listing as either an endangered species or a threatened species. In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions if we conclude that the protective regulation as a whole, including those additional prohibitions, is necessary and advisable to provide for the conservation of this subspecies. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the subspecies. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We

may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On September 25, 2012, we received a petition from the Center for Biological Diversity to list the Clear Lake hitch as an endangered or threatened species under the Act and to designate critical habitat. The Service issued a 90-day finding on April 10, 2015 (80 FR 19259), stating that the petition presented substantial information that listing the Clear Lake hitch may be warranted and initiating a status review of the subspecies. On December 3, 2020, we published our 12-month finding that the Clear Lake hitch was not warranted for listing under the Act (85 FR 78029).

The Center for Biological Diversity filed a complaint in the Northern District of California on August 17, 2021, challenging our 12-month not-warranted finding. By stipulated settlement agreement approved by the court on April 14, 2022, the Service agreed to submit to the **Federal Register** a new 12-month finding for the Clear Lake hitch on or before January 12, 2025 (*Center for Biological Diversity v. U.S. Fish and Wildlife Service, et al.*, No. 3:21-cv-06323-RS (N.D. Cal.)).

Peer Review

In 2020, a species status assessment (SSA) team prepared an SSA report (version 1.0; Service 2021, entire) for the Clear Lake hitch's 12-month finding (85 FR 78029; December 3, 2020). The SSA team was composed of Service biologists, in consultation with other species experts. In 2024, the SSA report was updated with new information (e.g., survey data, life history information, conservation actions) (version 2.0; Service 2024, entire). The SSA report (version 2.0; Service 2024, entire) represents a compilation of the best scientific and commercial data available concerning the status of the subspecies, including the impacts of past, present, and future factors (both negative and beneficial) affecting the subspecies.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review in listing and recovery actions under the Act (<https://www.fws.gov/sites/default/files/documents/peer-review-policy-directors-memo-2016-08-22.pdf>), we solicited independent

scientific review of the information contained in the Clear Lake hitch SSA report (version 2.0; Service 2024, entire). We sent the SSA report to three independent peer reviewers and we received responses from two reviewers. Results of this structured peer review process can be found at <https://www.regulations.gov>. In preparing this proposed rule, we incorporated the results of these reviews, as appropriate, into the SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed above in Peer Review, we received comments from two peer reviewers on the draft SSA report, version 2.0. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the SSA report. The peer reviewers generally concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions, including edits to improve the overall report. Otherwise, no substantive changes to our analysis and conclusions within the SSA report

were deemed necessary, and peer reviewer comments are incorporated in version 2.1 of the SSA report (Service 2024, entire).

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the Clear Lake hitch is presented in the SSA report (version 2.1; Service 2024, pp. 16–36) and in the previous 12-month finding (85 FR 78029; December 3, 2020). The Clear Lake hitch is a medium-sized freshwater fish subspecies classified in the *Lavinia* genus in the Leuciscidae family (Service 2024, p. 16). The subspecies is endemic to the Clear Lake watershed in the northern section of the California Coast Ranges.

Historically, Clear Lake hitch occurred in numerous lakes and ponds found throughout the Clear Lake watershed, including Clear Lake, Thurston Lake, Upper Blue Lake, Lower Blue Lake, and Lampson Pond. During the spring, the Clear Lake hitch could also be found spawning in the numerous tributaries to these larger

waterbodies, including Kelsey, Scott, Middle, Adobe, Seigler Canyon, Manning, Cole, Morrison, and Schindler creeks (figure 1). The subspecies still occurs in Clear and Thurston Lakes throughout the year until the spring, when reproductive adults migrate into tributaries to spawn. Annual surveys conducted in Clear Lake have shown that there are fluctuations in the estimated abundances from year to year. The Clear Lake hitch was thought to be extirpated from the Blue Lakes, but observations and fish rescue efforts in 2022 show evidence of hitch in both Upper Blue Lake and Lower Blue Lake (Ewing 2022a, entire; Santana 2022, entire). It is unclear whether Lampson Pond still exists (B. Ewing *in litt.* 2020); therefore, the status of the Clear Lake hitch in Lampson Pond is unknown. All of the described waterbodies besides Thurston Lake were hydrologically connected in the past, and it appears that Thurston Lake and its tributary, Thurston Creek, have always been isolated from the other waterways (B. Ewing *in litt.* 2020; P. Windrem *in litt.* 2020).

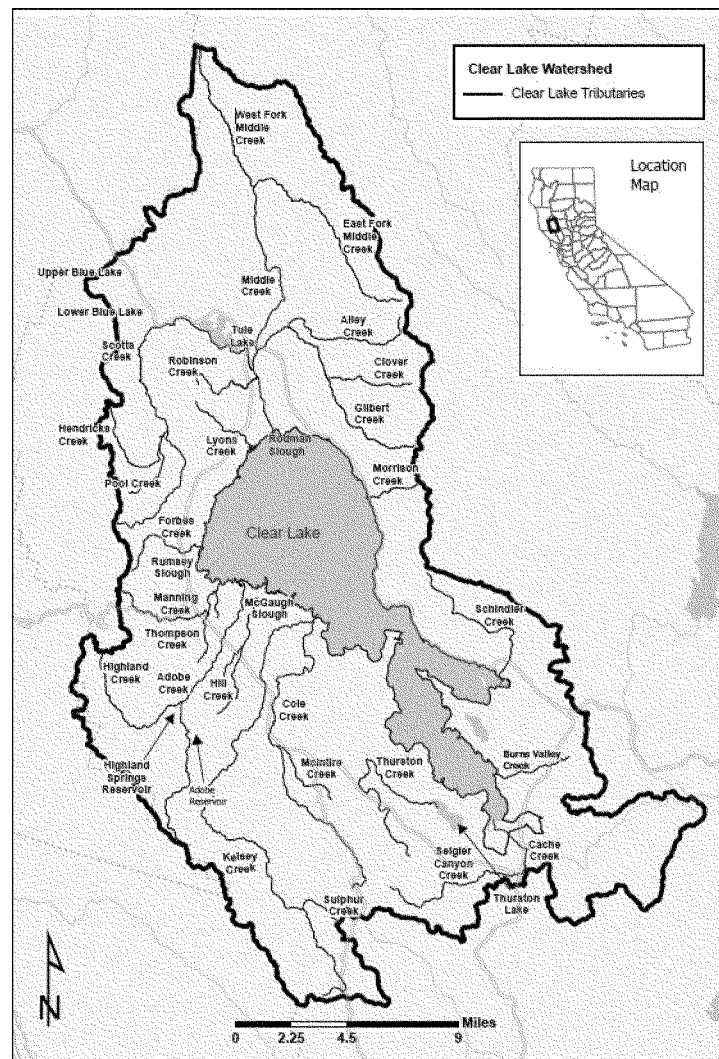


Figure 1. Clear Lake Hitch range map with tributaries and lakes.

Within the lacustrine habitats, the subspecies can be found in either the littoral zone (nearshore) as juveniles or the limnetic zone (sun-lit, offshore open water) as adults. During extreme drought conditions, the only successful reproduction may be within the lakes. Nonnative vegetative growth along the lake's shoreline can outcompete the growth of important native wetland plant species, such as tule. Nonnative plant species, such as Himalayan blackberry (*Rubus armeniacus*), growing along the tributaries can become so overgrown that they become passage barriers or they outcompete native species such as willows and cottonwoods.

Clear Lake hitch begin to migrate into spawning tributaries when there is sufficient runoff, typically between February and May, and sometimes into June if flows are sufficient (Macedo

1994, p. 2; California Department of Fish and Wildlife (CDFW) 2014, p. 1). Eggs are deposited on fine to medium-sized gravel that is along the margin or mid-channel of the stream (Shapovalov 1940 as cited in Murphy 1948b, p. 102; Kimsey 1960, p. 211; CDFW 2014, p. 8), where they hatch into larval fish called fry. Fry stay in the streams anywhere between 11 to 152 days, migrating to the lake once stream waters diminish (Murphy 1948b, pp. 105, 106, 109; Swift 1965, pp. 75, 77–79; Moyle et al. 1995, p. 154; Feyrer et al. 2019a, p. 1693). Juvenile hitch less than 2 inches (in., 50 millimeters (mm)) standard length (SL, length of a fish measured from the tip of their mouth/snout to the end of the tail, excluding the caudal (tail) fin) are found within the nearshore habitat of the lake, where they utilize stands of tule (*Schoenoplectus acutus*) and other submerged aquatic vegetation for cover

and feed on various diet items, including insects such as the Clear Lake gnat (*Chaoborus astictopus*), *Daphnia* and other planktonic crustaceans, and chironomid midges.

The Clear Lake hitch females are known to grow larger than males (Geary 1978, pp. 7, 9), and larger females produce more eggs (average annual fecundity is 36,000 eggs, with a range of 9,000–63,000) (Geary and Moyle 1980, p. 387). Males are sexually mature within their first or second year, whereas females are sexually mature in their second or third year (Murphy 1948b, pp. 103–104, 109; Moyle et al. 1995, p. 153). Hitch are thought to live 4 to 6 years based on scale analysis, but it is possible some individuals can live longer (Moyle 2002, p. 138; CDFW 2014, p. 8).

There is uncertainty around where current reproduction and recruitment

are successfully occurring, and whether other small waterbodies upstream of Clear Lake are supporting the Clear Lake population. In 2017 and 2018, 280 and 297 hitch were captured, respectively. The Clear Lake hitch was the fifth most abundant species/subspecies collected over the course of the 2017 survey and the most abundant species/subspecies captured during the 2018 effort (USGS 2018, p. 8). However, the number of hitch captured during the 2019, 2021, and 2022 surveys drastically declined to only 76, 40, and 6 individuals, respectively. In 2023, the number of individuals captured increased to 304 individuals and included multiple stage classes (Clear Lake Hitch Summit Agenda and Presentations 2023, p. 84; Palm et al. 2023, entire). There is a working hypothesis that the increase in the number of hitch seen in 2023 is due to hitch presence in smaller lakes in the watershed (e.g., Blue Lakes, Tule Lake). The theory is that small populations of the Clear Lake hitch are successfully reproducing in these other waterbodies, and during a wet year, like the historically wet year in 2023, individuals were washed from these smaller lakes into Clear Lake.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species.

The Act defines an “endangered species” as a species that is in danger of extinction throughout all or a significant portion of its range, and a “threatened species” as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
- (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused

actions or conditions that could have an effect on a species’ continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term “threat” to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term “threat” includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term “threat” may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the species’ expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an “endangered species” or a “threatened species” only after conducting this cumulative analysis and describing the expected effect on the species.

The Act does not define the term “foreseeable future,” which appears in the statutory definition of “threatened species.” Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis which is further described in the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M–37021, January 16, 2009; “M–Opinion,” available online at <https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf>). The foreseeable future extends as far into the future as the U.S.

Fish and Wildlife Service and National Marine Fisheries Service (hereafter, the Services) can make reasonably reliable predictions about the threats to the species and the species’ responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We will describe the foreseeable future on a case-by-case basis, using the best available data and consider the species’ life-history characteristics, threat-projection timeframes, and environmental variability. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. “Reliable” does not mean “certain”; it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies.

To assess the Clear Lake hitch’s viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy is the ability of the species to withstand catastrophic events (for example, droughts, large pollution events); and representation is the ability of the species to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogens). In general, species viability will increase with increases in resiliency, redundancy, and representation (Smith et al. 2018, p. 306). Using these principles, we identified the Clear Lake hitch’s ecological requirements for survival and reproduction at the individual, population, and subspecies levels, and described the beneficial and risk factors influencing the subspecies’ viability.

The SSA process can be categorized into three sequential stages. During the

first stage, we evaluated the individual Clear Lake hitch's life-history needs. The next stage involved an assessment of the historical and current condition of the subspecies' demographics and habitat characteristics, including an explanation of how the subspecies arrived at its current condition. The final stage of the SSA involved making predictions about the subspecies' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of the Clear Lake hitch to sustain populations in the wild over time, which we then used to inform our regulatory decision.

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS-R8-ES-2024-0161 on <https://www.regulations.gov>.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the Clear Lake hitch and its resources, and the threats that influence the subspecies' current and future condition, in order to assess the subspecies' overall viability and the risks to that viability.

Additional information regarding the subspecies' needs can be found in the SSA report (Service 2024, pp. 24–36).

Subspecies Needs

The Clear Lake hitch has four life stages: egg/embryo, larvae/fry, juveniles, and adults. Below, we assess the best available information to identify the specific habitat components needed to support individual fitness at all four life stages for the Clear Lake hitch. Each life stage requires different environmental and habitat components according to the different habitats used throughout the species' lifetime for spawning, feeding, and sheltering. Once fertilized, Clear Lake hitch eggs require adequate stream flow to stay submerged and oxygenated; fine to medium-sized, clean gravel along the margin or within the mid-channel of the stream to hold position during development; and presumably temperatures between 55.4 and 64.4 degrees Fahrenheit (°F) (13 and 18 degrees Celsius (°C)) for successful development (Shapovalov 1940 in Murphy 1948b, p. 102; Kimsey 1960, p. 211; Swift 1965, pp. 75, 77; Moyle et al. 1995, p. 154; Moyle 2002, p. 138; CDFW 2014, p. 8; Feyrer 2019a, p. 227). To initiate hatching, water temperatures must be maintained at 59 to 71.6 °F (15 to 22 °C) for multiple days (Swift 1965, pp. 75, 77; Moyle 2002, p. 138).

Newly hatched larvae/fry have a small yolk sac that they require for nourishment until they are able to swim freely and capture aquatic invertebrate prey (Kimsey 1960, p. 212). For cover and temperature regulation, downstream migrating fry likely require instream and/or overhanging streamside vegetation. The fry life stage requires adequate stream flow to stay alive, and adequate flow needs to be maintained until the young of year are able to migrate downstream into the lake (Murphy 1948b, pp. 105, 106, 109; Swift 1965, pp. 75, 77–79; Moyle et al. 1995, p. 154; Feyrer et al. 2019a, p. 1693).

Within the lake, Clear Lake hitch fry and juveniles require stands of tule and/or other submerged aquatic vegetation to act as cover from predators and to provide for invertebrate prey items, including insects, planktonic crustaceans, and chironomid midges. Juveniles also require the lake water to be of sufficient quality (*i.e.*, well-oxygenated (more than 2 milligrams per liter (mg/L) of oxygen) and minimally contaminated) and for water temperatures to be 59 °F (15 °C) or greater for survival (Franson 2012, p. 15; CDFW 2014, p. 9). Juvenile hitch transition to adulthood when they reach about 2 in (50 mm) and they move from the lake's nearshore habitat out into the open water of the lake.

Adult Clear Lake hitch require a diet almost exclusively composed of *Daphnia*, but also other zooplankton species and adult midges and insects (Lindquist et al. 1943, p. 199; Geary 1978, pp. 17, 25; Geary and Moyle 1980, p. 388; Moyle et al. 1995, p. 153; Moyle 2002, pp. 137–138; Moyle et al. 2014, p. 3). Adult Clear Lake hitch also require well-oxygenated (more than 2 mg/L of oxygen) and minimally contaminated water within the lake to ensure survival (Franson 2012, p. 15; CDFW 2014, p. 9). Adult Clear Lake hitch are only found in the tributaries during the spawning season. A reproductive adult that is attempting to spawn requires an adequate amount of flow to migrate upstream to appropriate spawning locations and downstream back to the lake, and water temperatures between 55.4 and 64.4 °F (13 and 18 °C) to trigger spawning activity (Swift 1965, pp. 75, 77; Moyle 2002, p. 138; Feyrer 2019a, p. 227).

In addition to stream spawning, some reproductive adults spawn within the lake (or ponds) instead of migrating into the lake tributaries. Lake or pond spawning Clear Lake hitch have been documented spawning in areas with only a mud substrate that contains no gravel, so it is possible lake- or pond-spawning individuals do not require

gravel to successfully spawn (Kimsey 1960, p. 214; Geary 1978, p. 22).

Threats

In assessing the Clear Lake hitch's viability, we describe the threats acting on the subspecies and its habitat. We also provide a description of historical and ongoing activities or regulations that ameliorate the threats and provide conservation benefits to the subspecies. The threats acting on the Clear Lake hitch include habitat loss, degradation, and modification; predation; competition; mercury mining; and the effects of climate change. Due to the different aquatic habitats (lake and tributary) used by the subspecies, there are threats acting on different life stages of the subspecies. These threats along with other ongoing and future stressors acting on the species may act synergistically to cause declines in resiliency across populations and analysis units. An example includes the effects of climate change with increased temperatures and aridity, may lead to more fires in the area. Burned areas create more runoff into the lake and tributary systems, further degrading habitat and affecting all life stages of the Clear Lake hitch. We note here that Thurston Lake does not have the level of threats acting on the subspecies that are affecting the hitch in Clear Lake.

Habitat Loss, Degradation, and Modification

Habitat loss, degradation, and modification are affecting the subspecies in both the tributary and lake systems. Changes to the Clear Lake watershed have occurred since the mid-1800s. Various forms of past mining activities, agricultural and urban development, pesticide use, increased fire activity, past deforestation, and historical grazing practices have all contributed to the degradation of the Clear Lake watershed and are also the cause of toxic cyanobacteria blooms and periodic fish kills in the lake. The degradation of tributaries has changed their hydrology, reducing the amount of water retained in the streams over the Clear Lake hitch's spawning season. This loss of flow earlier in the season and the presence of numerous passage barriers in the tributaries have greatly reduced reproduction and early life stage survival (egg, larvae) of the Clear Lake hitch. The conversion of wetland habitats surrounding Clear Lake not only negatively impacted the lake's water quality but also reduced the amount of rearing habitat for any juvenile hitch that are able to migrate to the lake from their natal stream. This loss of rearing habitat also reduces early

life stage survival (juvenile), further reducing the likelihood of recruitment. The impacts to Clear Lake's water quality affect adult hitch survival, especially when poor lake conditions result in large fish kills.

The Clear Lake hitch relies on tributary habitat for spawning and early rearing (Murphy 1951, p. 480). It is estimated that, historically, the tributaries to Clear Lake ran until at least September; currently, however, besides a few tributaries, most are known to dry by early summer or late spring (Murphy 1951, p. 480; B. Ewing *in litt.* 2020; Ewing 2020, pp. 3–5; Ewing 2021, pp. 6–7; Ewing 2022b, p. 7; B. Ewing *in litt.* 2024). A combination of activities contributed, and are continuing to contribute, to the reduction in tributary flow during the Clear Lake hitch's spawning season. Increased fire activity and legacy effects from instream gravel removal and deforestation have likely increased the rate of runoff within the tributaries during the winter. For example, burned vegetation removes the root systems that hold soil in place and, with subsequent rainfall, increases runoff and sedimentation into the subspecies' habitat. Those same factors, possibly in conjunction with both in-creek and groundwater pumping for urban and agricultural uses, have greatly reduced the amount of flow that actually makes it to the lake during the summer (Murphy 1951, p. 480).

Gravel mining activities in the Clear Lake watershed first began in the latter half of the 19th century and occurred in most of the spawning tributaries to Clear Lake (Suchanek et al. 2003, pp. 1253–1254; Thompson et al. 2013, p. 19). Gravel mining originally occurred as scattered operations throughout the watershed until the early- to mid-20th century, when operations became centralized within the creeks (County of Lake 1992, p. 48; Richerson et al. 1994, p. III–19). This time period coincides with improved automobile technology and increased pressure to build more reliable roads (County of Lake 1992, p. 48). As the human population within the county grew in the 1960s and 70s, new houses and associated roads needed to be constructed to accommodate the new residents. Since the instream gravel was available as a convenient source of material, gravel was extracted from the tributaries and was used as building material for both homes and roads (County of Lake 1992, p. 48; Richerson et al. 1994, p. VIII–150). Until the 1981 partial moratorium on instream gravel extraction, approximately 1 million metric tons of instream gravel was extracted from the

watershed (Richerson et al. 1994, pp. III–19–III–20; CDFW 2014, p. 29). Although the amount of gravel mining within the Clear Lake tributaries has been reduced, mining and extraction are still known to occur in areas where the Clear Lake hitch occur, such as Scotts and Alley creeks (Murphy 1948b, p. 106; Richerson et al. 2008, p. A260; CDFW 2014, p. 29; B. Ewing *in litt.* 2020).

Past gravel mining in tributaries not only removed spawning substrate that the subspecies uses for reproduction and egg development, but it also lowered streambeds and destabilized channels, causing increased erosion, incision, and channelization. In addition, large swaths of riparian vegetation were removed from along the tributaries to allow access for gravel extraction, further exacerbating the issues with erosion. The flushing of eroded material not only negatively impacted tributaries by increasing the amount of suspended sediments and silt within the creek, ultimately increasing turbidity in some tributaries to zero visibility, but it also negatively impacted the lake ecosystem when those sediments eventually were transported into the lake (CDFG 1955, entire; Richerson et al. 1994, pp. III–19, VIII–2; Service 2024, pp. 44–48; Suchanek et al. 2003, p. 1254; CDFW 2014, pp. 29, 45).

In addition to gravel mining, agricultural practices have impacted, and still are impacting, the Clear Lake hitch's habitat. Agricultural production in the Clear Lake area has been important since the mid-1800s with crops that included apples, almonds, grapes, nectarines, peaches, pears, plums, and prunes, many of which are still grown today (Suchanek et al. 2003, p. 1256; U.S. Department of Agriculture (USDA) 2023, entire). Much of the land surrounding Clear Lake has been converted from forest lands to agricultural use. Large-scale deforestation and land conversion within the watershed began in the mid-19th century. The large-scale forest removal within the Clear Lake watershed increased the amount of erosion occurring in the tributaries, contributing to bank incision within the tributaries and causing increased sediment and nutrient transport into the lake (Suchanek et al. 2003, pp. 1247–1248). Increased erosion and bank cutting decrease the amount of time that water is retained within the tributaries, which affects water quantity and flow needed by the subspecies.

Agricultural development is found throughout the watershed; however, it is most concentrated in the southwestern

area of the watershed, primarily near Kelsey and Adobe creeks (USDA 2023, entire). The presence of agricultural production in the watershed not only has an impact on the amount of water flowing in the tributaries to Clear Lake, but it likely also increases the amounts of contaminants, in the form of pesticides and fertilizers, and sediment entering the lake.

Pesticides are used for agriculture production across the region. Pesticides not only affect the habitat but may also affect certain life stages of the Clear Lake hitch and affect the subspecies' prey species. The reported application of pesticides on agricultural lands in the region has increased from 2008 to 2021. In 2008, more than 589,500 pounds of different forms of chemicals used as pesticides were applied in Lake County (California Pesticide Information Portal (CALPIP) 2019, unpaginated). In 2021, that amount increased to almost 741,000 pounds (CALPIP 2021, unpaginated). Pesticides are also known to be used for illegal cannabis crops, and it is possible that pesticides associated with illegal grows could drain into the Clear Lake watershed, further exacerbating declining water quality conditions. The primary concerns of pesticide effects on Clear Lake hitch are the high toxicity. Growers can add these chemicals to their irrigation systems, causing the chemicals to seep into the surrounding soil and waterways (California Department of Pesticide Regulation 2021, p. 2; USDA 2023, entire). Pesticides are known to cause fish casualties, growth delays, and swimming abnormalities, making fish more susceptible to predation (Baker 2018, pp. 2–3).

Fertilizers that get into waterways can cause nutrient imbalances that affect oxygen levels in the water, causing cyanobacteria blooms and fish kills (Baker 2018, p. 6). Another concern is water diversions associated with these illegal cultivation sites, which can block fish passage, change flow regimes, and cause other secondary effects (Baker 2018, p. 6). However, it is unknown what effect agricultural pesticides or pesticides associated with illegal grows are having on the aquatic environment in Clear Lake or if pesticides are being transported through tributaries into the lake (Suchanek et al. 2003, p. 1252).

Herbicides Are Used To Control Nonnative Aquatic Vegetation in Clear Lake

Komeen™ (copper sulfate) and SONAR™ (fluridone) have been applied in the lake to control *Hydrilla verticillata*, a highly invasive, submerged aquatic weed (Suchanek et

al. 2003, p. 1250; CDFW 2014, p. 32). Two herbicides were used to target different parts of the plant; Komeen targets *Hydrilla* vegetative growth, while SONAR treats the tubers (Suchanek et al. 2003, p. 1250). SONAR is considered less toxic than Komeen because SONAR is a systemic herbicide that is slowly absorbed in the vascular system; SONAR also impacts similar non-target vegetation such as tule and other submerged vegetation (Bairrington 2000, pp. 64–65; CDFW 2014, p. 32). Because juvenile Clear Lake hitch require tule habitat for cover and prey, the use of Komeen can indirectly impact the hitch by reducing the amount of rearing habitat (CDFW 2014, p. 32). The use of the herbicide, SONAR, at high concentrations may have an impact on early hitch development.

To meet the needs for agricultural production, crops require sufficient water. Water extraction and the early drawdown of the tributaries, in conjunction with habitat modifications throughout the watershed, likely led to the extinction of the Clear Lake splittail (*Pogonichthys ciscooides*), another stream-spawning native fish restricted to the Clear Lake watershed (Moyle 2002, pp. 138–139; CDFW 2014, p. 27). The Clear Lake splittail spawned later in the season than the Clear Lake hitch does, and, as the tributaries began to dry earlier in the season, Clear Lake splittail young were not able to migrate to the lake (Cook et al. 1966, p. 146; Moyle 2002, pp. 138–139; CDFW 2014, p. 27).

Water extraction continues throughout the watershed today for agricultural and domestic purposes. Both surface and ground water are being diverted from Clear Lake tributaries (legally and illegally) (CDFW 2014, p. 27), with the primary supply, about 60 percent, coming from groundwater sources in an average year (County of Lake 2014, entire; Clear Lake Hitch Summit Agenda and Presentations 2023, p. 18). These particular diversions are legal extractions conducted under riparian and water rights associated with land ownership. Surface water is diverted via intake pumps, and groundwater is extracted via the installation of shallow wells near the tributary channel where they capture underflow (CDFW 2014, p. 27). In 2013 and 2014, water rights users in Kelsey Creek used 85 and 134.5 million gallons of water, respectively, as well as 31.4 million gallons in each of those years from Adobe Creek. In addition, from 2008 to 2014, 18 private water wells were permitted for installation along the two creeks. Although this amount of water withdrawal is legally permissible, it is unknown what effects this amount

of water extraction is having on the hydrology of these tributaries and the Clear Lake hitch (Big Valley 2015, p. 4).

Water extractions, both legal and illegal, are often cited as one of the primary reasons for the reduction in the Clear Lake hitch's population; however, although stream gauges are installed in some of the tributaries and continue to be installed, studies on the effects that water extraction is having on Clear Lake tributaries or the Clear Lake hitch are still in initial stages (Clear Lake Hitch Summit Agenda and Presentations 2023, pp. 63–72). The CDFW compared stream flow conditions at the U.S. Geological Survey (USGS) gauge on Kelsey Creek (USGS Station 11449500) and catch data from the early 1990s. Both 1990 and 1991 were considered dry water years with below average tributary flow during the spring; however, the highest number of hitch were captured during seining efforts during those years. Flow conditions improved to average or above average for the following 3 years, but the number of fish captured declined (CDFW 2014, p. 27). Clear Lake hitch abundance varies from year to year due to a number of factors, including streamflow. More data are needed to better understand the relationship between streamflow and population numbers as well as the effects that water extraction has on streamflow.

Historical land conversion was not only for the purposes of agricultural crops but also for livestock. The effects of livestock on the land can include overgrazing and the subsequent effects of exacerbated erosion and water quality degradation. Although overgrazing no longer appears to be occurring in the Clear Lake watershed, it was an issue until the mid-20th century. Past overgrazing in the watershed resulted in the loss of streamside vegetation, which decreased soil stability and increased the rate of runoff within the creeks, effectively reducing the amount of time water is retained within the channel (Murphy 1948b, p. 106; Suchanek et al. 2003, p. 1257). Although the amount of grazing pressure has decreased in the watershed, the impacts of past practices are still contributing to the issues seen in the watershed today.

Clear Lake hitch are affected by passage barriers that block the ability of the fish to move up and downstream. The lack of adequate tributary flow can act as a barrier to migrating fish, reducing the amount of available spawning habitat, and leaving young stranded before they can migrate to the lake. However, even when flow conditions allow for migration, most of the tributaries in the watershed contain physical barriers that prevent hitch

passage, reducing the amount of spawning and rearing habitat available.

The installation of dams, diversions, roadways, and crossings have had a negative impact on migrating hitch by eliminating access to portions of stream with suitable spawning habitat or impeding passage during certain years until specific flow conditions (*i.e.*, high flow) are met (Suchanek et al. 2003, p. 1254; CDFW 2014, pp. 45, 69–70). Using a variety of data sources, CDFW estimated that more than 92 percent of the Clear Lake hitch's historical 180 stream miles of tributary habitat is currently blocked or has reduced access due to the presence of barriers (CDFW 2014, pp. 24–25). In addition, since the presence of a barrier on a spawning stream reduces the amount of available spawning habitat, reproducing adults have to compete for available spawning substrate. Fertilized eggs have been known to accumulate just below a barrier to the point that they will die due to oxygen deprivation (Robinson Rancheria 2015, p. 1).

Numerous dam structures can be found throughout the Clear Lake watershed, including dams on Kelsey, Adobe, Highland Springs, and Manning creeks. These dams were installed in the mid- to late 20th century and were installed primarily for irrigation and recreation (Suchanek et al. 2003, p. 1248). In addition, CDFW identified potential barriers on Lyon's Creek, Scott's Creek, Seigler Canyon Creek, Clover Creek, and Kelsey Creek (Ewing 2016a, entire). Additional barriers in the watershed include flood and water infrastructure that are not regularly maintained that may block hitch passage (CDFW 2014, p. 69). Flood control projects have also contributed to increased nutrient and sediment transport in the watershed by channelizing and armoring tributaries with rip-rap and by reclaiming large portions of wetland habitat that once surrounded the lake (CDFW 2014, p. 29). There are almost 14 miles of levee structures that are maintained by the U.S. Army Corps of Engineers (USACE) on Scotts, Middle, Clover, and Alley creeks (USACE 2012, p. 3). The loss of wetland habitat and increased nutrient and sediment transport further exacerbates water quality issues within Clear Lake, likely reducing hitch survival. Further, the loss of wetland habitat to install the flood projects reduced the amount of rearing habitat for juvenile hitch, reducing the likelihood of successful recruitment. The lake habitat for the Clear Lake hitch is also affected by habitat loss, degradation, and modification through wetland/tule habitat loss, cyanobacteria

(blue- green algae) blooms, and fish kills. Because of the impacts from the historical land conversion, surrounding wetland habitats were lost, essentially removing Clear Lake's natural filter. Over time, increasing amounts of sediment and nutrients from the degraded tributaries were transported directly into the lake, and nutrient inputs from surrounding urban and agricultural development ended up in the lake. This increase in nutrients and sediments entering Clear Lake degraded its water quality, resulting in increased cyanobacteria blooms that contributed to or caused periodic fish kills.

With the loss of the extensive tule expanses within the lake's nearshore habitat, there has been an increase in the amount of sedimentation and nutrients entering the lake (Prine et al. 1975, p. 21). Wetlands act as a filter for sediments and nutrients transported from the tributaries into the lake and the loss of these large wetland complexes directly surrounding the lake has had negative consequences to Clear Lake's water quality (Richerson et al. 1994, pp. III-1, V-1, VIII-1; Suchanek et al. 2003, p. 1255). One result from the wetland loss and water quality impacts is blue-green algae blooms that occur in Clear Lake from phosphorus input.

The blue-green algae, a cyanobacteria and not an actual alga, will float to the surface of the lake during the day and can form large mats or scums. These mats will either be broken down or re-submerged into the lake via wind action or will deteriorate from sun exposure. Phosphorus is found naturally in underlying sediments within the Clear Lake watershed (Richerson et al. 1994, p. V-99), and the degradation of tributaries have exposed those sediments, allowing for transport into the lake during rain events. A major factor in the persistence and formation of cyanobacteria blooms in Clear Lake relates to periods of anoxia (deficiency of oxygen), and where phosphorus is released from sediments (Florea et al. 2022, p. ii). Blue-green algae blooms can be toxic to fish (Gorham 1960, p. 242; Prine et al. 1975, p. 23; Richerson et al. 1994, p. III-9); however, it is unknown what impact they have on the Clear Lake hitch.

Fires have occurred naturally in the Clear Lake watershed as part of the ecological cycle; however, with Euro-American settlement in the middle of the 19th century, widespread intentional burning occurred throughout the watershed to clear brush or promote grass growth for livestock grazing (Suchanek et al. 2003, pp. 1243-1245, 1246-1247). Numerous fires have occurred in the Clear Lake area during

the 20th century, with several large ((10,000+ acres (ac), 4047 hectares (ha)) fires occurring directly in the watershed (Suchanek et al. 2003, pp. 1244, 1248). The fire seasons in California during 2017, 2018, and 2020 were some of the worst on record. The 2018 Mendocino Fire Complex, a portion of which occurred in Lake County, was the third largest fire on record in California (CalFire 2022a, entire). Past fire suppression practices within the State of California have reduced the occurrence of fire, but due to the accompanying fuel accumulation, these practices have made fires more devastating when they do occur (Suchanek et al. 2003, p. 1247). Fire activity within the watershed results in increased erosion and bank incision, which channelize the stream and increase water turbidity; fire activity is likely to continue to increase within the Clear Lake watershed (CalFire 2022b, entire). Channelization can decrease the amount of time water is retained within the tributary channel (Murphy 1948b, p. 106; County of Lake 1992, p. 13). A reduction of flow in the tributaries during the spawning season can eliminate or greatly reduce the likelihood for successful reproduction and/or recruitment, and due to the Clear Lake hitch's very narrow range, the effects of channelization can impact the subspecies' viability.

Summary of Habitat Loss, Degradation, And Modification

Habitat loss, degradation, and modification due to agricultural and urban development, pesticide use, increased fire activity, and legacy impacts from past mining activities, past deforestation, and historical grazing practices will continue to affect the Clear Lake hitch at the individual, population, and subspecies level into the future throughout its range.

The Clear Lake hitch habitats that are affected include the tributaries and lake habitat. Impacts to both habitat types will affect the Clear Lake hitch by reducing survival and recruitment, which reduces resiliency by decreasing the size of the overall population. For the tributaries, the loss of consistent flow during the spawning season is seen throughout the Clear Lake hitch's range. This influence is affecting the hitch at the individual, population, and subspecies level and is likely to continue into the future. The loss of consistent tributary flow, loss of wetland/tule habitat, and reduced lake water quality, has reduced, and will continue to reduce, population resiliency by reducing reproductive success, early life stage survival, and the

likelihood of recruitment. Loss of resiliency may reduce the Clear Lake hitch's overall representation and redundancy because fewer individuals spawn in each of the tributaries and natal habitat types. The reduction in resiliency may result in a reduction to the hitch's overall representation and redundancy.

There are no existing regulatory mechanisms or management actions that fully ameliorate habitat loss, degradation, and modification within the watershed, primarily because much of the degradation occurred in the past, although the effects are still occurring today and will continue into the future. There are planned activities associated with the Clear Lake watershed, the Middle Creek Flood Damage Reduction and Ecosystem Restoration Project, that will benefit improve water quality, increase available wetland habitat for the Clear Lake hitch and mitigate some of the ongoing habitat loss, degradation, and modification.

Construction of this project would greatly benefit juvenile hitch by providing increased cover from predators and competitors, and increased prey abundance. The county's Clear Lake Shoreline Ordinance has prohibited the destruction of tule on residential properties along the shoreline around Clear Lake and requires full mitigation for any tule habitat that is destroyed. This ordinance benefits the Clear Lake hitch by providing a consistent amount of tule habitat for juveniles. In addition, the county recently began a tule planting initiative that informs the public about the importance of tule habitat and how to plant tule (Lake County 2024a, entire).

Predation

Non-native fish introduced into Clear Lake for recreational or biological control purposes are known to prey upon the Clear Lake hitch and all introduced piscivorous (fish-eating) fish species in Clear Lake are potential predators of Clear Lake hitch. Clear Lake hitch have been found in the stomach contents of nonnative fish species in the Clear Lake watershed including largemouth bass (*Micropterus nigricans*) and channel catfish (*Ictalurus punctatus*; Macedo 1994, p. 5; Moyle et al. 1995, pp. 154-155; Moyle et al. 2014, p. 10). Mississippi silversides (*Menidia audens*) are also known to prey on larval fish, so it is likely some predation of Clear Lake hitch larvae by silversides is occurring in Clear Lake (Bennett and Moyle 1996, pp. 526, 529; Moyle et al. 2014, p. 9-10). The nonnative species predation will

continue to affect the Clear Lake hitch at the individual, population, and subspecies level into the future throughout its range. Nonnative species predation pressure within Clear Lake impacts the hitch by reducing survival and recruitment, which reduces resiliency by decreasing the size of the overall population.

Predation pressure within the tributaries to Clear Lake impacts the hitch by reducing survival, reproduction, and recruitment, which further reduces resiliency by decreasing the size of the spawning population in any given year and by reducing the overall population altogether. This loss of resiliency may reduce the hitch's overall representation and redundancy because it results in fewer individuals spawning in each of the tributaries and natal habitat types.

Competition

Competition from other nonnative aquatic species affects the Clear Lake hitch by reducing the available resources for breeding, feeding, and sheltering. For example, largemouth bass (*Micropterus nigricans*) feed on insects and zooplankton, directly competing with both juvenile and adult hitch for food resources (Moyle and Holzhauser 1978, pp. 577–578, 581). Threadfin shad (*Dorosoma petenense*) and Mississippi silversides also compete with the Clear Lake hitch because they depend on the same aquatic prey base (Anderson et al. 1986, entire; Bairrington 2000, p. 33; CDFW 2014, p. 35). During years when silverside or threadfin shad abundances are especially high, they could reduce or deplete prey resources on which the hitch depends. A comparison of hitch trend data and abundances of silversides and threadfin shad suggests there may be a correlation between their abundances (CDFW 2014, p. 35), but more detailed studies need to be completed. There are currently no regulatory mechanisms that address competition by non-native species.

Mercury Mining Contaminants

Historically, small-scale commercial mining operations along the shores of Clear Lake occurred in 1864 and 1865. Originally, the mining included borax and sulfur (Suchanek et al. 2003, p. 1253). Large-scale commercial sulfur extraction along the eastern shore of Clear Lake began in 1865, when the Sulphur Bank Mercury Mine was established. The sulfur mining operation switched over to mercury mining in 1873, after mercury sulfide deposits were found beneath their sulfur source. Early extraction methods were

not as destructive; however, in 1927, the mine began to implement open-pit mining at a large-scale level and would bulldoze any waste products into the lake (Richerson et al. 2008, p. A259). The company continued to mine sporadically throughout the 1950s until the Sulphur Bank Mercury Mine was officially closed in 1957, although waste continued to contaminate the lake well into the 1990s (Suchanek et al. 2008, p. A153).

The highest concentrations of mercury were found in the Oaks Arm area, near the southeastern area of the lake, which is where the Sulphur Bank Mercury Mine is located; however, elevated mercury levels have also been detected lake-wide (Richerson et al. 2008, p. A271). The use of heavy ground-moving equipment associated with the open-pit mining also likely contributed to the algal blooms seen in the lake; this equipment can excavate and disturb large swaths of sediments, which increase nutrient runoff (Richerson et al. 2008, p. A260).

Mercury and other mining-associated contaminants have entered the lake via erosion of waste piles, purposeful dumping/bulldozing of mine waste, atmospheric deposition, and subsurface drainage (Richerson et al. 2008, p. A275). Since 1992, the Environmental Protection Agency (EPA) has implemented numerous remediation projects to address the continued mercury contamination originating from the Sulphur Bank Mercury Mine. The remediation projects include the removal of waste rock piles that erode and discharge mercury, removal of contaminated soil from residential areas, installation of diversions to prevent contaminated water and sediments from entering Clear Lake, closure of three abandoned geothermal wells, capping of mine waste used to build an old road, and installation of two test sediment covers to contain mercury-contaminated sediment within Clear Lake (Richerson et al. 2008, pp. A265, A275; EPA 2019, entire).

The Sulphur Bank Mercury Mine became an EPA Superfund Site in 1990, due to the elevated mercury levels found in Clear Lake's larger piscivorous fish (Curtis 1977, p. 1; Suchanek et al. 2003, p. 1253; Thompson et al. 2013, p. 19). Elevated levels of mercury in fish can significantly impair reproductive success; however, effects can vary based on a multitude of factors, including species and life stage, and there are no specific studies for the Clear Lake hitch (Crump and Trudeau 2008, pp. 902, 904; CDFW 2014, pp. 32–33). Mercury concentrations found in developed hitch caught in Clear Lake in 2019 and

2020 averaged 0.14 milligrams per kilogram (mg/kg) (Pierce et al. 2022, entire), which exceed the Regional Water Quality Control Board's proposed target of 0.09 mg/kg for fish in trophic level 3, which includes the Clear Lake hitch (CEPA 2008, p. 1). Although these levels may exceed the Regional Water Quality Control Board's target, the best available science does not provide the lethal concentration of mercury specific for Clear Lake hitch or levels that may cause acute or chronic health effects to the Clear Lake hitch, or whether they are currently exposed to those levels in Clear Lake. The threat of mercury mining contaminants impacts the Clear Lake population and has not affected the Thurston Lake population.

Climate Change

Climate change affects the Clear Lake hitch and its habitat due to shifts in normal weather patterns. Changes in temperature and precipitation regimes can affect water quality and quantity for the subspecies and can exacerbate other effects, such as increased drought and fire frequency. Annual average air temperatures in California have increased by 1.5 °F (0.83 °C) since the beginning of the 20th century (Bales 2013, p. 2).

Temperatures are expected to continue to increase in California's North Coast Region, which includes Lake County (Grantham 2018, entire). Drought conditions within the Clear Lake watershed can have detrimental effects on the Clear Lake hitch by reducing the amount of flow within the tributaries over the spawning season, reducing water quality in the lake, and possibly reducing emergent vegetation growth in the lake. In 1946 and 1947, there was almost a complete lack of spawning runs due to the lack of water flow in the tributaries (Murphy 1948b, p. 105). However, the hitch's ability to spawn along the lake shore provides an alternative to tributary spawning for at least a small proportion of the population.

More arid conditions can impact the Clear Lake hitch by reducing the amount of water that enters, and the time period that water is retained within, the tributaries and wetland habitats that the hitch requires for spawning and rearing. Increases in aridity also reduce wetland/emergent vegetation growth, which the hitch requires for rearing and for cover from predators. All of these factors can impact the reproductive success and recruitment of the hitch; these factors could also reduce the hitch's survival if flows drop too drastically in the tributaries and wetland habitats, or if

hitch are subject to increased predation due to a reduction in cover from aquatic vegetation.

A reduction of flow in the tributaries during the spawning season can eliminate or greatly reduce the likelihood for successful reproduction and/or recruitment, and due to the Clear Lake hitch's very narrow range, the effects of drought will impact the entire subspecies. The ability to spawn along the shore provides for some redundancy within each population, but it is unknown whether shore spawning would be able to support a viable population in the lakes over the long term. Having a longer lifespan (4 to 6+ years) is likely an adaptation to variable environmental conditions, but prolonged droughts can have devastating effects on the overall population, especially in conjunction with other factors that are currently acting on the Clear Lake hitch.

There have been numerous efforts over the last 10 years to save Clear Lake hitch that become stranded in pools within the tributaries when the tributaries began to rapidly dry up. In March 2014, 197 individuals were rescued from two pools within Adobe Creek, and the surviving fish were released into Kelsey Creek (Ewing 2014a, entire). A few months later, in June 2014, more than 1,400 hitch were rescued from Cooper Creek and 389 hitch were rescued from Adobe Creek when the flow within those creeks began to rapidly drop. The surviving individuals from both rescues were released into Rodman Slough and at the Konocti Vista Casino boat ramp, respectively (Ewing 2014e, pp. 3, 6). Unfortunately, during visual spawning surveys that same year, approximately 300 adult hitch were found dead in a portion of Adobe Creek that had dried (Ewing 2014c, p. 7).

During the spring of 2018, numerous young of year were stranded in a pool within Cole Creek when the water flow began to rapidly drop. The creek no longer had continuous flow into the lake, and the small pool where the fish were stranded would have eventually dried, killing all of the 3,100+ young fish. Fortunately, members of Robinson Rancheria and CDFW were able to rescue the fish and transport them for release at Clear Lake State Park, which is located where Cole Creek enters the lake (Ewing 2018a, p. 1). In April 2022, 268 individuals were rescued from two pools within Adobe Creek and transported to Konocti Casino Harbor on Clear Lake where they were released (Ewing 2022a, p. 1). On August 8, 2022, 295 hitch were rescued from a pool off of Cooper Creek; the rescued hitch were

translocated to Upper Blue Lake for release (Santana 2022, p. 2). The effects of climate change will continue to affect both Clear Lake hitch populations, Clear Lake and Thurston Lake.

Regulatory mechanisms and management actions that are or could potentially provide some protection from the effects of climate change include the California Global Warming Solutions Act. This Act addresses climate change by reducing greenhouse gas emissions within California. There are no regulatory mechanisms or management actions that fully address the effects of the climate change.

Synergistic Effects

Multiple influencing factors can act on a species or its habitat at the same time, which can result in impacts that are not accounted for when factors are analyzed separately. Factors that appear minor when considered alone may have greater impacts on individuals, populations, or habitat when analyzed in combination with other factors.

The Clear Lake hitch evolved in Lake County, California, which has always had a highly variable climate with natural periodic droughts. However, the degradation and loss of water retention within their spawning streams and the loss of large stretches of suitable spawning habitat due to various instream barriers has likely reduced reproductive success and recruitment. During drought conditions this can reduce or eliminate all tributary-based spawning in a given year. If drought conditions persist over multiple years, stream-based reproduction can also be reduced or eliminated for multiple years. Furthermore, climate change projections show the Clear Lake area will experience more varied precipitation and higher air temperatures during the spring, which could result in even less water flow being retained within the tributary streams during the hitch's spawning season (Pierce *et al.* 2013, pp. 842, 844, 848–850). Although the hitch has the ability to spawn within the lake, it is unknown whether that method of reproduction would be able to sustain a viable population of hitch in Clear Lake.

Additionally, groundwater extraction for agriculture and other uses likely affects the Clear Lake hitch and its habitat, particularly combined with other chronic threats, such as habitat loss, degradation, and modification along with climate change that are synergistically acting on the subspecies. Water extraction in the summer is likely to lower the water level in pool habitat that acts as refugia for the subspecies in disconnected tributaries until those

tributaries become reconnected by spring rains. It is the loss of this pool habitat that affects the Clear Lake hitch resiliency.

The combination of wetland habitat loss and drought can increase predation pressure and competition. Past habitat loss has left only a small proportion of wetland habitat surrounding Clear Lake and drought conditions can reduce the amount of emergent vegetation growth within those remaining wetland habitats. This reduction in emergent vegetative growth reduces the amount of cover the hitch uses to hide from predators, increasing predation pressure. It can also increase competition as more fish concentrate into this limited habitat type.

Conservation Efforts and Regulatory Mechanisms

The Clear Lake hitch is protected through existing regulatory mechanisms and management actions that result in conservation of the subspecies or its habitat or both. Additional actions from Tribes and other interested groups also provide a benefit to the subspecies. Below, we present some of the ongoing efforts that provide conservation benefits to the Clear Lake hitch or its habitat or both from Federal, State, Tribal, and local regulations and management plans.

I. Federal

U.S. Forest Service (USFS)

The Clear Lake hitch has been designated a USFS sensitive species. Species identified as sensitive by the USFS are species in which population viability is a concern, as evidenced by significant current or predicted downward trends in population numbers or density, or significant current or predicted downward trends in habitat capability that would reduce a species' existing distribution, or both. The designation of sensitive species ensures USFS: assists States, including California, in achieving their goals for conservation of endemic species; as part of the process under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), reviews programs and activities, through a biological evaluation, to determine their potential effect on sensitive species; avoids or minimizes impacts to species whose viability has been identified as a concern; if impacts cannot be avoided, analyzes the significance of potential adverse effects on the population or its habitat within the area of concern and on the species as a whole; establishes management objectives in cooperation with the States when projects on

National Forest System lands may have a significant effect on sensitive species population numbers or distributions; and establishes objectives for Federal candidate species, in cooperation with the Service or National Marine Fisheries Service, and the States. Most of the Clear Lake hitch's range is on private land and only the headwaters of a few tributaries to the east of Clear Lake fall within USFS lands.

II. State

California Endangered Species Act (CESA)

On August 6, 2014, the CFGC determined that the Clear Lake hitch warranted listing as a threatened species under the CESA due to the present or threatened modification or destruction of the subspecies' habitat, predation on and competition with the hitch, and the anticipated impacts of climate change (CDFW 2014, pp. 1–2). Section 2067 of the California Fish and Game Code defines a “threatened species” as a native species or subspecies of bird, mammal, fish, amphibian, reptile, or plant that, although not presently threatened with extinction, is likely to become an endangered species in the foreseeable future in the absence of the special protection and management efforts required by the State. As a threatened species under the CESA, the take of Clear Lake hitch individuals is prohibited unless the take is authorized by a State-issued permit.

However, CESA regulations only apply to the take of individuals (*i.e.*, they do not apply to the destruction or modification of habitat). It should be noted that California's definition of take (see section 86 of the California Fish and Game Code) is not the same as the Act's definition of take (16 U.S.C. 1532(19)).

California Environmental Quality Act (CEQA) of 1970

The CEQA does not regulate land use but requires all local and State agencies in California to avoid or minimize environmental damage, where feasible, during the course of proposed projects. The CEQA provides protection for species that are State-listed or federally listed as endangered, threatened, or rare. Compliance with the CEQA may be required for watershed restoration work and any restoration work that requires a “lake or streambed alteration agreement” (also known as a “1600 agreement”; see sections 1600–1616 of the California Game and Fish Code).

Sustainable Groundwater Management Act (SGMA)

The SGMA is a California State law that provides a framework for sustainable groundwater management in California. Under section 10933(b) of the California Water Code, groundwater basins throughout the State have been classified into four categories of prioritization (high, medium, low, very low). Phase 1 of the categorization process was finalized in January 2019, and 458 basins were prioritized during that phase. Fifty-seven basins were categorized under phase 2, which was finalized on December 17, 2019 (DWR 2020, p. AD–3). The SGMA requires water agencies and governments of high- priority and medium-priority basins to reduce overdraft and bring groundwater basins into balance. The State of California ensures the SGMA goals are met as planned.

Several groundwater basins in the Clear Lake watershed were prioritized during the phase 1 prioritization. The Big Valley basin to the southwest of Clear Lake received a medium prioritization, whereas the other eight basins in the watershed (Scotts Valley, Upper Lake Valley, Middle Creek, Long Valley, High Valley, Clear Lake Cache Formation, Burns Valley, and Lower Lake Valley) were given a low priority. The high- priority and medium-priority basins will be managed by a group of local agencies, referred to as “groundwater sustainability agencies,” and they will be tasked with reaching sustainability in their basin within 20 years of implementing their groundwater sustainability plans. Groundwater sustainability agencies have been formed for the Big Valley and Scotts Valley basins, and a groundwater sustainability plan was developed for the Big Valley basin and published in January 2022 (DWR 2019a, entire; DWR 2019b, entire; DWR 2019c, entire; DWR 2022, entire). Reducing overdraft from groundwater pumping in the Big Valley basin could improve flow conditions in Thompson Creek, Adobe Creek, Kelsey Creek, Cole Creek, McGaugh Slough, and Manning Creek and could provide sufficient water quantity for the Clear Lake hitch to traverse the tributaries during their spawning season.

III. Local

Clear Lake Integrated Watershed Management Plan (CLIWMP)

The local resource conservation districts developed CLIWMP to document the historical and current conditions of the Clear Lake watershed and any management actions that have been, or are currently being,

implemented. Actions to enhance and/or protect the watershed are then identified using that background information and timeframes for each action are described. The CLIWMP describes specific implementation actions needed to create an environmentally and economically healthy watershed, both for the benefit of the existing local community and for future generations (County of Lake et al. 2010a, entire). Implementation of the actions described in the CLIWMP would benefit the Clear Lake hitch by increasing the amount of wetland habitat used for rearing, improving fish passage within the tributary streams, and restoring degraded tributary stream and lake habitats. In addition to the CLIWMP, the local conservation districts also developed watershed assessments for Scotts, Middle, and Kelsey creeks. The purpose of those assessments is similar to the CLIWMP; they document the historical and current conditions of those watersheds and any management actions implemented. The assessments will aid in educating watershed users and landowners on the condition of that particular watershed, the management and restoration actions that need to be implemented to improve conditions, and how the conditions of those particular watersheds impact the condition of Clear Lake (County of Lake et al. 2010b, entire; County of Lake et al. 2010c, entire; County of Lake et al. 2010d, entire). Aggregate Resources Management Plan

Lake County developed an Aggregate Resources Management Plan (County of Lake 1992, entire) to address concerns about the impacts of gravel mining on the watershed. The plan describes the policies regarding mining in specific areas, identifies areas deemed as suitable for future mining projects, and informs the public about mining in Lake County. The plan calls for a moratorium on mining in certain creeks and limits mining activities to certain areas (County of Lake 1992, pp. 83–86). The regulation of gravel mining in the county has reduced the rate of erosion in the tributaries and increased the amount of riparian habitat along the stream channels, where the Clear Lake hitch occurs. Although instream sources of gravel are no longer the primary source of aggregate in Lake County because gravel is now acquired from other sources, illegal gravel mining or extraction has been known to occur in the watershed (CEPA 2008, pp. 8, 89; B. Ewing *in litt.* 2020).

Middle Creek Flood Damage Reduction and Ecosystem Restoration Project

The Middle Creek Flood Damage Reduction and Ecosystem Restoration Project (Middle Creek Project) is both a flood risk reduction project for urban and agricultural areas along the northern end of Clear Lake and an ecosystem restoration project that will improve degraded wetland habitat and water quality in Clear Lake. The Middle Creek Project area was once approximately 1,400 ac (567 ha) of wetland habitat that was lost in the early 1900s through the construction of levees and conversion to agricultural use.

Because these levees are no longer functional and there is an urgent need to restore surrounding wetland habitats to improve the lake and the watershed, Lake County requested USACE assistance to evaluate the project in 1995. The Middle Creek Project consists of acquiring reclaimed land, breaching existing levees to flood historical wetland and floodplain areas, and reconnecting Scotts and Middle creeks. Final NEPA and CEQA review was completed in 2003 and 2004, respectively, and the Middle Creek Project was authorized under the Water Resources Development Act of 2007 (33 U.S.C. 2201 *et seq.*). Federal funding for the Middle Creek Project has not yet been appropriated to start project design; however, funding for land acquisition has been acquired (USACE 2012, pp. 1–2; USACE 2023, entire).

The Middle Creek Project will benefit the Clear Lake watershed by reducing the amount of sediment and nutrients entering Clear Lake, improving overall water quality. It will also increase the existing amount of wetland habitat within the Clear Lake watershed by approximately 79 percent (USACE 2012, p. 3). If the Middle Creek Project were to be implemented, it would benefit adult hitch by improving the water quality of Clear Lake, which would likely reduce the incidence of large fish kills. The Middle Creek Project would also greatly benefit juvenile hitch by increasing the amount of wetland habitat surrounding the lake, providing increased cover from predators and competitors, and increased prey abundance.

Clear Lake Shoreline Ordinance

The destruction of woody species and tule on residential properties along the shoreline around Clear Lake is prohibited under section 23–15 of the Clear Lake Shoreline Ordinance. These types of vegetation can be managed via mowing, pruning, or trimming, but

those activities cannot result in the death of the plant. In addition, the ordinance applies a no-net-loss program for commercial, resort, or public properties that require mitigation for any areas of vegetation cleared by providing replacement plantings (County of Lake et al. 2010a, pp. ES–16, 3–10; CDFW 2014, p. 42). The measures associated with this ordinance benefit the Clear Lake hitch by providing a consistent amount of tule habitat for juveniles.

Clear Lake Hitch Conservation Strategy

A group including local Tribes, local government, State agencies, and Federal agencies have been working on the development of a conservation strategy for the Clear Lake hitch. The strategy, which is still in draft form, documents the past and current status of the subspecies, describes the negative influences that have resulted in the subspecies' current status, and identifies the actions that will address those negative influences in order to maintain a viable population of Clear Lake hitch throughout the subspecies' range. This conservation strategy will provide benefits to the subspecies through public outreach regarding Clear Lake hitch conservation; it will also direct funds to implement actions or projects that will specifically benefit the hitch.

Clear Lake Hitch Task Force

In August 2022, Tribal leaders and members of the Tribal Environmental Protection Agencies representing the Big Valley Rancheria of Pomo Indians, Elem Indian Colony Pomo Tribe, Robinson Rancheria Band of Pomo Indians, and the Habematolel Pomo of Upper Lake went before the CFGC to express their concern for the status of the Clear Lake hitch. To address these concerns and focus attention on the subspecies, the Clear Lake Hitch Task Force (Task Force) was formed. The Task Force had its first meeting on September 14, 2022, and consisted of Tribal and CDFW representatives.

Since 2022, the Task Force has expanded to include the California Department of Water Resources, State Water Resources Control Board, Central Valley Regional Water Board, Lake County Water Resources Department, Fish and Game Commission, California Natural Resources Agency, Service, USGS, California Conservation Corps, Bureau of Land Management (BLM), USACE, and USFS. The Task Force's mission involves collaborative planning for long-term responses to the decline in the Clear Lake hitch population, coordinating projects, identifying funding sources, and facilitating

information exchange among agencies. The Task Force meets monthly and has held three summits to help relay information and coordinate projects between different agencies.

IV. Miscellaneous

Lake County, the California Department of Transportation, USFS, State Water Resources Control Board, and BLM have undertaken various actions to prevent or reduce nutrients and contaminants from entering Clear Lake, or to track the amount of water being used throughout the watershed (West Lake Resource Conservation District, undated, entire; CDFW 2014, p. 41). These actions include the Eightmile Valley Sediment Reduction and Habitat Enhancement Project, for which BLM and the Scotts Valley Band of Pomo Indians received a grant (CDFW 2014, p. 41). CDFW has two conceptual area protection plans (CAPPs) that cover different areas of the Clear Lake watershed. A CAPP allows different organizations and agencies to apply for land acquisition funding through the Wildlife Conservation Board. Both plans focus on the protection of wetland and riparian habitats, which would benefit the Clear Lake hitch during its early life stages (CDFW 2014, p. 42). Lastly, the State Water Resources Control Board issued draft emergency information order regulations for the Clear Lake watershed in September 2023. These regulations were adopted by the Water Resources Control Board on December 6, 2023. These regulations allow the Water Resources Control Board to gather information on water usage, particularly groundwater pumping, in the Clear Lake watershed and learn how, if at all, it influences surface tributary flow (State Water Resource Control Board 2023, entire).

Lastly, the CDFW has begun to address some of the fish passage barriers in the Clear Lake hitch's spawning tributaries by installing fish ladders. The reconstruction of one project included installation of holding pools for the fish to rest as they move upstream and breaks in the ladder to help slow the rate of water flow (Ewing 2017c, entire).

Cumulative Effects

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have analyzed the cumulative effects of identified threats and conservation actions on the subspecies. To assess the current and future condition of the subspecies, we evaluate the effects of all the relevant factors that may be influencing the

subspecies, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire subspecies, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

Current Condition

In order to evaluate the current condition of the Clear Lake hitch, we describe the resiliency of each population along with the redundancy and representation of the subspecies. We considered demographic factors and habitat elements to evaluate the population-level resiliency. We divided the population in Clear Lake to ensure a more focused analysis regarding how different areas of the lake contribute to the subspecies' survival.

We established that there are two separate populations of Clear Lake hitch within the Clear Lake watershed: one is found in Clear Lake and its associated tributaries and small lakes (*i.e.*, Blue Lakes and Tule Lake), and the other is in Thurston Lake and its associated tributary. Because Thurston Lake is not currently hydrologically connected to Clear Lake and possibly never was, we do not anticipate it to be connected in the future. The Clear Lake and Thurston Lake populations were further delineated into units to capture the aquatic habitat features at a local, sub-watershed level. We then grouped some of the smaller delineated units into five "analysis units" using otolith (calcium carbonate structure found in the inner ear of the Clear Lake hitch) strontium signatures that indicated natal origins can be assigned to one of five strontium isotope groups (SIGs) throughout the watershed (Feyrer *et al.* 2019a, entire). The use of adult otoliths for the natal habitat strontium groupings indicates that those areas associated with the SIGs are contributing to reproduction and recruitment. The terms "analysis unit" and "SIG" may be used interchangeably for this analysis.

We delineated six analysis units across the subspecies' range. Thurston Lake and Thurston Creek are described as a single analysis unit. The Clear Lake population includes five analysis units described according to the general location: Cole Creek; Kelsey Creek; Adobe Creek and Clear Lake; Rodman Slough; and Middle, Clover, and Siegler Canyon creeks (SIGs 1 through 5, respectively; Service 2024, p. 34). Additional description of the populations and analysis units can be found in the SSA report (Service 2024, pp. 26–28); see table 2, below, for a list of the AUs.

In order to determine resiliency, we assessed the conditions at the population and analysis unit levels. We used demographic and habitat factors associated with each population. The demographic factors include reproduction, recruitment, and survival at both the adult and juvenile life stages. The habitat factors we used include water quantity (tributaries) and quality (lake) and wetland/tule habitat condition.

Influencing those factors is the quality and accessibility of Clear Lake hitch habitat, which determines how well the spawning areas allow for successful reproduction, whether the nearshore nursery areas allow for young-of-year survival and subsequent recruitment, and whether individuals can move between tributary spawning habitats and the lake. Within the tributaries, water quantity and quality are important factors influencing survival at all life stages, reproductive success, and recruitment, and water quantity and quality are important for connectivity between the tributaries and lakes. Environmental stochastic events that have the potential to affect the subspecies include severe storms, drought, contaminant exposure, and the modification of habitat via natural (*i.e.*, fire, drought, etc.) and anthropogenic (*i.e.*, conversion to agriculture, vegetation management) means. Additional information regarding the

resiliency factors can be found in the SSA report (Service 2024, pp. 28–34).

We describe the population and analysis unit resiliency conditions using categories of high, medium, and low (with transitional stages). The methodology for determining the condition category includes assessment of the demographic and habitat factors within each analysis unit and within each population (Service 2024, p. 79). An overall high condition for a population is an indicator of high probability of population persistence. Populations in high condition have: accessible tributaries available throughout the spawning season, different natal habitats available for reproduction, individuals that are reproducing successfully and populations that are actively recruiting, and a sufficient amount and quality of spawning and rearing habitat to allow for varying population densities. An overall moderate condition is an indicator that probability of persistence for that population may be compromised by the lack and/or degradation of one or more of the subspecies' needs, and a low overall condition indicates low probability of population persistence due to the lack and/or degradation of multiple of the subspecies' needs. An extirpated condition indicates no probability of population persistence due to lack and/or degradation of all of the subspecies' needs. Conditions of low/extirpated, moderate/low, and high/moderate are transitional between each of the qualitative categories.

In order to determine the current population estimates and distribution, we used recent data (2015–2023) from surveys conducted on spawning in the tributaries, along the lake shore, and throughout Clear Lake. That data also informed the resiliency analysis for each population and analysis unit. The demographic and habitat parameters used in the resiliency analysis for each population and analysis unit is provided in table 1, below (Service 2024, p. 67).

TABLE 1—DEMOGRAPHIC AND HABITAT FACTORS CONDITION CATEGORIES FOR POPULATION AND ANALYSIS UNIT RESILIENCY WITH HIGH CONDITION AS THE BEST CONDITION AND ZERO AS THE LOWEST CONDITION

Condition category	Demographic factor—reproduction	Demographic factor—recruitment	Habitat element—tributary water quantity	Habitat element—lake water quality
High	Overall total from reproduction analysis is high.	Overall total from recruitment analysis is high.	Water is retained within the tributaries throughout the spawning season.	Lake water is well oxygenated and minimally contaminated.

TABLE 1—DEMOGRAPHIC AND HABITAT FACTORS CONDITION CATEGORIES FOR POPULATION AND ANALYSIS UNIT RESILIENCY WITH HIGH CONDITION AS THE BEST CONDITION AND ZERO AS THE LOWEST CONDITION—Continued

Condition category	Demographic factor—reproduction	Demographic factor—recruitment	Habitat element—tributary water quantity	Habitat element—lake water quality
Moderate	Overall total from reproduction analysis is moderate.	Overall total from recruitment analysis is moderate.	Water is retained within the tributaries throughout a large portion of the spawning season.	Lake water is oxygenated most of the time, hypoxic conditions do occur periodically. Some contaminants are present, but not at lethal levels.
Low	Overall total from reproduction analysis is low.	Overall total from recruitment analysis is low.	Water is retained within the tributaries throughout a small portion of the spawning season.	Lake water is not well oxygenated and hypoxic conditions occur frequently. Contaminants are present, sometimes at lethal levels.
0 (Zero)	No reproduction	No recruitment	Water is not retained within the tributaries during any portion of the spawning season.	Lake water quality is uninhabitable.

Of the six Clear Lake hitch analysis units, for reproduction, there are currently three analysis units that are in moderate condition (SIGs 1, 2, and 4), and two analysis units that are in low condition (SIGs 3 and 5). The current recruitment condition for SIG 3 is high, moderate for SIGs 2 and 4, and low for

SIGs 1 and 5. The current condition of lake water quality is at a low condition for all five analysis units, and the current condition for tributary water quantity is low for SIGs 1, 2, and 3, and moderate for SIGs 4 and 5. Currently, the Clear Lake population has three analysis units at a moderate condition

(SIGs 2, 3, and 4), and two units at a low condition (SIGs 1 and 5), for an overall Clear Lake population resiliency of moderate (Service 2024, p. 83). The Thurston Lake population is currently in high condition and, therefore, has high resiliency. See table 2, below.

TABLE 2—SUMMARY TABLE OF CURRENT AND FUTURE RESILIENCY FOR EACH POPULATION (P) AND ANALYSIS UNIT (AU)

Population	Analysis unit	Current condition	Future condition scenario 1	Future condition scenario 2
Clear Lake		Moderate	Moderate/Low	Low.
	Cole Creek (SIG 1)	Low	Low	Low.
	Kelsey Creek (SIG 2)	Moderate	Moderate/Low	Low.
	Clear Lake, Adobe Creek (SIG 3).	Moderate	Moderate/Low	Low.
	Rodman Slough (SIG 4) ...	Moderate	Moderate	Moderate/Low.
Thurston Lake	Middle Creek, Clover Creek, Seigler Canyon Creek (SIG 5).	Low	Low	Low.
	Thurston Lake	High	Moderate	Moderate.

In describing the overall current condition, we not only include resiliency of each population and analysis unit, but also consider the representation and redundancy across the range of the subspecies. Because both populations of the Clear Lake hitch are narrowly distributed and occupy the same ecological niche, the subspecies has likely never had much environmental diversity and likely does not have much genetic diversity due to its endemism to a single watershed, suggesting inherently limited representation. Given the subspecies' narrow range, both populations of the subspecies (Clear Lake and Thurston Lake) could be affected simultaneously by large-scale events. However, the

Clear Lake hitch uses different types of spawning habitats (tributary, lake, or interface between the two) across its narrow range, which may provide some current capacity to withstand a catastrophic drought event.

Because of the historical connectivity within a single, large watershed, Clear Lake provided better habitat conditions for the subspecies. Currently, Thurston Lake does not have the level of threats acting on the subspecies that are affecting the hitch in Clear Lake. Surveys in 2023 of the Clear Lake population show there is an influx of age classes, thus indicating there is reproduction occurring. This diverse demographic make- up of the subspecies' population in Clear Lake

indicates that there is redundancy across subspecies' range and bolsters the subspecies' resiliency. Currently, the Clear Lake hitch has two extant populations: the Clear Lake population, which has a moderate resiliency; and the Thurston Lake population, which has a high resiliency. Both of these populations are able to withstand stochastic environmental variation. Representation and redundancy are similar to historical conditions, with both populations narrowly distributed and occupying the same ecological niche.

The current resiliency analysis uses the best available information; however, we recognize there are some uncertainties around the subspecies' life

history, including recruitment, and the factors that influence its viability. Some of the uncertainties include the lack of robust, statistically valid population or abundance estimates for the historical population of the Clear Lake hitch. Further, current population estimates are still in initial stages, as local Tribes, CDFW, and USGS are accruing more data to provide a more accurate rangewide population estimate. Because this information is not available, there is no baseline to compare for our current condition analysis; therefore, we had to use available demographic and habitat data to inform our analysis, which could result in an overestimation or underestimation of population resiliency.

There is some uncertainty in how successful recruitment is in the lower Clear Lake watershed, including within Clear Lake itself. Our analysis in the SSA report assumes reproduction is successful when adults are documented in the tributaries over the spawning season and that some lake spawning is successful (Service 2024, p. 70). It is possible these assumptions are overestimating how successful reproduction is, resulting in an overestimation of population resiliency.

Future Condition

In order to determine the Clear Lake hitch's viability in the future, we assessed the condition of the subspecies' resiliency, redundancy, and representation within a timeframe that we can make reliable predictions about the threats and the subspecies' response to the threats. The future conditions projections were timeframe we applied for the future conditions' analyses found that the most reliable timeframe extends out to the next 40 to 50 years. We considered two plausible future scenarios that represent the extremes of a range of future changes in environmental conditions and success of implemented conservation efforts. Using these two scenarios allows us to consider the full range of future possibilities for forecasting future viability of the subspecies and incorporates any uncertainty regarding the impact of future environmental conditions and the success of implemented conservation efforts.

The future scenarios project the influences on viability into the future and consider how those influences would potentially impact the Clear Lake hitch's viability. As under Current Condition, we assessed the subspecies' resiliency, redundancy, and representation under each future scenario. For resiliency, we projected the impact to the subspecies'

reproduction, recruitment, water quantity (tributary), and water quality (lake) at the population level and the analysis unit level.

The following six factors affecting the Clear Lake hitch were included in both of the two plausible future scenarios:

1. The loss of spawning habitat due to past watershed modifications that have blocked access to or altered the flow regime of tributaries. The lack of consistent tributary flow will continue due to the effects of past instream gravel mining, deforestation, and grazing practices; existing flood control project infrastructure; fire activity; and water utilization for agricultural and urban uses. Because the rate of urban development has slowed in the last decade, we do not anticipate a significant amount of urban growth into the future. The timeframe for the current Lake County General Plan is 20 years and only projects growth out to 2028; however, we still do not expect growth to increase much after 2028. Although the amount of agricultural development increased substantially leading up to the 21st century, over the last 10 years or so the acreage of fruit, nut, field, seed, and vegetable crops in Lake County only slightly increased.

Therefore, we do not anticipate a substantial increase in the amount of agricultural production into the future (Service 2024, pp. 29, 34). Furthermore, future climate change is projected to further exacerbate the degradation and inaccessibility of tributaries by increasing the incidence of fire activity, flood events, and aridity. Various passage barriers, both physical barriers and lack of flow, will continue to persist in the watershed. And there are no there are no groundwater sustainability plans for low priority basins.

2. The loss of wetland/tule habitat. The current remaining wetland/tule habitat surrounding the lake will persist into the future, primarily due to the implementation of Lake County's Clear Lake Shoreline Ordinance.

3. Continued reductions in lake water quality due to the past loss of wetland/tule habitat surrounding the lake, contamination from past mercury mining along the lake's shore and from pesticide use for agricultural and urban uses, the input of sediment and nutrients from degraded tributaries, and nutrient inputs from surrounding urban and agricultural development. As mentioned above, we do not project agricultural production or urban development to increase substantially into the future. Elevated nutrient and sediment inputs continue to contribute to periodic cyanobacteria blooms,

further reducing water quality. Periodic fish kills continue to occur.

4. Nonnative fish species from past introductions are still established within the lakes.

5. Drought incidence and intensity increase due to climate change, reducing tributary flow during the spawning season in some years.

6. The continued implementation of current regulatory mechanisms (*e.g.*, CESA, Lake County's Clear Lake Shoreline Ordinance) and management actions (*e.g.*, Lake County's Aggregate Resources Management Plan, other miscellaneous restoration actions occurring throughout the watershed).

Scenario 1 assesses the viability of the subspecies if the trend and magnitude of threats were to continue at the current trajectory into the future with implemented management efforts being fully successful. Scenario 2 assesses the subspecies' future viability with an increase in the trend and magnitude of threats with implemented management efforts having mixed success. Additional details regarding the scenarios are described in the SSA report (Service 2024, pp. 89–91).

Under Scenario 1, many of the factors that are having an influence on each of the Clear Lake hitch populations continue at current rates, or slightly increase. The effects of climate change, specifically increased aridity, are already occurring throughout the watershed, although the effects of increased aridity are not apparent every year. Future drought conditions are projected to increase in both the number of years drought conditions persist and the intensity of drought. Due to the increased incidence of aridity, and because future climate projections show the timing of precipitation will change, in some years, the number of spawning tributaries available to the Clear Lake hitch over the spawning season will decrease. A slight increase in fire and flooding incidence will increase the amount of erosion occurring in the tributaries, further decreasing lake water quality. As conditions worsen in the tributaries, the hitch will have to increasingly rely on spawning in the lake or in the mouths of streams. Because the Clear Lake hitch is a State-listed species, direct take will continue to be prohibited without a permit. Due to Lake County's Clear Lake Shoreline Ordinance, the amount of existing wetland/tule habitats surrounding the lake will continue to persist. Under Scenario 1, the SGMA has been implemented, and general restoration projects, such as contaminant remediation, tributary function, and barrier removal, continue to be

implemented at a small scale throughout the watershed.

Under Scenario 1, both populations decline in resiliency; the Thurston Lake population is in moderate condition, and the Clear Lake population is in moderate/low condition. Each Clear Lake analysis unit is either unchanged from current condition, or declines. The resiliency for SIGs 1 and 5 remains in low condition. SIG 4 remains in moderate condition, and SIGs 2 and 3 decline from moderate to moderate/low condition. For representation, because both populations of Clear Lake hitch are narrowly distributed and occupy the same ecological niche, environmental and genetic diversity are not expected to change dramatically under Scenario 1. Therefore, representation for the Clear Lake hitch under current conditions is maintained under Scenario 1.

For redundancy, given the narrow range, both populations of the subspecies could be affected simultaneously by large-scale events. However, the Clear Lake hitch uses different types of spawning habitats (tributary, lake, or interface between the two) across its narrow range, which may increase the ability of the subspecies to withstand a catastrophic drought event, which is not expected to change dramatically under Scenario 1. Therefore, redundancy for the Clear Lake hitch under current conditions is maintained under Scenario 1.

Under Scenario 2, some of the factors that are having an influence on each of the Clear Lake hitch populations continue at current rates, while others will increase (Service 2024, pp. 92–94). In this scenario, climate change results in more arid conditions throughout the subspecies' range and impacts from increased fire and flooding increase erosion occurring in the tributaries, further decreasing water quality within the lake. As conditions worsen in the tributaries, the Clear Lake hitch will have to increasingly rely on spawning in the lake or in the mouths of streams. In addition, under this scenario, agricultural production slightly increases in areas currently not prioritized by the SGMA, small-scale restoration projects have been implemented but not all are successful, the Middle Creek Project has not been implemented, and few passage barriers have been removed. Under Scenario 2, Lake County's Clear Lake Shoreline Ordinance will continue to limit tule habitat loss, and the CESA will continue to limit the take of Clear Lake hitch individuals.

The overall resiliency of each population will decline under Scenario 2. The projections result in a moderate

condition for the Thurston Lake population and low condition for the Clear Lake population. Within Clear Lake, each SIG declines to or maintains a low condition except for Rodman Slough, which has a moderate/low condition.

Under Scenario 2, due to declines in abundance and recruitment predicted under this future scenario, we anticipate representation will be somewhat reduced from current conditions, and, therefore, the subspecies will be less able to adapt to changing environmental conditions. We also anticipate that redundancy will be somewhat reduced from current conditions due to predicted declines in abundance and recruitment, and, therefore, the subspecies will be more susceptible to a catastrophic event.

We also present uncertainties associated with the future conditions analyses for the Clear Lake hitch. As described above under *Current Condition*, there is uncertainty regarding some of the subspecies' life-history traits, including recruitment, and some of the factors influencing the subspecies' viability that were used in the future condition scenarios. Although there is a current population estimate for the subspecies, this estimate is in its initial stages and additional years of monitoring data are needed to provide a more accurate estimate. Because we do not have an accurate current number to compare to, and therefore cannot project changes in the size of either population, we must qualitatively describe how future influences will impact Clear Lake hitch populations. There is uncertainty in how successful recruitment is in the lower Clear Lake watershed, including within Clear Lake itself. Our analysis assumes reproduction is successful when adults are documented in the tributaries over the spawning season and that some lake spawning is successful. It is possible these assumptions are overestimating how successful reproduction is, resulting in an overestimation of population resiliency.

Lastly, there is uncertainty around the degree of impact from water extraction for agricultural use on the Clear Lake hitch and its habitat. Groundwater pumping can deplete surface water in streams and reduce flow and available water (USGS 2013, entire). Water extractions may be one of the reasons for the reduction in the Clear Lake hitch's population; however, the Clear Lake watershed is complex, and we do not fully understand how surface and ground water interact in most of the watershed because studies have not been completed. We also do not have a

full understanding of where water extractions are occurring or how much water is being extracted; however, there are ongoing studies to better understand the magnitude of impacts on the Clear Lake watershed (Santana 2024, pers. comm.). Although we do not fully understand if or how groundwater extraction is having an impact on the Clear Lake hitch, we do know that water extraction in the summer lowers the water level in pool habitat that acts as refugia for native fish in the disconnected streams until they become reconnected by spring rains. It is the loss of this pool habitat that affects the Clear Lake hitch. However, because groundwater extraction is likely affecting water availability for the subspecies, for our analysis, it is a logical assumption that groundwater pumping for agricultural production is likely having a negative impact on the subspecies. We also assumed the highest rates of pumping are occurring where the most agricultural production occurs. Therefore, it is possible we are overestimating the impact from this threat, resulting in an underestimate of current population resiliency.

Additional uncertainty is presented regarding future impacts to the subspecies and its habitat from climate change, the future trajectory of current negative influences to the subspecies (*i.e.*, agricultural production and urban development), the long-term success of current conservation actions, and the implementation and success of future conservation actions. Our overall future condition analysis assumes climate change will exacerbate the current negative influences (*e.g.*, drought) acting on the subspecies; both future scenarios capture the full risk of this influence within the 40-to-50-year timeline. For agricultural production and urban development, we assume future trends will be similar to trends over the last decade, which only showed slight increases. It is possible we underestimated the future trajectory of these influences, which would result in an overestimation of future population resiliency. The number of conservation actions being implemented in the watershed has increased over the past few years; however, we are uncertain about their success over the long term and whether the current trend in implementation will continue into the future. Since the two future condition scenarios consider the breadth of future implementation and success of conservation activities for the Clear Lake hitch, the overall future condition analysis captures the full benefits of this influence on the subspecies.

Determination of the Clear Lake Hitch's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an “endangered species” as a species in danger of extinction throughout all or a significant portion of its range, and a “threatened species” as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

After evaluating the threats to the Clear Lake hitch and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we have determined that the overall viability of the Clear Lake hitch has declined from historical levels due to the past and ongoing threats of habitat loss, degradation, and modifications (Factor A), predation (Factor C), competition (Factor E), and the effects of climate change (Factor E).

Currently, the subspecies has two extant populations: the Clear Lake population, which has a moderate resiliency, and the Thurston Lake population, which has a high resiliency. Both populations are able to withstand stochastic environmental variation. Representation and redundancy are similar to historical conditions, with both populations narrowly distributed and occupying the same ecological niche. Because of the historical connectivity within a single, large watershed, Clear Lake provided better habitat conditions for the subspecies. Currently, Thurston Lake does not have the level of threats acting on the subspecies that are affecting the hitch in Clear Lake. Surveys in 2023 of the Clear Lake population show there is an influx of age classes, thus indicating there is reproduction occurring. The diverse demographic makeup of the subspecies' population in Clear Lake provides support that there is redundancy across

the Clear Lake hitch's range and bolsters the subspecies' resiliency. Therefore, the Clear Lake hitch is not currently at risk of extinction throughout its range and does not meet the Act's definition of an endangered species.

However, under both future scenarios we see declines in population resiliency in the foreseeable future as a result of factors that will continue to affect the subspecies. Our analysis of the past, current, and future factors influencing viability revealed there are six primary factors affecting the viability of the Clear Lake hitch. These risks to viability are primarily related to habitat changes but also includes others with more direct effect to the subspecies:

1. The loss of spawning habitat due to past watershed modifications that have blocked access to or altered the flow regime of tributary streams.

2. The loss of wetland/tule habitat. The current remaining wetland/tule habitat surrounding the lake will persist into the future, primarily due to the implementation of Lake County's Clear Lake Shoreline Ordinance.

3. Continued reductions in lake water quality due to the past loss of wetland/tule habitat surrounding the lake, contamination from past mercury mining along the lake's shore and from pesticide use for agricultural and urban uses, the input of sediment and nutrients from degraded tributaries, and nutrient inputs from surrounding urban and agricultural development. As mentioned above, we do not project agricultural production or urban development to increase substantially into the future. Elevated nutrient and sediment inputs continue to contribute to periodic cyanobacteria blooms, further reducing water quality. Periodic fish kills continue to occur.

4. Nonnative fish species from past introductions are still established within Clear Lake.

5. Drought incidence and intensity increase due to climate change, reducing tributary flow during the spawning season in some years (Hayhoe *et al.* 2004, pp. 12424–12425, Pierce *et al.* 2013, pp. 848–850).

6. The continued implementation of current regulatory mechanisms (*e.g.*, CESA, Lake County's Clear Lake Shoreline Ordinance), management actions (*e.g.*, Lake County's Aggregate Resources Management Plan, and other miscellaneous restoration actions occurring throughout the watershed) that limits the amount of gravel extract.

Under both future scenarios, Thurston Lake declines to a moderate resiliency and Clear Lake declines to a moderate/low or low resiliency, suggesting the subspecies will be less likely to

withstand stochastic environmental variation in the future. Under future Scenario 1, redundancy and representation are mostly maintained but begin to be impacted by the declines in population resiliency. Under future Scenario 2, both redundancy and representation are reduced due to the limited availability of some spawning habitats and the subspecies being less able to adapt to changing environmental conditions. Because of this future reduction in resiliency, redundancy, and representation, the subspecies is likely to become endangered within the foreseeable future throughout its range and meets the Act's definition of a threatened species. Thus, after assessing the best scientific and commercial data available, we conclude that the Clear Lake hitch is not in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity v. Everson*, 435 F. Supp. 3d 69 (D.D.C. 2020) (*Everson*), vacated the provision of the Final Policy on Interpretation of the Phrase “Significant Portion of Its Range” in the Endangered Species Act's Definitions of “Endangered Species” and “Threatened Species” (hereafter “Final Policy”; 79 FR 37578, July 1, 2014) that provided if the Services determine that a species is threatened throughout all of its range, the Services will not analyze whether the species is endangered in a significant portion of its range.

Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the “significance” question or the “status” question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Everson*, we now consider whether the Clear Lake hitch is in danger of extinction in a significant portion of its

range. In undertaking this analysis for the Clear Lake hitch, we chose to address the significance question first. We identified Clear Lake and its tributaries as a significant portion of the subspecies' range; this portion is biologically meaningful to the subspecies due to its large geographical size (*i.e.*, it encompasses the greatest proportion of the subspecies' entire range and near 95 percent of the available lake habitat). Additionally, Clear Lake and its tributaries support the majority of the subspecies' entire population. We include the tributaries in this portion because the Clear Lake hitch uses them for spawning, and they are important for the reproduction aspect of the subspecies' lifecycle.

After determining the portion's significance, we evaluated the Clear Lake hitch's status within that portion. Since we found the subspecies meets the Act's definition of threatened across its entire range, we considered the status of the portion to determine if the subspecies within Clear Lake and its tributaries meets the Act's definition of an endangered species. The current resiliency of this population is scored as moderate (see table 2, above). Seasonal surveys conducted in Clear Lake from 2017 to 2023 indicate fluctuations in the populations; the 2023 surveys yielded the highest number (304) of individual hitch captured. The increase could possibly be due to more water available from a rainy year. The 2023 surveys also show there is an influx of age classes, thus indicating there is reproduction occurring across a range of years and climatic conditions. This diverse demographic makeup of the subspecies' population in Clear Lake provides support that there is currently redundancy within the portion and bolsters the subspecies' resiliency. Representation and redundancy in this portion are similar to historical conditions, with the population narrowly distributed and occupying the same ecological niche. The current resiliency is moderate for this portion, and this portion retains sufficient resiliency such that it will be able to withstand stochastic environmental variation in the near term. Therefore, the subspecies is not in danger of extinction within this portion of its range.

Therefore, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This does not conflict with the courts' holdings in

Desert Survivors v. U.S. Department of the Interior, 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018) and *Center for Biological Diversity v. Jewell*, 248 F. Supp. 3d 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy, including the definition of “significant” that those court decisions held to be invalid.

Determination of Status

Based on the best scientific and commercial data available, we determine that the Clear Lake hitch meets the Act's definition of a threatened species throughout its range. Therefore, we propose to list the Clear Lake hitch as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition as a listed species, planning and implementation of recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, foreign governments, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies, including the Service, and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

The recovery planning process begins with development of a recovery outline made available to the public soon after a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions while a recovery plan is being developed. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental

organizations, and stakeholders) may be established to develop and implement recovery plans. The recovery planning process involves the identification of actions that are necessary to halt and reverse the species' decline by addressing the threats to its survival and recovery. The recovery plan identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (“downlisting”) or removal from protected status (“delisting”), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery outline, draft recovery plan, final recovery plan, and any revisions will be available on our website as they are completed (<https://www.fws.gov/program/endangered-species>), or from our Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.*, restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If the Clear Lake hitch is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of California would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Clear Lake hitch. Information on our grant programs that are available to aid species recovery can be found at: <https://www.fws.gov/service/financial-assistance>.

Although the Clear Lake hitch is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery

efforts for this subspecies. Additionally, we invite you to submit any new information on this subspecies whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7 of the Act is titled, “Interagency Cooperation,” and it mandates all Federal action agencies to use their existing authorities to further the conservation purposes of the Act and to ensure that their actions are not likely to jeopardize the continued existence of listed species or adversely modify critical habitat. Regulations implementing section 7 are codified at 50 CFR part 402.

Section 7(a)(2) states that each Federal action agency shall, in consultation with the Secretary, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Each Federal agency shall review its action at the earliest possible time to determine whether it may affect listed species or critical habitat. If a determination is made that the action may affect listed species or critical habitat, formal consultation is required (50 CFR 402.14(a)), unless the Service concurs in writing that the action is not likely to adversely affect listed species or critical habitat. At the end of a formal consultation, the Service issues a biological opinion, containing its determination of whether the Federal action is likely to result in jeopardy or adverse modification.

In contrast, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. Although the conference procedures are required only when an action is likely to result in jeopardy or adverse modification, action agencies may voluntarily confer with the Service on actions that may affect species proposed for listing or critical habitat proposed to be designated. In the event that the subject species is listed or the relevant critical habitat is designated, a conference opinion may be adopted as a biological opinion and serve as compliance with section 7(a)(2) of the Act.

Examples of discretionary actions for the Clear Lake hitch that may be subject to conference and consultation procedures under section 7 of the Act are management of Federal lands

administered by BLM and USFS, as well as actions that require a Federal permit (such as a permit from USACE under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or actions funded by Federal agencies such as the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency. Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation. Federal agencies should coordinate with the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**) with any specific questions on section 7 consultation and conference requirements.

Section 9 of the Act provides a specific list of prohibitions for endangered species but does not provide these same prohibitions for threatened species. Instead, pursuant to section 4(d) of the Act, for any species listed as a threatened species, the Secretary must issue protective regulations that are “necessary and advisable to provide for the conservation of such species” (these are referred to as “4(d) rules”). Additional measures for the Clear Lake hitch are described below (see Protective Regulations Under Section 4(d) of the Act, below).

We may issue permits to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits for threatened wildlife are codified at 50 CFR 17.32, and general Service permitting regulations are codified at 50 CFR part 13. With regard to threatened wildlife, a permit may be issued: for scientific purposes, for enhancing the propagation or survival of the species, or for take incidental to otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

II. Protective Regulations Under Section 4(d) of the Act

Background

As discussed in Available Conservation Measures, section 9 of the Act provides a specific list of prohibitions for endangered species but does not provide these same prohibitions for threatened species. Instead, pursuant to section 4(d) of the Act, for any species listed as a threatened species, the Secretary must issue protective regulations that are

“necessary and advisable to provide for the conservation of such species” (these are referred to as “4(d) rules”). Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened species.

Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. With these two sentences in section 4(d), Congress delegated broad authority to the Secretary to determine what protections would be necessary and advisable to provide for the conservation of threatened species, and even broader authority to put in place any of the section 9 prohibitions, for a given species. Courts have recognized the extent of the Secretary’s discretion under section 4(d) to develop rules that are appropriate for the conservation of a species. For example, courts have upheld, as a valid exercise of agency authority, rules developed under section 4(d) that included limited prohibitions against takings (see *Alsea Valley Alliance v. Lautenbacher*, 2007 WL 2344927 (D. Or. 2007); *Washington Environmental Council v. National Marine Fisheries Service*, 2002 WL 511479 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana v. Verity*, 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, “once an animal is on the threatened list, the Secretary has an almost infinite number of options available to [them] with regard to the permitted activities for those species. [They] may, for example, permit taking, but not importation of such species. [They] may, for example, permit taking, but not importation of such species, or [they] may choose to forbid both taking and importation but allow the transportation of such species” (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Under our 4(d) authorities, we put in place protections intended to both prevent a threatened species from becoming an endangered species and to promote its recovery. We have two ways to put in place these protections for a

threatened species: (1) we can issue a species-specific 4(d) rule (at 50 CFR 17.40–17.47 or 17.73–17.74), which would contain all of the protective regulations for that species; or (2) we can apply a “blanket rule” (for more information, see 89 FR 23919, April 5, 2024), which extends to threatened species without a species-specific rule all of the prohibitions that apply to endangered species under section 9 (with certain exceptions applicable to threatened species).

Both “blanket rules” and species-specific 4(d) rules explain what is prohibited for a threatened species, thus making the activity unlawful without a permit or authorization under the Act for the prohibited activity unless otherwise excepted in the 4(d) rule (species-specific 4(d) rules may also include affirmative requirements). Section 4(d) rules are therefore directly related to what actions may require permits in the future. As discussed in Available Conservation Measures, permits may be issued for purposes described in our threatened species permitting regulations at 50 CFR 17.32 and 17.72, including for recovery actions, conservation benefit agreements (previously referred to as candidate conservation agreements with assurances and safe harbor agreements), or habitat conservation plans. We may also except otherwise prohibited activities through a 4(d) rule itself, in which case threatened species permits would not be required for those activities. For example, there are two categories of exceptions that we frequently include in 4(d) rules, and these are for otherwise prohibited acts or forms or amounts of “take” that are: (1) unavoidable while conducting beneficial actions for the species, or (2) considered inconsequential (de minimis) to the conservation of the species. For otherwise prohibited take activities that require section 10 permits, programmatic approaches—such as general conservation plans and template habitat conservation plans—may be available as another way for project proponents to comply with take prohibitions or requirements applicable to one or more species while reducing the time that would otherwise be associated with developing individual permit applications. In addition, the Service and project proponents can reduce the need for such permits by developing standardized conservation measures that avoid the risk of “take.”

The provisions of the Clear Lake hitch’s proposed protective regulations under section 4(d) of the Act are one of many tools that we would use to promote the conservation of the Clear

Lake hitch. The proposed protective regulations would apply only if and when we make final the listing of the Clear Lake hitch as a threatened species. Nothing in 4(d) rules change in any way the recovery planning provisions of section 4(f) of the Act or the consultation requirements under section 7 of the Act. As mentioned previously in Available Conservation Measures, section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, even before the listing of any species or the designation of its critical habitat is finalized, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. These requirements are the same for a threatened species regardless of what is included in its 4(d) rule.

Whether a threatened species is protected through a “blanket rule” or a species-specific 4(d) rule, protective regulations do not alter section 7 obligations, including the criteria for informal or formal consultations or the analytical process used for biological opinions or concurrence letters. Section 7 consultation is required for Federal actions that “may affect” a listed species regardless of whether take caused by the activity is prohibited or excepted by a 4(d) rule (the “blanket rule” or a species-specific 4(d) rule).

For example, as with an endangered species, if a Federal agency determines that an action is “not likely to adversely affect” a threatened species, this will require the Service’s written concurrence (50 CFR 402.13(c)). Similarly, if a Federal agency determines that an action is “likely to adversely affect” a threatened species, the action will require formal consultation with the Service and the formulation of a biological opinion (50 CFR 402.14(a)). Because consultation obligations and processes are unaffected by 4(d) rules, we may consider developing tools to streamline future intra-Service and interagency consultations for actions that result in forms of take that are not prohibited by the 4(d) rule (but that still require consultation). These tools may include consultation guidance; streamlined,

online consultation processes via the Service’s digital project planning tool (Information for Planning and Consultation; <https://ipac.ecosphere.fws.gov/>); template language for biological opinions; or programmatic consultations.

Provisions of the Proposed 4(d) Rule

Exercising the Secretary’s authority under section 4(d) of the Act, we have developed a proposed rule that is designed to address the Clear Lake hitch’s conservation needs. As discussed above under Summary of Biological Status and Threats, we have concluded that the Clear Lake hitch is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss, degradation, and modification; nonnative species’ predation; competition; and the effects of climate change. Section 4(d) requires the Secretary to issue such regulations as she deems necessary and advisable to provide for the conservation of each threatened species and authorizes the Secretary to include among those protective regulations any of the prohibitions that section 9(a)(1) of the Act prescribes for endangered species. We are not required to make a “necessary and advisable” determination when we apply or do not apply specific section 9 prohibitions to a threatened species (In re: Polar Bear Endangered Species Act Listing and 4(d) Rule Litigation, 818 F. Supp. 2d 214, 228 (D.D.C. 2011) (citing *Sweet Home Chapter of Cmty. for a Great Or. v. Babbitt*, 1 F.3d 1, 8 (D.C. Cir. 1993), *rev’d on other grounds*, 515 U.S. 687 (1995))). Nevertheless, even though we are not required to make such a determination, we have chosen to be as transparent as possible and explain below why we find that, if finalized, the protections, prohibitions, and exceptions in this proposed rule as a whole satisfy the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Clear Lake hitch.

The protective regulations we are proposing for the Clear Lake hitch incorporate prohibitions from the Act’s section 9(a)(1) to address the threats to the subspecies. The prohibitions of section 9(a)(1) of the Act, and implementing regulations codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or to cause to be committed any of the following acts with regard to any endangered wildlife: (1) import into, or export from, the United States; (2) take (which

includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct) within the United States, within the territorial sea of the United States, or on the high seas; (3) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such wildlife that has been taken illegally; (4) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or (5) sell or offer for sale in interstate or foreign commerce. This protective regulation includes all of these prohibitions because the Clear Lake hitch is at risk of extinction within the foreseeable future and putting these prohibitions in place would help prevent further declines in the subspecies, preserve the species remaining populations, and decrease synergistic, negative effects from other ongoing or future threats.

In particular, this proposed 4(d) rule would provide for the conservation of the Clear Lake hitch by prohibiting the following activities, unless they fall within specific exceptions or are otherwise authorized or permitted: importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, carrying, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce. Under the Act, “take” means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating take would help to sustain water quality and water flow within the tributaries and improve reproductive success, prevent further declines preserve or improve the resiliency of the remaining populations, and decrease synergistic, negative effects from other ongoing or future threats. Therefore, we propose to prohibit take of the Clear Lake hitch, except for take resulting from those actions and activities specifically excepted by the 4(d) rule.

Exceptions to the prohibition on take would include all of the general exceptions to the prohibition on take of endangered wildlife, as set forth in 50 CFR 17.21, and additional exceptions, as described below.

Despite these prohibitions regarding threatened species, we may under certain circumstances issue permits to carry out one or more otherwise

prohibited activities, including those described above. The regulations that govern permits for threatened wildlife state that the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened species. These include permits issued for the following purposes: for scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act (50 CFR 17.32). The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

In addition, to further the conservation of the species, any employee or agent of the Service, any other Federal land management agency, the National Marine Fisheries Service, a State conservation agency, or a federally recognized Tribe, who is designated by their agency or Tribe for such purposes, may, when acting in the course of their official duties, take threatened wildlife without a permit if such action is necessary to: (i) Aid a sick, injured, or orphaned specimen; (ii) dispose of a dead specimen; (iii) salvage a dead specimen that may be useful for scientific study; or (iv) remove specimens that constitute a demonstrable but nonimmediate threat to human safety, provided that the taking is done in a humane manner; the taking may involve killing or injuring only if it has not been reasonably possible to eliminate such threat by live capturing and releasing the specimen unharmed, in an appropriate area.

We recognize the special and unique relationship that we have with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist us in implementing all aspects of the Act. In this regard, section 6 of the Act provides that we must cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with us in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve

the Clear Lake hitch that may result in otherwise prohibited take without additional authorization.

The proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions that incentivize conservation actions or that, while they may have some minimal level of take of the Clear Lake hitch, are not expected to rise to the level that would have a negative impact (*i.e.*, would have only de minimis impacts) on the subspecies’ conservation. The proposed exceptions to these prohibitions include activities associated with the cleanup of illegal cannabis cultivation sites in the Clear Lake watershed, Tribal collection, fish rescues, fuels and fire management activities, habitat management and restoration, and nonnative fish species removal (described below) that are expected to have negligible impacts to the Clear Lake hitch and its habitat.

Cleanup of Illegal Cannabis Cultivation Sites

Illegal cannabis cultivation in California has been an ongoing problem, and illegal grows are known to occur in Lake County within the Clear Lake hitch’s range (Lake County News 2023, entire; California Statewide Law Enforcement Association 2020, entire). Although species-specific studies on the impact that illegal cannabis grows have on the Clear Lake hitch are not currently available, these illegal cannabis sites are known to impact fish and their habitats, not only during active operation but also when sites are left abandoned. As described above in the Threats section, many pesticides can be highly toxic and used illegally at cannabis grow sites. Fertilizers are also used at these sites. Growers can add these chemicals to their irrigation systems, causing the chemicals to seep into the surrounding soil and waterways (California Department of Pesticide Regulation 2021, p. 2; USDA 2023, entire). Fertilizers affect the water quality and may increase cyanobacteria blooms and fish kills (Baker 2018, p. 6). Water diversions associated with illegal cannabis cultivation sites, block fish passage, change flow regimes, and cause other secondary effects (Baker 2018, p. 6).

Cleanup efforts to address chemical contamination and water diversion structures from these illegal grow sites will help protect the surrounding ecosystem and discourage other growers from returning to the same sites (USDA 2023, entire). During cleanup efforts, some localized, short-term disturbances to Clear Lake hitch habitat may occur if activities occur within or adjacent to

that habitat. Implementation of these cleanup activities will not appreciably reduce the likelihood of survival and recovery of the Clear Lake hitch and will result in a long-term benefit to the subspecies and surrounding ecosystem. Therefore, we propose to except take incidental to otherwise lawful activities that remove toxicants, other chemicals, and related water diversion infrastructure from illegal cannabis cultivation sites in the Clear Lake watershed.

Tribal Collection

The Clear Lake area is one of the earliest known sites to be occupied by Native Americans, approximately 10,000 years ago (Richerson et al. 2008, p. A259). For their subsistence, the local Pomo Tribes historically relied on the large spawning runs of hitch and other native migrating fish during the spring, drying and storing them to eat throughout the year. Tribes continued to harvest hitch until the mid-1980s, when the spawning runs began to decline (Big Valley Environmental Protection Agency 2013 in CDFW 2014, p. 26). California State regulations allowed capture of Clear Lake hitch on tributaries by hand or dip-net until the subspecies was designated a candidate for State listing under the CESA (CDFW 2014, p. 26).

In recognizing the Tribe's long-standing relationship to the subspecies, we propose to except take caused by collection of Clear Lake hitch by members of federally recognized Tribes for ceremonial use or traditional consumption if the collection is conducted pursuant to a Tribal conservation plan.

Fish Rescues

Clear Lake hitch may become stranded during drought or at other times when there is low water availability. Due to their reliance on connectivity between tributaries and lakes for the reproductive cycle, a reduction of flow in the tributaries during the spawning season can completely eliminate or greatly reduce the likelihood for successful reproduction or recruitment or both. The effects of drought will affect the entire subspecies because of its inherently narrow range and will result in strandings. Several entities aid stranded Clear Lake hitch, including State, Federal, Tribal, local, and private individuals.

Therefore, we propose to except take caused by rescue of individual Clear Lake hitch that are at risk of stranding and eventual death in drying or warming pools, and the subsequent

transport and release into a flowing, connected tributary stream or into a larger waterbody (e.g., Clear Lake, Blue Lakes, Tule Lake).

Fuels and Fire Management Activities

In certain areas, the use of fire and wildfire management such as prescribed burns, fuel reduction activities, and maintenance of fuel breaks (not including the use of heavy equipment such as bulldozers, backhoes, or tractors) may assist in protecting and maintaining land adjacent to the aquatic systems used by the Clear Lake hitch.

Establishing and maintaining required minimum vegetation clearance from dwellings or structures to reduce wildland fire risks to human life and property may assist in protecting and maintaining habitat for the Clear Lake hitch by controlling erosion and improving water quality. This process includes activities necessary to maintain the minimum clearance (defensible space) requirement from any occupied dwelling or occupied structure, or to the property line, whichever is nearer, to provide reasonable fire safety and to reduce wildfire risks consistent with the State of California fire codes or local fire codes/ordinances. Therefore, we propose to except take incidental to an otherwise lawful activity caused by fuels and fire management activities (such as prescribed fire) to reduce the risk or severity of catastrophic wildfire, and when such activities will be carried out in accordance with an established and recognized fuels or forest management plan that includes measures to minimize impacts to the Clear Lake hitch or aquatic habitats and will result in conservation benefits to the Clear Lake hitch.

Habitat Management and Restoration

Clear Lake hitch individuals require connectivity to lakes and tributaries throughout their lives. Different life stages depend on different habitat types. Tributaries are used for spawning and successful reproduction. During the spawning season, most adults likely migrate into the connected tributaries; however, some reproductive adults may stay within the lake and spawn along the shore, the mouth of tributaries, or in backwater areas (e.g., Rodman Slough in Clear Lake). Outside of the spawning season, the Clear Lake hitch is primarily found in Clear Lake or Thurston Lake, but can also be found in Tule Lake, the Blue Lakes, and other permanent waterbodies such as reservoirs and ponds. Within the lacustrine habitats, the subspecies can be found in either the littoral zone (nearshore) as juveniles or the limnetic zone (sun-lit, offshore

open water) as adults. During extreme drought conditions, the only successful reproduction may be within the lakes.

Nonnative vegetative growth along the lake's shoreline can outcompete the growth of important native wetland plant species, such as tule. Nonnative plant species, such as Himalayan blackberry (*Rubus armeniacus*), growing along the tributaries can become so overgrown that they become passage barriers or they outcompete native species such as willows and cottonwoods. Removal and maintenance of excessive nonnative vegetation may assist the restoration of wetland and riparian habitats throughout the watershed so that these habitats can be used as breeding and rearing habitat for the Clear Lake hitch.

Therefore, we propose to except take incidental to otherwise lawful activity caused by habitat management and restoration efforts that specifically provide for the habitat needs of the Clear Lake hitch and include measures that minimize impacts to the subspecies and its habitat. These efforts must be carried out in accordance with finalized conservation plans or strategies for the Clear Lake hitch that have the approval of appropriate State or Federal agencies. These activities will most likely have some limited short-term impacts but overall will provide for conservation of the subspecies.

Nonnative Fish Species Removal

As noted earlier in this document, 25 different species of nonnative fish have been introduced into Clear Lake for recreational or biological control purposes, and although not all of them have become established, about 20 are still found in the lake today (Thompson et al. 2013, pp. 12–17). All of the piscivorous species in Clear Lake are potential predators of the Clear Lake hitch, and there have been accounts of the subspecies in the digestive tracts of both largemouth bass and channel catfish (Macedo 1994, p. 5; Moyle et al. 1995, pp. 154–155; Moyle et al. 2014, p. 10). Anecdotal reports suggest the Clear Lake hitch may be a main prey-item for largemouth bass. Predation and competition from the nonnative species will continue to affect the Clear Lake hitch at the individual, population, and subspecies level into the future throughout its range, reducing survival, reproduction, and recruitment, which reduces resiliency by decreasing the size of the spawning and overall population.

Nonnative species removal will significantly increase the viability of the Clear Lake hitch. Actions with the primary or secondary purpose of removing nonnative fish species that

compete with, predate upon, or degrade the habitat of the Clear Lake hitch are beneficial to the Clear Lake hitch. Therefore, we propose to exempt take incidental to otherwise lawful activity caused by removal or eradication of nonnative fish species. This exception does not include actions that disturb habitat or involve the use of chemicals.

III. Critical Habitat

Background

Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, we designate a species' critical habitat concurrently with listing the species. Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features:

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.*, migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the

requirement that each Federal action agency ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect an area designated as critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal agency would have already been required to consult with the Service even absent the designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement "reasonable and prudent alternatives" to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4(b)(2) of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information compiled in the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge. Habitat is dynamic, and species may move from one area to another over time.

We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in the 4(d) rule. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may

still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best scientific data available at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Critical Habitat Determinability

Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

- (i) Data sufficient to perform required analyses are lacking, or
- (ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of “critical habitat.”

We reviewed the available information pertaining to the biological needs of the subspecies and habitat characteristics where this subspecies is located, but sufficient data to perform the required consideration of economic impacts are lacking at this time.

Therefore, we conclude that the designation of critical habitat for the Clear Lake hitch is not determinable at this time. The Act allows the Service an additional year to publish a critical habitat designation that is not determinable at the time of listing (16 U.S.C. 1533(b)(6)(C)(ii)).

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in ADDRESSES. To

better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Regulations adopted pursuant to section 4(a) of the Act are exempt from the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations and species-specific protective regulations promulgated concurrently with a decision to list or reclassify a species as threatened. The courts have upheld this position (e.g., *Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir. 1995) (critical habitat); *Center for Biological Diversity v. U.S. Fish and Wildlife Service*, 2005 WL 2000928 (N.D. Cal. Aug. 19, 2005) (concurrent 4(d) rule)).

Government-to-Government Relationship With Tribes

In accordance with the President’s memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951, May 4, 1994), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), the President’s memorandum of November 30, 2022 (Uniform Standards for Tribal Consultation; 87 FR 74479, December 5, 2022), and the Department of the Interior’s manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes and Alaska Native Corporations (ANCs) on a government-to-government basis. In accordance with Secretary’s Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for

healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We contacted all federally recognized Tribes in the range of the Clear Lake hitch during the initiation of our SSA development process. Two of the local Tribes provided technical review of the SSA report. We will continue to work with relevant Tribal entities during the development of a final rule for listing of, and a proposed rule for the designation of critical habitat for, the Clear Lake hitch.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <https://www.regulations.gov> and upon request from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are members of Fish and Wildlife Service’s Species Assessment Team and Sacramento Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

- 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

- 2. In § 17.11, in paragraph (h), amend the List of Endangered and Threatened Wildlife by adding an entry for “Hitch, Clear Lake” in alphabetical order under FISHES to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *
(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* FISHES	*	*	*	*

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Hitch, Clear Lake	<i>Lavinia exilicauda chi</i>	Wherever found	T	[Federal Register citation when published as a final rule]; 50 CFR 17.44(mm). ^{4d}
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

■ 3. Amend § 17.44 by adding paragraph (mm) to read as follows:

§ 17.44 Species-specific rules—fishes.

* * * * *

(mm) Clear Lake hitch (*Lavinia exilicauda chi*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Clear Lake hitch. Except as provided under paragraph (mm)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (4) for endangered wildlife.

(iii) Take, as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(v) Take incidental to an otherwise lawful activity caused by:

(A) Activities that remove toxicants, other chemicals, and related water diversion infrastructure from illegal cannabis cultivation sites in the Clear Lake watershed.

(B) Fuels and fire management activities (such as prescribed fire) to reduce the risk or severity of catastrophic wildfire, and when such activities will be carried out in accordance with an established and recognized fuels or forest management plan that includes measures to minimize impacts to the Clear Lake hitch or aquatic habitats and will result in conservation benefits to the Clear Lake hitch. This exception does not include the use of heavy equipment, such as bulldozers, backhoes, or tractors, for fuels and fire management activities.

(C) Habitat management and restoration efforts that are specifically designed to provide for the conservation of the Clear Lake hitch's habitat needs

and include measures that minimize impacts to the Clear Lake hitch and its habitat. These efforts must be carried out in accordance with finalized conservation plans or strategies for the Clear Lake hitch that have the approval of appropriate State or Federal agencies.

(D) Removal or eradication of nonnative fish species, including, but not limited to, carp and goldfish, for the conservation benefit of the Clear Lake hitch. This exception does not include actions that disturb habitat or involve the use of chemicals.

(vi) Purposefully take associated with:

(A) Collection of Clear Lake hitch individuals by members of federally recognized Tribes for ceremonial use or traditional Tribal consumption if the collection is conducted pursuant to a Tribal conservation plan.

(B) Activities associated with rescuing Clear Lake hitch individuals that are at risk of stranding in drying or warming pools and relocating them into connected waterways.

* * * * *

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

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Part IV

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Hawaii-Southern California Training and Testing Study Area; Proposed Rule

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 218**

[Docket No. 241220–0334]

RIN 0648–BL72

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Hawaii-Southern California Training and Testing Study Area

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

ACTION: Final rule; notification of issuance of Letters of Authorization.

SUMMARY: NMFS, upon request from the U.S. Navy (Navy), issues these regulations pursuant to the Marine Mammal Protection Act (MMPA) to govern the taking of marine mammals incidental to the training and testing activities conducted in the Hawaii-Southern California Training and Testing (HSTT) Study Area between 2018 and 2025. In 2021, two separate U.S. Navy vessels struck unidentified large whales on two separate occasions, one whale in June 2021 and one whale in July 2021, in waters off Southern California. The takes by vessel strike of the two whales by the U.S. Navy were covered by the existing regulations and Letters of Authorization (LOAs), which authorize the U.S. Navy to take up to three large whales by serious injury or mortality by vessel strike between 2018 and 2025. The Navy reanalyzed the potential of vessel strike in the HSTT Study Area, including the recent strikes, and as a result, requested two additional takes of large whales by serious injury or mortality by vessel strike for the remainder of the current regulatory period. In May 2023, a U.S. Navy vessel struck a large whale in waters off Southern California. NMFS reanalyzed the potential for vessel strike based on new information, including the three strikes, and authorizes two additional takes of large whales by serious injury or mortality by vessel strike for the remainder of the current regulatory period (two takes in addition to the three takes authorized in the current regulations). The Navy's activities qualify as military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA).

DATES: Effective from January 16, 2025 to December 20, 2025.

ADDRESSES: Copies of the Navy's applications, NMFS' proposed and final rules and subsequent LOAs for these regulations, NMFS' proposed and final rules and subsequent LOAs for the associated 5-year HSTT Study Area regulations, other supporting documents cited herein, and a list of the references cited in this document may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>. In case of problems accessing these documents, please use the contact listed here (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Leah Davis, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Purpose of Regulatory Action**

These regulations, promulgated under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), modify previous regulations which allow for the authorization of take of marine mammals incidental to the Navy's training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers, in-water detonations, air guns, impact pile driving/vibratory extraction, and the movement of vessels throughout the HSTT Study Area (50 CFR part 218, subpart H; hereafter “2020 HSTT regulations”).

NMFS received a request from the Navy to modify the 2020 HSTT regulations and LOAs to authorize two additional takes of large whales by serious injury or mortality by vessel strike over the remainder of the HSTT regulatory period. The 2020 HSTT regulations and LOAs authorized the incidental take, by serious injury or mortality, of three large whales by vessel strike. Here, in consideration of the best available science, including updated information related to vessel strikes, NMFS analyzes and authorizes the incidental serious injury or mortality by vessel strike of five large whales over the effective period of the regulations (December 2018–December 2025). The effective period remains unchanged from the existing regulations. Further, the Navy's planned activities remain unchanged; however, this final rule includes two additional mitigation measures and revision of two existing mitigation measures to further reduce the probability of vessel strike, as well as two additional reporting measures (described below in the

Changes from the Proposed Rule to the Final Rule section) from that included in the 2020 HSTT regulations. With the exception of these new mitigation measures and revisions to two existing mitigation measures, the required mitigation and monitoring measures remain unchanged from the 2020 HSTT regulations.

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce (as delegated to NMFS) 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, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this final rule and the subsequent LOAs. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

The following is a summary of the major provisions of this final rule regarding the Navy's activities. Major provisions include, but are not limited to:

- The use of defined powerdown and shutdown zones (based on activity);
- Measures to reduce or eliminate the likelihood of ship strikes;
- Activity limitations in certain areas and times that are biologically important (*i.e.*, for foraging, migration, reproduction) for marine mammals;
- Implementation of a Notification and Reporting Plan (for dead, live stranded, or marine mammals struck by a vessel); and
- Implementation of a robust monitoring plan to improve our understanding of the environmental effects resulting from the Navy training and testing activities.

Additionally, the rule includes an adaptive management component that allows for timely modification of mitigation or monitoring measures based on new information, when appropriate.

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et*

seq.) direct the Secretary of Commerce (as delegated to NMFS) 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, the public is provided with notice of the proposed incidental take authorization and the opportunity to review and submit comments.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in this rulemaking as “mitigation”); and requirements pertaining to the monitoring and reporting of such takings. The MMPA defines “take” to mean to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. The Analysis and Negligible Impact Determination section below discusses the definition of “negligible impact.”

The 2004 NDAA (Pub. L. 108–136) amended section 101(a)(5) of the MMPA to remove the “small numbers” and “specified geographical region” provisions indicated above and amended the definition of “harassment” as applied to a “military readiness activity.” The definition of harassment for military readiness activities (section 3(18)(B) of the MMPA) is (i) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment); or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B harassment). In addition, the 2004 NDAA amended the MMPA as it relates to military readiness activities such that the least practicable adverse impact analysis shall include consideration of

personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The NDAA for Fiscal Year 2019 (2019 NDAA) (Pub. L. 115–232), amended the MMPA to allow incidental take rules for military readiness activities under section 101(a)(5)(A) to be issued for up to 7 years. Prior to this amendment, all incidental take rules under section 101(a)(5)(A) were limited to 5 years.

Under the MMPA implementing regulations, incidental take regulations may be modified, in whole or in part, as new information is developed and after notice and opportunity for public comment (50 CFR 216.105). An LOA must be withdrawn or suspended if, after notice and opportunity for public comment, NMFS determines that the regulations are not being substantially complied with, or the taking is having, or may have, more than a negligible impact on species or stock. (*Id.* at 216.106(e)). Note, in its application, Navy relied on §§ 218.76, and 218.77. These sections outline the process for modification of an LOA without modifying the applicable incidental take regulation. These sections do not apply here because the Navy requested modification of the 2020 HSTT regulations.

Summary of Request

On December 27, 2018, NMFS issued a 5-year final rule governing the taking of marine mammals incidental to Navy training and testing activities conducted in the HSTT Study Area (83 FR 66846; hereafter “2018 HSTT final rule”). Previously, on August 13, 2018, and towards the end of the time period in which NMFS was processing the Navy’s request for the 2018 regulations, the 2019 NDAA amended the MMPA for military readiness activities to allow incidental take regulations to be issued for up to 7 years instead of the previous 5 years. The Navy’s training and testing activities conducted in the HSTT Study Area qualify as military readiness activities pursuant to the MMPA, as amended by the 2004 NDAA. On March 11, 2019, the Navy submitted an application requesting that NMFS extend the 2018 HSTT final rule (83 FR 66846, December 27, 2018) and associated LOAs such that they would cover take incidental to 7 years of training and testing activities instead of 5, extending the expiration date from December 20, 2023 to December 20, 2025. On July 10, 2020, NOAA Fisheries issued regulations (85 FR 41780) to govern the taking of marine mammals incidental to the training and testing activities conducted in the HSTT Study

Area over the course of 7 years, effectively extending the effective period from December 20, 2023 to December 20, 2025.

On March 31, 2022, NMFS received an adequate and complete application (2022 Navy application) from the Navy requesting that NMFS modify the existing regulations and LOAs to authorize two additional takes of large whales by serious injury or mortality by vessel strike over the remainder of the HSTT authorization period. The 2020 HSTT regulations (50 CFR part 218, subpart H) and LOAs authorize the take of marine mammals from the Navy’s training and testing activities in the HSTT Study Area through December 20, 2025. These regulations and LOAs authorize the take of three large whales by serious injury or mortality by vessel strike.

The Navy’s 2022 request is based upon new information regarding U.S. Navy vessel strikes off the coast of Southern California. As described in the 2022 Navy application, in 2021, two separate U.S. Navy vessels struck unidentified large whales off the coast of Southern California on two separate occasions, one whale in June 2021 and one whale in July 2021. Separately, a foreign naval vessel struck two fin whales off the coast of Southern California in May 2021.

In the 2022 Navy application, the Navy proposed no changes to the nature of the specified activities covered by the 2020 HSTT final rule. The Navy stated that the level of activity within and between years would be consistent with that previously analyzed in the 2020 HSTT final rule, and all activities would be conducted within the same boundaries of the HSTT Study Area identified in the 2020 HSTT final rule. The training and testing activities (*e.g.*, equipment and sources used, exercises conducted) are identical to those described and analyzed in the 2020 HSTT final rule, and the mitigation, monitoring, and reporting measures are similar to those described and analyzed in the 2020 HSTT final rule. The only changes included in the Navy’s request are for additional take by serious injury or mortality by vessel strike.

The Navy’s mission is to organize, train, equip, and maintain combat-ready naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. This mission is mandated by Federal law (10 U.S.C. 8062), which ensures the readiness of the naval forces of the United States. The Navy executes this responsibility by establishing and executing training programs, including at-sea training and exercises, and ensuring naval forces

have access to the ranges, operating areas (OPAREAs), and airspace needed to develop and maintain skills for conducting naval activities.

For a summary of the training and testing activities within the HSTT Study Area, see the Navy's previous rulemaking and LOA applications submitted for HSTT Phase III activities (October 13, 2017 initial rulemaking and LOA application (hereafter "2017 Navy application") and March 11, 2019 extension rulemaking and LOA application (hereafter "2019 Navy application")) and the 2020 HSTT regulations that were subsequently promulgated, which can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>. These activities are deemed by the Navy necessary to accomplish military readiness requirements and are anticipated to continue into the reasonably foreseeable future. The 2022 Navy application and this rule cover training and testing activities that would occur over the remainder of the effective period of the current regulations, valid from the publication date of this final rule through December 20, 2025.

Summary of the Regulations

NMFS is modifying the incidental take regulations and associated LOAs to cover the same Navy activities covered by the 2020 HSTT regulations but authorize five takes of large whales by serious injury or mortality by vessel strike (two takes in addition to the three takes authorized in the 2020 HSTT regulations). In its 2022 application, the Navy proposed no additional changes and explained that its training and testing activities, including the level of vessel use, remain unchanged. Nearly all mitigation, monitoring, and reporting measures remain unchanged from the 2020 HSTT regulations (85 FR 41780, July 10, 2020) with the exception of two additional mitigation measures (see the Mitigation Measures section of this final rule), revision of two existing mitigation measures (see the Mitigation Measures section of this final rule), and two additional reporting measures resulting from discussions between the Navy and NMFS (see the Reporting section of this final rule).

In response to the Navy's request, we focus our analysis on the new information related to vessel strike. We also review any new information that may be pertinent to our analysis of the impacts from all other activities that comprise Navy's specified activity, and our analysis of mitigation, monitoring, and reporting. Where there is any new

information pertinent to the descriptions, analyses, or findings required to authorize the incidental take for military readiness activities under MMPA section 101(a)(5)(A), that information is provided in the appropriate sections below. Where there is no new information or any new information does not change our previous analysis or findings, we indicate as such and refer the reader to the original analysis in the 2018 HSTT proposed and final rule, 2020 HSTT final rule or the 2019 HSTT Final Environmental Impact Statement (FEIS)/Overseas Environmental Impact Statement (OEIS).

After reviewing all new information and as discussed below, we largely find that our previous analyses and findings remain current and applicable. For vessel strike, we provide a new analysis and authorize two additional takes of large whales, for a total of five takes by serious injury or mortality by vessel strike over the 7-year period. We authorize these additional takes after analyzing the best available scientific information and after considering the effects of the entire specified activity and the total taking as required by MMPA section 101(a)(5)(A). When setting forth the permissible methods of taking pursuant to the activity and other means of effecting the least practicable adverse impact on the species or stock, we require new and modified mitigation and also consider whether to require any new or modified mitigation for the entire specified activity.

The regulatory language included at the end of this final rule, which is published at 50 CFR part 218, subpart H, remains largely the same as that under the HSTT 2020 regulations, except for a small number of technical changes related to the Navy's 2022 request, new and revised mitigation measures, and two new reporting measures. Therefore, in this final rule, we refer the reader to complete analyses described in the 2018 HSTT final rule or an updated analysis in the 2020 HSTT final rule, where appropriate.

Below is a list of the regulatory documents referenced in this final rule. The list indicates the short name by which the document is referenced in this final rule as well as the full titles of the cited documents. All of the documents can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities> and <http://www.hstteis.com/>.

- NMFS June 26, 2018, Hawaii-Southern California Training and Testing (HSTT) proposed rule (83 FR 29872; 2018 HSTT proposed rule);

- NMFS December 27, 2018, Hawaii-Southern California Training and Testing (HSTT) final rule (83 FR 66846; 2018 HSTT final rule);
- NMFS September 13, 2019, Hawaii-Southern California Training and Testing (HSTT) proposed rule (84 FR 48388; 2019 HSTT proposed rule);
- NMFS July 10, 2020, Hawaii-Southern California Training and Testing (HSTT) final rule (85 FR 41780; 2020 HSTT final rule);
- NMFS October 3, 2023, Hawaii-Southern California Training and Testing (HSTT) proposed rule (88 FR 68290; 2023 HSTT proposed rule);
- Navy October 13, 2017, MMPA rulemaking and LOA application (2017 Navy application);
- Navy March 11, 2019, MMPA rulemaking and LOA extension application (2019 Navy application);
- Navy March 31, 2022, MMPA rulemaking and LOA revision application (2022 Navy application); and
- October 26, 2018, Hawaii-Southern California Training and Testing (HSTT) Final Environmental Impact Statement/Overseas Environmental Impact Statement (FEIS/OEIS) (2018 HSTT FEIS/OEIS).

Description of the Specified Activity

The Navy requested authorization to take marine mammals incidental to conducting training and testing activities. The Navy has determined that acoustic and explosives stressors are most likely to result in impacts on marine mammals that could rise to the level of harassment. In addition to take by harassment, the Navy has determined that vessel movement may result in serious injury or mortality to marine mammals. Detailed descriptions of these activities are provided in chapter 2 of the 2018 HSTT FEIS/OEIS and in the 2017 Navy application.

Overview of Training and Testing Activities

The Navy routinely trains in the HSTT Study Area in preparation for national defense missions. Training and testing activities and components covered in the 2022 Navy application are described in detail in the *Overview of Training and Testing Activities* sections of the 2018 HSTT proposed rule, the 2018 HSTT final rule, and chapter 2 (*Description of Proposed Action and Alternatives*) of the 2018 HSTT FEIS/OEIS (<http://www.hstteis.com/>). Each military training and testing activity described meets mandated Fleet requirements to deploy ready forces. The Navy proposed no changes to the specified activities

described and analyzed in the 2018 HSTT final rule and subsequent 2020 HSTT final rule. The boundaries of the HSTT Study Area (see figure 2–1 of the 2019 Navy application); the dates and duration of the activities; and the training and testing activities (e.g., equipment and sources used, exercises conducted) analyzed in this final rule are identical to those described and analyzed in the 2020 HSTT final rule and therefore, are not repeated herein. Please see the 2020 HSTT final rule for more information. The manner of vessel movement presented in this final rule is also identical to that analyzed in the 2020 HSTT final rule.

Vessel Strike

Vessel strikes are not specific to any particular training or testing activity but rather, a limited, sporadic, and incidental result of Navy vessel movement within the HSTT Study Area. Vessel strikes from commercial, recreational, and military vessels are known to seriously injure and occasionally kill cetaceans (Abramson *et al.* 2011; Berman-Kowalewski *et al.* 2010; Calambokidis, 2012; Douglas *et al.* 2008; Laggner, 2009; Lammers *et al.* 2003; Van der Hoop *et al.* 2012; Van der Hoop *et al.* 2013; Crum *et al.* 2019), although reviews of the literature on vessel strikes mainly involve collisions between commercial vessels and whales (Jensen and Silber, 2003; Laist *et al.* 2001). Vessel speed, size, and mass are all important factors in determining both the potential likelihood and impacts of a vessel strike to marine mammals (Conn and Silber, 2013; Gende *et al.* 2011; Silber *et al.* 2010; Vanderlaan and Taggart, 2007; Wiley *et al.* 2016). For large vessels, speed and angle of approach can influence the severity of a strike.

Navy vessels transit at speeds that are optimal for fuel conservation or to meet training and testing requirements. Small craft (for purposes of this analysis, less than 18 meters (m) in length) have much more variable speeds (0–50+ knots (kn; 0–92.6 kilometers (km) per hour), dependent on the activity). Submarines generally operate at speeds in the range of 8–13 kn (14.8–24.1 km per hour), and the average speed of large Navy ships range between 10 and 15 kn (18.5 and 27.8 km per hour). While these speeds are considered averages and representative of most events, some vessels need to operate outside of these parameters for certain times or during certain activities. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier engaged in flight operations must adjust its speed through the water

accordingly. Also, there are other instances when vessels would be dead in the water or moving slowly ahead to maintain steerage, such as launch and recovery of a small rigid hull inflatable boat; vessel boarding, search, and seizure training events; or retrieval of a target. There are a few specific events, including high-speed tests of newly constructed vessels, where vessels would operate at higher speeds. By comparison, this is slower than most commercial vessels where full speed for a container ship is typically 24 kn (44.4 km per hour; Bonney and Leach, 2010).

Large Navy vessels (greater than 18 m in length) within the offshore areas of range complexes and testing ranges operate differently from commercial vessels in ways that may reduce the probability of whale collisions. Surface ships operated by or for the Navy have multiple personnel assigned to stand watch at all times when a ship or surfaced submarine is moving through the water (underway). A primary duty of personnel standing watch on surface ships is to detect and report all objects and disturbances sighted in the water that may indicate a threat to the vessel and its crew, such as debris, a periscope, surfaced submarine, or surface disturbance. Per vessel safety requirements, personnel standing watch also report any marine mammals sighted in the path of the vessel as a standard collision avoidance procedure. All vessels proceed at a safe speed so they can take proper and effective action to avoid a collision with any sighted object or disturbance and can be stopped within a distance appropriate to the prevailing circumstances and conditions. As described in the *Standard Operating Procedures* section, the Navy utilizes Lookouts to avoid collisions, and Lookouts are also trained to spot marine mammals so that vessels may change course or take other appropriate action to avoid collisions. Should a vessel strike occur, we consider that it would likely result in incidental take in the form of serious injury and/or mortality and, accordingly, for the purposes of the analysis, we assume that any vessel strike would result in serious injury or mortality.

The Navy proposed no changes to the nature of the specified activities, the training and testing activities, the manner of vessel movement, the speeds at which vessels operate, the number of vessels that would be used during various activities, or the locations in which Navy vessel activity would be concentrated within the HSTT Study Area described in the 2018 HSTT final

rule and referenced in the 2020 HSTT final rule.

Vessel Movement

Vessels used as part of the planned activities include ships, submarines, unmanned vessels, and boats ranging in size from small, 22 feet (ft; 7 m) rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft (333 m). The average speed of large Navy ships ranges between 10 and 15 kn (18.5 and 27.8 km per hour) and submarines generally operate at speeds in the range of 8–13 kn (14.8–24.1 km per hour) while a few specialized vessels can travel at faster speeds. Small craft (for purposes of this analysis, less than 18 m in length) have much more variable speeds (0–50+ kn (0–92.6 km per hour), dependent on the activity) but generally range from 10 to 14 kn (18.5 to 25.9 km per hour). From unpublished Navy data, average median speed for large Navy ships in the HSTT Study Area from 2011–2015 varied from 5–10 knots (kn; 9.2–18.5 km per hour) with variations by ship class and location (i.e., slower speeds close to the coast). While these speeds for large and small craft are representative of most events, some vessels need to temporarily operate outside of these parameters. Typical speed of Navy vessels in HSTT core high use areas from 2014–2018 were between 10 and 15 kn (18.5 and 27.8 km per hour; Starcovic and Mintz 2021). This core area is a region including the approaches to San Diego, and immediate offshore areas west of San Diego, centered north and south of San Clemente Island. A full description of Navy vessels that are used during training and testing activities can be found in the 2017 Navy application and chapter 2 (*Description of Proposed Action and Alternatives*) of the 2018 HSTT FEIS/OEIS.

The number of Navy vessels used in the HSTT Study Area varies based on military training and testing requirements, deployment schedules, annual budgets, and other dynamic factors. Most training and testing activities involve the use of vessels. These activities could be widely dispersed throughout the HSTT Study Area but would typically be conducted near naval ports, piers, and range areas. Navy vessel traffic would be especially concentrated near San Diego, California and Pearl Harbor, Hawaii. Based on historical data, we anticipate the annual number of at-sea hours by U.S. Navy vessels in the HSTT action area will be around 26,800 hours per year (Starcovic and Mintz 2021). We expect that about 25 percent of this vessel activity would occur within the Hawaii Range Complex

(HRC) and 75 percent within the Southern California Range Complex (SOCAL; Mintz 2016). There is no seasonal differentiation in Navy vessel use because of continual operational requirements from Combatant Commanders. The majority of large vessel traffic occurs between the installations and the OPAREAs. The transit corridor, notionally defined by the great circle route (*e.g.*, shortest distance) from San Diego to the center of the HRC, as depicted in the 2018 HSTT FEIS/OEIS, is generally used by ships transiting between SOCAL and HRC. While in transit, ships and aircraft would, at times, conduct basic and routine unit-level activities such as gunnery, bombing, and sonar training and maintenance. Of note, support craft would be more concentrated in the coastal waters in the areas of naval installations, ports, and ranges. Activities involving vessel movements occur intermittently and are variable in duration, ranging from a few hours up to weeks. More information on Navy and non-Navy vessel traffic patterns in the HSTT Study Area may be found in several studies prepared by the Navy (Starcovic and Mintz 2021; Mintz, 2016; Mintz and Filadelfo, 2011; Mintz, 2012; Mintz and Parker, 2006).

Foreign Navies

In addition, we note that in some cases, foreign militaries may participate in U.S. Navy training or testing activities in the HSTT Study Area. The Navy does not consider these foreign military activities as part of the “specified activity” under the MMPA, and NMFS defers to the applicant to describe the scope of its request for an authorization.

The participation of foreign navies varies from year to year, but overall is infrequent compared with Navy’s total training and testing activities. The most significant joint training event is the Rim of the Pacific (RIMPAC), a multinational training exercise held every-other-year primarily in the HRC. The participation level of foreign military vessels in U.S. Navy-led training or testing events within the HRC and within SOCAL differs greatly between RIMPAC and non-RIMPAC years. For example, in 2019 (a non-RIMPAC year), there were 0.1 foreign navy surface vessel at-sea days (*i.e.*, 1 day = 24 hours) within HRC and 20 foreign navy at-sea days within SOCAL (Navy 2021). Out of 56 U.S.-led training events in 2019, 4 involved foreign navy vessels, with an average time per event of 8.7 hours. In 2020, a RIMPAC year, foreign vessels participating in U.S. Navy-led events accounted for 32 at-sea days in the HRC

from August through September (some of this activity occurred after the RIMPAC exercise). During RIMPAC 2022, foreign vessels operated and/or transited through the HRC for 576 hours (24 days). In 2023 (another non-RIMPAC year), there was no foreign vessel participation within SOCAL. Even in a RIMPAC year, the days at sea for foreign militaries engaged in a Navy-led training or testing activity accounts for a small, but variable, percentage compared to the U.S. Navy activities. For instance, the 2020 foreign military participation (a RIMPAC-year) was 1.5 percent of the U.S. Navy’s average days at sea (32 days out of an estimated 2,056 days at sea). During RIMPAC 2024, twenty-five foreign surface vessels participated for a combined 5,000 hours in U.S.-led training events. Therefore, foreign surface vessel activity is estimated to conservatively account for up to 10 percent of the U.S. Navy’s annual at sea time in HSTT (205 days out of an estimated 2,056 days at sea).

According to the U.S. Navy, consistent with customary international law, when a foreign military vessel participates in a U.S. Navy exercise within the U.S. territorial sea (*i.e.*, 0 to 12 nautical miles (nmi); 0 to 22.2 km) from shore), the U.S. Navy will request that the foreign vessel follow the U.S. Navy’s mitigation measures for that particular event. When a foreign military vessel participates in a U.S. Navy exercise beyond the U.S. territorial sea but within the U.S. Exclusive Economic Zone, the U.S. Navy will encourage the foreign vessel to follow the U.S. Navy’s mitigation measures for that particular event (Navy 2022a; Navy 2022b). In either scenario (*i.e.*, both within and beyond the territorial sea), U.S. Navy personnel will provide the foreign vessels participating with a description of the mitigation measures to follow.

According to the U.S. Navy, the May 2021 vessel strike of two fin whales by an Australian navy vessel did not occur while that vessel was participating in a U.S. Navy-led training exercise. The Royal Australian Navy vessel was adhering to its standard operating procedures at the time of the strike. The Royal Australian Navy provided a report of the incident, which is discussed below to inform our analysis.

NMFS analyzes the effects of these foreign military activities. First, effects of all past foreign military activities are captured in the baseline for the analysis, through marine mammal abundance estimates and population trends found in the Stock Assessment Reports (SARs). Second, NMFS considers foreign military activities, including recent

strikes, qualitatively in this final rule. For instance, in preparing this rulemaking, NMFS and the U.S. Navy discussed the nature, frequency, and control over joint or U.S. Navy-led training and testing activities with foreign entities to identify opportunities to encourage foreign militaries to adopt mitigation. NMFS and the U.S. Navy examined the Royal Australian Navy 2021 strike report for any lessons that could inform U.S. Navy strike mitigation. NMFS considered the Royal Australian Navy strikes along with other recent U.S. Navy strikes to determine whether these strikes indicate an increased risk of strike by the U.S. Navy in this region during the early summer months. NMFS also considered the species struck in this incident, fin whales, along with other literature, when considering the likelihood of certain species to be struck by the U.S. Navy. NMFS considered the fact that two fin whales were struck by the Royal Australian Navy qualitatively when considering other fin whale population and mortality trends, as well as the authorized take, as part of the negligible impact analysis.

This final rule includes a new reporting measure that requires that the Navy’s annual HSTT reports shall include confirmation that foreign military use of sonar and explosives, when such militaries are participating in a U.S. Navy-led exercise or event, combined with the U.S. Navy’s use of sonar and explosives, would not cause exceedance of the analyzed levels (within each Navy Acoustic Effects Model (NAEMO) modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of our acoustic impacts effects analysis that was used to estimate take in this final rule. This new reporting measure will allow NMFS to ensure that its analysis remains valid.

Standard Operating Procedures

For training and testing to be effective, personnel must be able to safely use their sensors and weapon systems as they are intended to be used in a real-world situation and to their optimum capabilities. While standard operating procedures (SOPs) are designed for the safety of personnel and equipment and to ensure the success of training and testing activities, their implementation often yields additional benefits on environmental, socioeconomic, public health and safety, and cultural resources. Because SOPs are essential to safety and mission success, the Navy considers them to be part of the proposed activities under the National Environmental Policy Act

(NEPA) and included them in the environmental analysis. We consider SOPs as part of Navy's specified activity for the purposes of MMPA but also, where procedures are utilized (even in part) to reduce impacts to marine mammal species and Navy's commitment to follow the measures are practicable, certain SOPs may also be required as mitigation. Details on SOPs were provided in the 2018 HSTT proposed rule; please see the 2018 HSTT proposed rule, the 2017 Navy application, and chapter 2 (*Description of Proposed Action and Alternatives*) of the 2018 HSTT FEIS/OEIS for more information.

As stated in its 2022 application, in 2018, the Navy updated its SOPs related to vessel safety to incorporate revised procedures regarding Lookouts for certain ship classes as per the 2021 Surface Ship Navigation Department Organization and Regulations Manual (NAVDORM). The 2021 NAVDORM requires the use of three Lookouts on Navy cruisers and destroyers as compared to the previous requirement of one Lookout when a vessel was underway and not engaged in sonar training or testing. However, as discussed in the Mitigation Measures section below, the Navy informed NMFS that requiring the additional Lookouts as mitigation is not practicable because this SOP may change in response to manning issues and national security needs. Further, since submission of its 2022 application, the Navy has updated its Lookout Training Handbook and implemented other training improvements, as described in the Mitigation Measures section (September 2022).

Comments and Responses

We published a proposed rule in the **Federal Register** on October 3, 2023 (88 FR 68290), with a 45-day comment period. That notice described, in detail, Navy's request for modification of the 2020 HSTT final rule and LOAs, new information regarding the occurrence of large whale strikes by naval vessels in the southern California portion of the HSTT Study Area and NMFS' proposal to authorize two additional takes of large whales by serious injury or mortality. In that notice, we requested public input on the proposed promulgation of modified regulations and associated LOAs for the Navy governing this additional incidental taking of marine mammals. During the 45-day comment period, we received 20 comment submissions. Of this total, one submission was from a non-governmental organization (NGO) and the remainder were from private

citizens. NMFS has reviewed and considered all public comments received on the proposed rule and issuance of the LOAs. All substantive comments and our responses are described below. We organize our comment responses by major categories.

Take Estimates

Comment 1: A commenter recommended ensuring that any modifications to existing regulations or authorizations are based on recent and rigorous scientific evaluations. This can be achieved by conducting regular environmental impact assessments to account for changes in marine mammal populations and habitat conditions.

Response: NMFS concurs with the commenter that modifications to existing regulations or authorizations must be based on rigorous scientific evaluations. NMFS has conducted a rigorous scientific evaluation in the promulgation of this rulemaking and has used the best available science to inform its analysis. These final regulations and LOAs include reporting provisions to ensure compliance and that the most value is obtained from the required monitoring. Monitoring results are considered annually through the adaptive management process described in the Adaptive Management section herein. Further, incidental take authorizations for military readiness activities can be effective for no more than 7 years. Therefore, at minimum, NMFS must reconduct its analysis every 7 years, and in doing so, it considers changes in marine mammal populations and habitats in its analyses. However, during the effective period of an LOA(s), if NMFS were to find that the Navy's activities are having more than a negligible impact on a species or stock, NMFS is required to withdraw or suspend the LOA(s) for a certain time (16 U.S.C. 1371(a)(5)(B)).

Comment 2: A commenter stated that the 2022 Navy application is based on 50 CFR 216.015 [the commenter is likely referring to section 216.105], which allows incidental take regulations to "be modified, in whole or in part, as new information is developed." The commenter asserted that the only "new information" in the 2022 application is the information that the Navy has already reached its 7-year take limit and that failure to meet our own standards does not constitute "new information" in the sense of 50 CFR 216.015. The commenter stated that "new information" for this purpose would be either (1) evidence that allowing two additional takes (and relaxing mitigation procedures as requested in the application) during this time period will

have no impact on threatened cetacean populations or (2) a dramatic increase in the level of military activity in HSTT.

Response: The MMPA provides for the authorization of incidental take caused by specified activities at the request of an applicant, provided certain findings are made. The law directs NMFS to process adequate and complete applications for incidental take authorization, and issue the authorization provided all statutory findings and requirements, as well as all associated legal requirements, are met. Under 50 CFR 216.105, as new information is developed, through monitoring, reporting, or research, the regulations may be modified, in whole or in part, after notice and opportunity for public review. On March 31, 2022, NMFS received an adequate and complete application from the Navy requesting that NMFS modify the existing regulations and LOAs to authorize two additional takes of large whales by serious injury or mortality by vessel strike over the remainder of the HSTT regulatory period based on probabilities derived from a Poisson distribution using new vessel strike data between 2009–2021 in the HSTT Study Area, as well as historical at-sea days in the HSTT Study Area from 2009–2015 and estimated at-sea days for the period from 2016 to 2025, informed by monitoring and reporting. NMFS independently analyzed the request based on updated vessel strike data and days-at-sea, as well as using updated probability methodology, and also determined that the strike of up to two large whales could occur over the remaining duration of the regulations. NMFS, following its own analysis and proposed rule, has determined it is appropriate to promulgate a revised final rule and LOAs pursuant to 16 U.S.C. 1371(a)(5)(A) and 50 CFR 216.105.

Comment 3: A commenter stated that Kuehne *et al.* (2020), referenced in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), indicates that noise from Navy aircraft penetrates more deeply into the water than the Navy or NMFS considered in their analyses. The commenter stated that the study found that noise from aircraft can permeate the water to at least 30 m and that the detected noise level (134 ± 3 dB re 1 μ Pa rms) exceeds volumes that can cause behavioral changes in marine mammals (Houser *et al.* 2013; Kastelein *et al.* 2012; Kuehne *et al.* 2020; Williams *et al.* 2002). The commenter asserted that, therefore, the Navy's reliance on this paper to assert that aircrafts do not impact marine mammals is misplaced, and the proposed rule's dismissal of the

study because it “did not include behavioral observations of wildlife, and the authors’ conclusions about potential impacts to wildlife were unsupported by data from the study” ignores the valid bases for these conclusions.

Response: NMFS disagrees with the commenter that Kuehne *et al.* (2020) shows impacts to marine mammals from Navy’s HSTT activities that were not considered by NMFS and the Navy in their respective analyses. As stated in the comment, the strongest one-second window of underwater sound measured by Kuehne *et al.* (2020) was 134 ± 3 dB RMS re 1 μ Pa rms at 30 m below the sea surface. While sound levels between the hydrophone and the surface may have been stronger than those measured at 30 m (Kuehne *et al.* 2020), for the reasons discussed in the 2023 HSTT proposed rule, there is no new information presented in this study to indicate that exposures closer to the surface or in air would have resulted in behavioral responses that would qualify as take by Level B harassment.

We conclude that the information presented in Kuehne *et al.* (2020) does not reveal effects of the action on marine mammals in a manner or to an extent not already considered. We reiterate that NMFS reviewed the Navy’s analysis and conclusions that aircraft noise will not result in incidental take of marine mammals and finds the analysis and conclusions remain complete and supportable, as stated in the 2018 HSTT final rule and in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023). Please see section 3.7 (Marine Mammals) of the 2018 HSTT FEIS/OEIS for additional information. Of note, even if the sound level in the water were to exceed the Level B harassment threshold, a marine mammal would need to cross the path of the aircraft while the animal is relatively close to the surface in order for a take to occur, which is unlikely.

In addition to Kuehne *et al.* (2020), the commenter referenced several other studies that it described as indicating that other Navy activities in the HSTT Study Area may affect listed species to an extent not previously considered. These studies include Goldbogen *et al.* (2013), Pirotta *et al.* (2019), Pirotta *et al.* (2021), Pirotta *et al.* (2022), Simonis *et al.* (2020), Southall *et al.* (2019), Southall *et al.* (2021), and Szesciorka *et al.* (2019). NMFS considered Pirotta *et al.* (2021), Pirotta *et al.* (2022), and Southall *et al.* (2021) in its 2023 HSTT proposed rule (88 FR 68290, October 3, 2023). NMFS considered Goldbogen *et al.* (2013) in the 2018 HSTT proposed rule (83 FR 29872, June 26, 2018) and 2018 HSTT final rule (83 FR 66846,

December 27, 2018), and NMFS considered Southall *et al.* (2019) in the 2019 HSTT proposed rule (84 FR 48388, September 13, 2019). Pirotta *et al.* (2019) found that environmental changes could severely affect a population’s vital rates, but that, depending on the context of a disturbance, individuals were tolerant of anthropogenic disturbance. Simonis *et al.* (2020) correlated strandings in the Mariana islands with naval activities. NMFS is aware of this study and has considered it along with global information related to the correlation of sonar with strandings in our analysis. In a case study of a close vessel encounter with a blue whale, Szesciorka *et al.* (2019) noted that the ship’s reduced speed (*i.e.*, 11.3 kn (20.9 km per hour)) may have played a role by giving the whale enough time to respond to the nearby vessel and that higher vessel speeds increase the risk that a whale could have been struck at the surface or get close enough to the ship’s draft that the propeller suction effect created by the ship’s hydrodynamic flow could pull the whale toward the hull. Additionally, feeding whales may be distracted and thus be less capable of detecting and avoiding approaching vessels (Szesciorka *et al.* 2019). NMFS determined that the information presented in these studies does not substantively affect our analysis of impacts on marine mammals and their habitat that appeared in the 2023 HSTT proposed rule, all of which remains applicable and valid for our assessment of the effects of the Navy’s activities during the 7-year period of this final rule. Please see NMFS’ response to Comment 14 regarding vessel speed restrictions.

Comment 4: A commenter expressed support for Navy use of marine mammals for military purposes through its Marine Mammal Program. However, the commenter stated that to “take” mammals simply as a training opportunity via severe injury or mortality is unethical and to allow the killing of innocent animals as cross-fire or training shouldn’t be tolerated.

Response: The actions the Navy takes through its Marine Mammal Program are outside the scope of this action; we note that no animals are intentionally exposed to serious injury or mortality through that program. For additional information about the Navy’s Marine Mammal Program, please see the Navy’s website at <https://www.niwc-pacific.navy.mil/About/Departments/Intelligence-Surveillance-and-Reconnaissance/Marine-Mammal-Program/>.

Comment 5: A commenter stated that the recent whale deaths indicate that (1) NMFS’ earlier assumptions that vessel strikes would be unlikely and easily detected if they did occur were proven wrong, (2) vessel strikes are occurring at rates well-above that analyzed in NMFS’ analyses, (3) whales cannot avoid vessel strike at the level NMFS assumed in issuing the regulations, (4) and that sonar affects blue whales in ways not adequately considered.

Response: In the 2018 HSTT final rule, 2020 HSTT final rule, and 2023 HSTT proposed rule, NMFS described why a strike by a Navy vessel is unlikely in comparison to a strike by a non-Navy vessel, and that, overall, it is unlikely that the Navy would hit a large whale for these reasons. However, even in consideration of these factors that make vessel strike unlikely, given the history of vessel strike by the U.S. Navy in the HSTT Study Area, NMFS, in the 2018 and 2020 HSTT final rules concluded that vessel strikes could occur and that authorization of three takes by vessel strike was appropriate. Therefore, NMFS disagrees that the recent vessel strikes disprove NMFS’ assumption that vessel strikes would be unlikely.

To date, NMFS is aware of three confirmed vessel strikes of large whales by U.S. Navy vessels during the current regulatory period. Therefore, the strikes that have occurred to date have been within what NMFS anticipated could occur, though, NMFS’ current analysis suggests that two additional strikes may occur during the current regulatory period based on the best available scientific information since promulgation of the 2020 HSTT final rule.

NMFS further disagrees that the recent vessel strikes disprove NMFS’ assumption that vessel strikes would be detected if they did occur. As demonstrated by the June 2021, July 2021, and May 2023 U.S. Navy strikes, NMFS is confident that whales struck by Navy vessels are detected and reported, and Navy strikes are the numbers used in NMFS’ analysis to support the authorized number of strikes. Navy ships have multiple Lookouts, including on the forward part of the ship that can visually detect a hit whale (which has occasionally occurred), in the unlikely event ship personnel do not feel the strike. The Navy’s strict internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Navy’s discipline, extensive training (not only for detecting marine mammals but for detecting and reporting any potential navigational obstruction), and strict

chain of command give NMFS a high level of confidence that all strikes are reported. Accordingly, NMFS is confident that the information used to support the analysis is accurate and complete. Regarding the 2021 Royal Australian Navy vessel strikes, while the U.S. Navy cannot speculate on the configurations of other ships bows and even sonar dome specifications (that may be at the bow), the Navy believes it would be implausible for a marine mammal to become lodged on the sonar dome of a U.S. Navy ship and remain undetected due to a technological standard operating procedure.

While the 2018 HSTT final rule, the 2020 HSTT final rule, and this final rule include mitigation to reduce the potential for vessel strike, NMFS neither states nor implies vessel strike avoidance of a particular “level”. However, it is important that NMFS and the Navy consider the new information regarding vessel strikes in southern California consistent with 50 CFR 216.105(c). Consideration of this new information in an updated analysis allows NMFS to reassess its negligible impact determination and to determine whether additional potential mortality would still constitute a negligible impact on the potentially affected stocks, as it has determined would be the case here.

The commenter referenced several studies related to blue whales and sonar. Please see NMFS’ response to Comment 3.

Comment 6: A commenter stated that NMFS should deny the Navy’s request for authorization of two additional takes of large whales by vessel strike because for at least two of the impacted marine mammal stocks (Eastern North Pacific stock of blue whale and Central America/Southern Mexico—California/Oregon/Washington stock of humpback whale) mortality and serious injury already exceeds potential biological removal (PBR). The commenter stated that NMFS’ reasoning for authorizing the take amounts to “take by a thousand cuts” and defies the stated purpose and objectives of the MMPA.

A commenter stated that NMFS may allow take of marine mammals incidental to military readiness activities only if the taking will have a “negligible impact” on an affected species or stock. The commenter further stated that as one court has explained, “[b]ecause any mortality level that exceeds PBR will not allow the stock to reach or maintain its optimum sustainable population (‘OSP’), such a mortality level could not be said to have only a ‘negligible impact’ on the stock.” (See *Conservation Council for Hawai’i v.*

Nat’l Marine Fisheries Serv., 97 F. Supp. 3d 1210, 1225 (D. Haw. 2015); see also 54 FR 40338, 40341, 40342 (Sept. 29, 1989) (“In order to make a negligible impact finding, the proposed incidental take must not prevent a depleted population from increasing toward its OSP.”)). Indeed, NMFS itself has previously recognized that when mortality of a species is above its PBR, “a negligible impact finding under section 101(a)(5)(A) cannot be made” (61 FR 54,157, October 17, 1996).

Response: The commenter is correct that PBR for the Eastern North Pacific stock of blue whales and the Central America/Southern Mexico—California/Oregon/Washington stock of humpback whales is currently exceeded. However, NMFS is not authorizing take by mortality of the Central America/Southern Mexico—California/Oregon/Washington stock of humpback whales. In this final rule, NMFS is authorizing take of the Mainland Mexico-CA/OR/WA stock of humpback whale, and PBR is not exceeded for this stock. A stock’s PBR is part of the best scientific information available and therefore, is considered in the negligible impact determination (see *Conservation Council for Hawai’i v. Nat’l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1228 (D. Haw. 2015)). However, exceedance of PBR does not inherently imply that a negligible impact determination cannot be made for an authorization that includes mortality or serious injury (M/SI) of that stock. As explained in the *Serious Injury or Mortality* subsection of the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule and 2020 HSTT final rule, and referenced in the same section of this final rule, in the commercial fisheries setting for Endangered Species Act (ESA)-listed marine mammals (which is similar to the non-fisheries incidental take setting, in that a negligible impact determination is required that is based on the assessment of take caused by the activity being analyzed), NMFS may find the impact of the authorized take from a specified activity to be negligible even if total human-caused mortality exceeds PBR, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.*, other than the specified activities covered by the incidental take authorization in consideration). When those considerations are applied in the section 101(a)(5)(A) context here, the authorized lethal take (0.14 annually) of blue

whales from the Eastern North Pacific stock is less than 10 percent of PBR (4.1) and there are management measures in place to address the mortality and serious injury from the activities other than those the Navy is conducting. For the complete discussion of how NMFS carefully considered potential mortalities from the Navy’s activities in light of PBR levels, including an explanation for why mortality above PBR will not necessarily induce population-level non-negligible impacts, see the discussion in the *Analysis and Negligible Impact Determination* section of this rule, the 2020 HSTT final rule, and the 2018 HSTT final rule.

The commenter references a 1996 NMFS notice of receipt and request for comments (61 FR 54,157; October 17, 1996) that stated that a negligible impact finding under section 101(a)(5)(A) could not be made where PBR for the North Atlantic right whale stock was 0.4. The method that NMFS has articulated herein to evaluate negligible impact of potential mortality was adopted in 1999 to evaluate negligible impact pursuant to MMPA section 101(a)(5)(E). NMFS uses these same criteria adopted in 1999 to inform (*i.e.*, it is not the sole factor considered) our negligible impact analysis of potential mortality under section 101(a)(5)(A).

The 1996 decision that a negligible impact determination could not be made was regarding a request for take by mortality of North Atlantic right whale (61 FR 54,157; October 17, 1996)). PBR for North Atlantic right whale at that time was 0.4. If NMFS were to apply its current method for evaluating negligible impact of potential mortality to that request, the results would suggest that take by mortality should not be authorized (though again, the PBR evaluation is not the sole factor considered).

Comment 7: A commenter stated that the Navy and NMFS must consider serious injury and mortality that results from joint training exercises the Navy engages in with foreign nations as “take” under the regulations and that NMFS must reexamine the impacts of the Navy’s full suite of activities (including joint activities with foreign fleets) on marine mammals using the best available science. In the proposed rule, NMFS states that “[a]ccording to the U.S. Navy, the May 2021 vessel strike of two fin whales by an Australian navy vessel did not occur while that vessel was participating in a U.S. Navy-led training exercise. The Royal Australian Navy vessel was adhering to its standard operating procedures at the time of the strike.” The commenter stated that this contradicts coverage of

the incident, including by the Navy Times/AP that reported: “[t]he Sydney has been holding joint exercises with the U.S. Navy in the area since early April” (The Navy Times, 2021).

The commenter stated that elsewhere in the rule, NMFS appears to say that regardless of whether it considered vessel strikes that occurred during joint training or not, NMFS lets the Navy decide what activities it requests authorization for, and there is no reasoned explanation provided for this position. These joint activities led by the U.S. Navy pose serious threats to marine mammals, kill whales, and should be included as specified activities. The commenter recommended that NMFS not “defer to the applicant to describe the scope of its request for an authorization.”

Response: Under the MMPA, only a U.S. Citizen may request NMFS authorize the incidental take of marine mammals (16 U.S.C. 1371(a)(5)(A)). Further, the MMPA requires NMFS to authorize the incidental take caused by the applicant’s specified activities, provided certain findings are made (*Id.*). In some cases, foreign militaries may participate in U.S. Navy training or testing activities in the HSTT Study Area. As stated in the proposed rule, the HMAS Sydney most likely struck the two fin whales around 6:25 a.m. the morning of May 7, 2021 while the HMAS Sydney was getting into position to participate in a U.S. Navy-led exercise later that day but was not actively engaged in an exercise at the presumed time of the strike. The Navy does not consider the Royal Australian Navy’s vessel movements at the time of strike as part of the ‘specified activity’ under the MMPA, as the strike did not occur while the HMAS Sydney was actively participating in a joint training exercise with the U.S. Navy. The MMPA is necessarily an applicant-driven process (*Melone v. Coit*, 100 F.4th 21, 32 (1st Cir. 2024)) and NMFS has appropriately deferred to the Navy’s reasoned explanation of why the Royal Australian Navy’s operations were not part of the “specified activity.”

As explained in the *Foreign Navies* section of this final rule, in preparing this rulemaking, NMFS and the U.S. Navy discussed the nature, frequency, and control over joint or U.S. Navy-led training and testing activities with foreign entities. Consistent with customary international law, U.S. Navy requests or encourages participating foreign entities to follow U.S. Navy’s mitigation measures for that particular event, depending on whether the activity is in the U.S.’s territorial sea or the EEZ. NMFS and the U.S. Navy also

examined the Royal Australian Navy 2021 strike report, and NMFS concurred with U.S. Navy’s conclusion that the strike most likely occurred before, but not during, a joint exercise, and the Royal Australian Navy vessel was adhering to its standard operating procedures at the time of the strike.

As noted by the commenter in its letter, NMFS assessed the effects of foreign military activities. First, the impacts of all activities are captured in the baseline for the analysis, through marine mammal abundance estimates and population trends found in the SARs. Second, NMFS considers foreign military activities, including recent strikes, qualitatively in its analysis, as described in the *Foreign Navies* section of this final rule. For instance, NMFS and the U.S. Navy examined the Royal Australian Navy 2021 strike report for any lessons that could inform U.S. Navy strike mitigation.

This final rule includes a new reporting measure related to foreign vessels. The new measure requires that the Navy’s annual HSTT reports shall include confirmation that foreign military use of sonar and explosives, when such militaries are participating in a U.S. Navy-led exercise or event, combined with the U.S. Navy’s use of sonar and explosives, did not cause exceedance of the analyzed levels (within each NAEMO modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of our acoustic impacts effects analysis that was used to estimate take in this final rule. This new reporting measure will allow NMFS to ensure that its analysis remains valid.

Comment 8: A commenter stated that it supports the Navy’s request for two additional incidental takes of large whales by vessel strike. The commenter discussed a U.S. Supreme Court case, *Winter v. NRDC, Inc.*, 555 U.S. 7 (2008), in support of its assertion that preparing for war still plainly outweighs the interests in the safety of marine life. Considering these interests, the commenter recommended that NMFS consider granting the Navy’s request for two additional incidental takes.

Response: NMFS has made the required findings on the Navy’s request consistent with the statutory criteria under the MMPA and has authorized two additional takes of large whales by serious injury or mortality by vessel strike for the remainder of the current regulatory period (two takes in addition to the three takes authorized in the current regulations). NMFS does not weigh the necessity of Navy training and testing against the risks to marine mammals as part of the required

analysis for issuance of take regulations under the MMPA. The MMPA requires NMFS to authorize the incidental take of marine mammals caused by specified activities upon request, provided certain findings are made (16 U.S.C.

1371(a)(5)(A)). NMFS’ least practicable adverse impact determination for military readiness activities must include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (16 U.S.C. 1371(a)(5)(a)(iii)).

Comment 9: A commenter noted NMFS’ reference to Cure *et al.* (2021) and Isojunno *et al.* (2020) in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) discussing sperm whale behavioral responses to exposure to pulsed active sonar (PAS) and continuous active sonar (CAS). The commenter stated that physical trauma, sensory impairment (PTS, TTS, and acoustic masking), physiological responses (particularly stress responses), and behavioral disturbances are all part of the harassment of the whales and that these factors have not been included in the “take” of the three whales already, only the mortalities have been counted. The commenter stated that even brief and transient exposure to modest levels of mid-frequency military sonar has been observed to cause whales to strand or perish at sea within hours (Dave, D.M., & Dave, M., 2023). These studies do not include the permanent injuries to these marine mammals’ hearing and sonar capabilities. The commenter stated that effects on marine mammal hearing are not mentioned outside of some studies on stranding and should include more study and data collection by marine mammal experts when it comes to PTS and sonar damage to these animals due to the impact of the U.S. Navy’s military ocean noise pollution.

Response: In the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), NMFS included a discussion of relevant literature that had published since publication of the 2020 HSTT final rule (85 FR 41780, July 10, 2020), and in this final rule, NMFS has included a discussion of relevant literature that has published since publication of the 2023 HSTT proposed rule. Herein, and in the 2023 HSTT proposed rule, NMFS discussed all relevant literature, not just that related to vessel strike. (See the New Pertinent Science Since Publication of the 2020 HSTT Final Rule section of the 2023 HSTT proposed rule and the Potential Effects of Specified Activities on Marine Mammals and their Habitat section of this final rule.)

The commenter's statement that "even brief and transient exposure to modest levels of mid-frequency military sonar has been observed to cause whales to strand or perish at sea within hours" is not supported. The proposed rule discussed the limited examples of when tactical active sonar, in certain circumstances, have been found to have likely contributed to marine mammal stranding events. The reference that the commenter cites (Dave, D.M. & Dave, M., 2023) states that "even a brief and transient exposure to modest levels of mid-frequency military sonar has been observed to cause whales to strand or perish at sea within hours," citing Fernández *et al.* (2005) and NOAA and U.S. Department of the Navy (2001). These publications discuss two specific stranding events in the Canary Islands and the Bahamas, respectively. NMFS is aware of stranding events coincident with military MFAS use in which exposure to sonar is believed to have been a contributing factor and discussed these cases in detail in the 2018 HSTT proposed rule. While NMFS did not repeat this information in the 2023 proposed rule as the analyses remain unchanged, NMFS stated in the rule that we refer the reader to complete analyses described in the 2018 HSTT final rule or an updated analysis in the 2020 HSTT final rule, where appropriate.

It is unclear what the commenter means by physical trauma, sensory impairment (PTS, TTS, and acoustic masking), physiological responses (particularly stress responses), and behavioral disturbances not having been included in the "take" of the three whales already, and that only the mortalities have been counted. In the 2020 HSTT final rule, NMFS discussed all of the likely impacts to marine mammals, including PTS, TTS, masking, and stress, and authorized take of marine mammals by Level B harassment, Level A harassment, and mortality. The 2023 HSTT proposed rule and this final rule only discuss changes to NMFS' analysis regarding mortality of marine mammals in detail, and refer back to the 2018 HSTT proposed and final rules and the 2020 HSTT final rule regarding take by Level A harassment and Level B harassment. However, NMFS' analysis, including its negligible impact determination, takes into consideration the total authorized take, not just mortality.

Comment 10: A commenter stated that in addition to blue, humpback, and fin whales, the Navy also identifies other large whales in its request (Bryde's whales, gray whales, minke whales, sperm whales, and sei whales) which are also all vulnerable to vessel strikes

(Laist *et al.* 2001, Glass *et al.* 2008, and van der Hoop *et al.* 2015). NMFS' 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) determined that the likelihood of vessel strikes to those whales is "discountable" due to their relatively low occurrence in the HSTT Study Area and the fact that they have rarely, if ever, been recorded struck by vessels. Due to the fact that reported collisions vastly underestimate actual strikes, the commenter asks NMFS and the Navy to approach vessel strikes and other harm very conservatively, particularly in light of how some of these whales are particularly vulnerable to vessel strike and at already-small population levels, as detailed in the commenter's July 1, 2022 letter.

Response: NMFS concurs with the commenter that all large whales are vulnerable to vessel strike, and that reported vessel strikes vastly underestimate actual strikes across many industries generally. However, NMFS has already conducted a conservative vessel strike analysis. While all large whales are vulnerable to vessel strike, it would be inappropriate to assume that all large whales that occur in the HSTT Study Area are likely to be struck by U.S. Navy vessels.

Of note, the commenter is correct that NMFS does not anticipate vessel strike of Bryde's whale, minke whale, or sperm whale. However, NMFS did propose to authorize take by M/SI by vessel strike of sei whale and Eastern North Pacific gray whale in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) and would authorize such take in this final rule. NMFS proposed authorizing one take (0.14 takes annually) of sei whale (Eastern North Pacific stock) and four takes (0.57 takes annually) of Eastern North Pacific gray whale.

Regarding stocks for which take by M/SI by vessel strike was not proposed, as stated in the proposed rule, stocks that have no record of ever having been struck by any vessel are considered to have a zero percent likelihood of being struck by the Navy in the 7-year period of the rule. This includes Bryde's whale, minke whale, and the CA/OR/WA stock of sperm whale raised by the commenter (an individual of the Hawaii stock of sperm whale was struck in 2007; see table 7 of this final rule). Stocks that have never been struck by the Navy, have rarely been struck by other vessels, and have a low percent likelihood based on the historical vessel strike calculation are also considered to have a zero percent likelihood of being struck by the Navy during the 7-year rule. We note that while vessel strike records have not differentiated between Eastern

North Pacific and Western North Pacific gray whales, given their small population size and the comparative rarity with which individuals from the Western North Pacific stock are detected off the U.S. West Coast, it is highly unlikely that they would be encountered, much less struck. Further, it is unlikely that the Hawaii stock of sperm whale would be struck given the zero percent likelihood of striking a sperm whale as indicated by the quantitative analysis in the *Estimated Take From Vessel Strikes and Explosives by Serious Injury or Mortality Vessel Strike* section of the proposed rule and the *Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section in this final rule. Vessel strikes of the Hawaii stock of sperm whale are also unlikely given the fact that the last U.S. Navy strike of a Hawaii stock sperm whale was in 2007, before the mitigation updates discussed above, and that, with the exception of humpback whales, vessel strikes (both military and non-military) of other large whale species in the HRC are extremely rare events (Carretta 2021b; Carretta 2022). Given this analysis, NMFS concludes that the proposed take by M/SI by vessel strike included in the proposed rule remains appropriately conservative, and has not included take by M/SI by vessel strike of Bryde's whale, Western North Pacific gray whale, minke whale, or sperm whale in this final rule.

Comment 11: A commenter stated that aside from excluding impacts from foreign vessels, the proposed rule looks at the impacts of vessel strikes on large whales almost in isolation and does not adequately assess new science on the combined impacts of the Navy's activities, in particular on large whales. The commenter asserted that while the Navy acknowledges that sonar and aircraft may affect whales, it does not adequately consider the extent of these impacts. Any analysis of the impacts of the Navy's exercises must include, in addition to vessel strike impacts, the impacts from sonar activities of domestic vessels and foreign vessels involved in joint training exercises and any other stressor caused by the Navy's activities. The commenter also asserted that the Navy's literature review does not adequately focus on the large baleen whales that are of concern in this most recent request.

The commenter stated that as it noted in its July 2022 letter, in its review of sound effects on animals, the Navy focuses heavily on pinnipeds (seals and sea lions) and odontocetes (dolphins and toothed whales), while their request for increased take focuses on mysticetes

(baleen whales). Mysticetes' hearing systems are different from those of pinnipeds and odontocetes, and so while they are closely related one cannot infer that each group will experience the same effects from sound pollution (Southall *et al.* 2019). Mysticetes' cochlea have their own unique shape, which in concert with the larger mass of baleen whales indicates that they are more sensitive to low-frequency sound (Southall *et al.* 2019). Though auditory capabilities in baleen whales are understudied (Southall *et al.* 2019), absence of literature on baleen whales does not indicate absence of effect. The commenter stated that furthermore, the Navy ignored key papers studying the effect of sonar on baleen whales. It specifically stated that the Navy failed to consider, and NMFS failed to address in its proposed rule, Goldbogen *et al.* (2013), and further references Southall *et al.* (2019) and Southall *et al.* (2021).

Response: NMFS disagrees with the commenter that the proposed rule looks at the impacts of vessel strikes on large whales almost in isolation and does not adequately assess new science on the combined impacts of the Navy's activities, in particular on large whales. While NMFS did not repeat discussion of a portion of the analysis that did not change (e.g., takes by harassment), this analysis was incorporated into the proposed rule and this final rule by reference, and NMFS considered those impacts in conjunction with the updated M/SI analysis in making its determinations.

NMFS further disagrees that the literature review should have focused on large baleen whales. In the proposed rule (88 FR 68290, October 3, 2023), and in this final rule, NMFS' literature review discussed recent literature concerning potential impacts from all of the Navy's activities, not just those related to vessel strike. As the commenter has noted in its letter, NMFS must consider the full range of effects of the Navy's activity, not just the potential for vessel strike of large whales in isolation. NMFS agrees with the commenter that an absence of literature on baleen whales does not indicate an absence of effects, nor has NMFS drawn such a conclusion. Rather, NMFS conducted a thorough analysis on the impacts of the Navy's activities, including sonar and explosive use, on mysticetes, as well as other taxa, as described in the proposed rule and this final rule, which in some cases, reference the 2018 (83 FR 66846, December 27, 2018) and 2020 HSTT final rules (85 FR 41780, July 10, 2020). Regarding the specific studies that the

commenter asserts NMFS failed to consider, while not directly cited to in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), NMFS considered and cited Goldbogen *et al.* (2013) in the 2018 (83 FR 66846, December 27, 2018) and 2020 HSTT final rules (85 FR 41780, July 10, 2020), and the Navy considered and cited this paper in the 2018 HSTT EIS/OEIS. NMFS considered and cited Southall *et al.* (2019) and Southall *et al.* (2021) in the 2023 HSTT proposed rule.

Please see NMFS' response to Comment 7 regarding foreign vessels.

Comment 12: A commenter stated that the rule overlooks the likelihood that the Navy's activities will take humpback whales from the endangered Central America distinct population segment (DPS). The commenter stated that its read of the science is that most of the humpback whale deaths that occur off California could be from the endangered Central America DPS. The commenter further stated that Wade *et al.* (2017) predicted a 67.2 percent movement probability for a whale in California to move to Central America. In other words, an estimated 7,056 Central America DPS humpback whales could die from vessel strikes off California annually (10.5 deaths * 0.672). The commenter stated in its letter that applying the Rockwood *et al.* (2021) model, 10.5 humpback mortalities occur annually off California from the January to April and July to November periods combined. The commenter stated that this does not include potential deaths from other sources or in other locations yet still represents a significant source of mortality for this already endangered population.

Response: NMFS carefully considered the potential for each stock of large whales to be taken by serious injury or mortality by vessel strike. As stated in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), regarding the likelihood of striking a humpback whale from a particular DPS, NMFS evaluated the relative abundance of each of these DPS in California waters. Curtis *et al.* (2022) estimated the abundance of the Central America DPS to be 1,496 whales. From Wade *et al.* (2017), about 93 percent (or 1,391 whales) of these humpbacks that winter in Central America will move to Oregon/California in the summer months. While there is currently no abundance estimate for the Mexico DPS, an estimated 3,477 whales from the Mexico DPS feed off the U.S. West Coast (Calambokidis and Barlow 2020; Curtis 2022). Based on this information, we estimate that approximately 30 percent of the humpback whales off the coast of

California may be from the Central America DPS and the remaining 70 percent are expected to be from the Mexico DPS. Therefore, we anticipate that if a Navy vessel strike of a humpback whale were to occur within SOCAL, it would likely be from the Mexico DPS.

The commenter is correct that Wade *et al.* (2017) predicts that 67.2 percent of whales that summer in Oregon and California will move to Central America for the winter. However, NMFS disagrees with the commenter's implication that it is more appropriate for NMFS to assume that 67.2 percent of humpbacks off of California are of the Central America DPS, and the commenter has not provided justification for doing so. (Of note, an updated paper from Wade (2021) shows that 58 percent of whales that summer in Oregon and California will move to Mexico (only 42 percent will move to Central America)). Rather, NMFS continues to find that it is appropriate to use the abundance estimates described above and the estimate that approximately 93 percent of humpbacks that winter in Central America will move to Oregon/California in the summer months to determine the relative abundance of each DPS off the coast of California. Therefore, NMFS continues to conclude that if a Navy vessel strike of a humpback whale were to occur within SOCAL, it would likely be from the Mexico DPS.

Mitigation and Monitoring

Comment 13: A commenter stated that in addition to strengthening the new and revised mitigation measures that NMFS included in the 2023 HSTT proposed rule, it should also require the following additional mitigation measures to ensure the least practicable adverse impact to marine mammals. The commenter noted that it and others have requested and expounded upon these measures in previous comment letters.

1. Reinstating more protective mitigation areas and restricted training exercises in key migration corridors, feeding habitat, and other biologically important areas (BIAs) and creating/expanding protective mitigation areas to protect newly recognized critical habitat and other BIAs. In a related comment, a separate commenter stated that the chances of an incidental take can be dramatically reduced by adjusting the time and location of exercises (e.g., minimizing activity in the vicinity of California's Channel Islands during July–October) and reducing speed in mitigation areas. The commenter further asserted that additional BIAs identified by Kratofil *et al.* 2023 provide new

information that necessitates reevaluation of mitigation measures, yet NMFS rejects adding these new mitigation areas as “impracticable.” A third commenter stated that it is crucial to integrate scientific research, public awareness, and proactive measures to ensure the sustained well-being of gray whales and the preservation of their migratory habitats.

2. Restricting activities when whale detection is particularly difficult, such as periods of low visibility (Williams *et al.* 2016).

3. Improving detection of marine mammals by adding alternative detection methods, including safe/ environmentally-sound drone, thermal, and/or acoustic technologies, to lookouts/observers (Verfuss *et al.* 2018). In a related comment, a commenter recommended utilizing existing acoustic detection systems to track marine mammals in near real-time.

4. Capping/reducing the level of naval activities authorized each year, in particular major exercises. In a related comment, a separate commenter stated that it is crucial to limit the [Navy]’s takes on marine mammals.

5. Halting training exercises when whale presence in the area is “High” or “Very High,” per WhaleSafe (see <https://whalesafe.com>).

Response: Under the MMPA, NMFS’ least practicable adverse impact determination for military readiness activities must include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (16 U.S.C. 1371(a)(5)(a)(iii)). NMFS has responded to these recommended measures, by corresponding number.

1. In the 2023 HSTT proposed rule, NMFS discussed that since publication of the 2020 HSTT final rule, Kratofil *et al.* (2023) identified updated BIAs in Hawaii. The HSTT Study Area overlaps the updated BIAs for small and resident populations of the following species in Hawaii: spinner dolphin, short-finned pilot whale, rough-toothed dolphin, pygmy killer whale, pantropical spotted dolphin, melon-headed whale, false killer whale, dwarf sperm whale, goose-beaked whale, common bottlenose dolphin, and Blainville’s beaked whale. Further, the HSTT Study Area overlaps updated BIAs for humpback whale reproduction in Hawaii. The updated BIAs overlap critical Navy training and testing areas within the HSTT Study Area, including most of the internal Navy operating areas. Please see Kratofil *et al.* (2023) for additional details about the BIAs.

Since publication of the 2023 HSTT proposed rule, Calambokidis *et al.* (2024) identified updated BIAs on the West Coast of the U.S. The HSTT Study Area overlaps feeding BIAs for blue whale and fin whale in SOCAL. Additionally, it overlaps a reproductive BIA as well as northbound and southbound migratory BIAs for gray whale. Please see Calambokidis *et al.* (2024) for additional details about the BIAs.

NMFS and the Navy considered additional mitigation areas (beyond those already identified with associated measures to reduce impacts to marine mammals, including odontocetes with small or resident populations in the HSTT Study Area, and large whales with feeding, reproductive, and migratory BIAs in the HSTT Study Area. This includes consideration of new mitigation areas that could be based on newly identified BIAs in Hawaii (Kratofil *et al.* 2023) and on the West Coast (Calambokidis *et al.* 2024). The HRC overlaps BIAs identified in Kratofil *et al.* (2023) for humpback whale, spinner dolphin, short-finned pilot whale, rough-toothed dolphin, pygmy killer whale, pantropical spotted dolphin, melon-headed whale, false killer whale, dwarf sperm whale, goose-beaked whale, common bottlenose dolphin, and Blainville’s beaked whale. All of the BIAs that overlap the HRC are small and resident population BIAs, with the exception of the humpback whale reproductive BIA. SOCAL overlaps BIAs identified in Calambokidis *et al.* (2024) for blue whale (feeding area), fin whale (feeding area), and gray whale (migratory route).

Additional restrictions in mitigation areas beyond those restrictions and areas included in the 2020 HSTT final rule (including mitigation to reduce vessel strike risk such as vessel speed restrictions, and in consideration of the newly identified BIAs (Kratofil *et al.* 2023 and Calambokidis *et al.* 2024)) is impracticable given overlap with critical Navy training areas in the HRC and SOCAL, including areas around the Channel Islands in SOCAL. However, many of the BIAs identified in Kratofil *et al.* 2023 and Calambokidis *et al.* (2024) partially or fully overlap the mitigation areas included in the 2020 HSTT final rule and this final rule and are aimed at reducing impacts to the same species for which Kratofil *et al.* 2023 and Calambokidis *et al.* (2024) identified BIAs. In the HRC, the existing mitigation areas are targeted and expected to reduce impacts to humpback whales, false killer whales, dwarf sperm whales, pygmy killer

whales, short-finned pilot whales, melon-headed whales, bottlenose dolphins, spotted dolphins, spinner dolphins, rough-toothed dolphins, goose-beaked whales, and Blainville’s beaked whales (*i.e.*, all species for which Kratofil *et al.* (2023) identified BIAs). In SOCAL, the existing mitigation areas are aimed at reducing impacts to blue whales, fin whales, and gray whales (*i.e.*, all species for which Calambokidis *et al.* (2024) identified BIAs). Further, as included in the 2023 HSTT proposed rule, this final rule requires that Navy personnel must issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in a select area of SOCAL, and that Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area. Last, this final rule includes modification of two mitigation measures from the 2020 HSTT final rule (85 FR 41780; July 10, 2020) to further reduce the potential for vessel strike.

Beyond the papers described herein, NMFS is not aware of, nor have commenters provided, additional research that suggests other areas warrant additional mitigation. While NMFS agrees with the commenter that public awareness can be an important part of gray whale conservation, NMFS does not anticipate that additional public awareness would assist in mitigating effects of Navy’s activities on gray whales, and therefore, has not required the Navy to implement measures related to public awareness. For a discussion of the mitigation measures required by this final rule, please see the Mitigation Measures section.

Please see NMFS’ response to Comment 14 regarding vessel speed restrictions.

2. Anti-submarine warfare training involving the use of mid-frequency active sonar (MFAS) typically involves the periodic use of active sonar to develop the “tactical picture,” or an understanding of the battle space (*e.g.*, area searched or unsearched, presence of false contacts, and an understanding of the water conditions). Developing the tactical picture can take several hours or days, and typically occurs over vast waters with varying environmental and oceanographic conditions. Training during both high visibility (*e.g.*, daylight, favorable weather conditions) and low visibility (*e.g.*, nighttime, inclement weather conditions) is vital because sonar operators must be able to understand the environmental differences between day and night and

varying weather conditions and how they affect sound propagation and the detection capabilities of sonar. Temperature layers move up and down in the water column and ambient noise levels can vary significantly between night and day, affecting sound propagation and how sonar systems are operated. Reducing or securing power in low-visibility conditions as a mitigation would affect a commander's ability to develop the tactical picture and would prevent sonar operators from training in realistic conditions. Further, during integrated training multiple vessels and aircraft may participate in an exercise using different dimensions of warfare simultaneously (*e.g.*, submarine warfare, surface warfare, air warfare, *etc.*). If one of these training elements were adversely impacted (*e.g.*, if sonar training reflecting military operations were not possible), the training value of other integrated elements would also be degraded. Additionally, failure to test such systems in realistic military operational scenarios increases the likelihood these systems could fail during military operations, thus unacceptably placing sailors' lives and the Nation's security at risk. Some systems have a nighttime testing requirement; therefore, these tests cannot occur only in daylight hours. Reducing or securing power in low visibility conditions would decrease the Navy's ability to determine whether systems are operationally effective, suitable, survivable, and safe for their intended use by the fleet even in reduced visibility or difficult weather conditions.

3. The Navy has compiled information related to the effectiveness of certain equipment to detect marine mammals in the context of their activities, as well as the practicality and effect on mission effectiveness of using various equipment. NMFS has reviewed this evaluation and concurs with the characterizations and the conclusions below.

Thermal detection—Thermal detection systems are more useful for detecting marine mammals in some marine environments than others. Current technologies have limitations regarding water temperature and survey conditions (*e.g.*, rain, fog, sea state, glare, ambient brightness), for which further effectiveness studies are required. Thermal detection systems are generally thought to be most effective in cold environments, which have a large temperature differential between an animal's temperature and the environment. Current thermal detection systems have proven more effective at detecting large whale blows than the

bodies of small animals, particularly at a distance. The effectiveness of current technologies has not been demonstrated for small marine mammals. Thermal detection systems exhibit varying degrees of false positive detections (*i.e.*, incorrect notifications) due in part to their low sensor resolution and reduced performance in certain environmental conditions. False positive detections may incorrectly identify other features (*e.g.*, birds, waves, boats) as marine mammals. In one study, a false positive rate approaching one incorrect notification per 4 min of observation was noted.

The Navy has been investigating the use of thermal detection systems with automated marine mammal detection algorithms for future mitigation during training and testing, including on autonomous platforms. Thermal detection technology being researched by the Navy, which is largely based on existing foreign military grade hardware, is designed to allow observers and eventually automated software to detect the difference in temperature between a surfaced marine mammal (*i.e.*, the body or blow of a whale) and the environment (*i.e.*, the water and air). Although thermal detection may be reliable in some applications and environments, the current technologies are limited by their: (1) Low sensor resolution and a narrow field of view, (2) reduced performance in certain environmental conditions, (3) inability to detect certain animal characteristics and behaviors, and (4) high cost and uncertain long-term reliability.

Thermal detection systems for military applications are deployed on various Department of Defense (DoD) platforms. These systems were initially developed for night time targeting and object detection such as a boat, vehicle, or people. Existing specialized DoD infrared/thermal capabilities on Navy aircraft and surface ships are designed for fine-scale targeting. Viewing arcs of these thermal systems are narrow and focused on a target area. Furthermore, sensors are typically used only in select training events, not optimized for marine mammal detection, and have a limited lifespan before requiring expensive replacement. Some sensor elements can cost upward of \$300,000 to \$500,000 per device, so their use is predicated on a distinct military need. One example of trying to use existing DoD thermal systems is being proposed by the U.S. Air Force. The Air Force agreed to attempt to use specialized U.S. Air Force aircraft with military thermal detection systems for marine mammal detection and mitigation during a limited at-sea testing event. It should be

noted, however, that these systems are specifically designed for and integrated into a small number of U.S. Air Force aircraft and cannot be added or effectively transferred universally to Navy aircraft. The effectiveness remains unknown in using a standard DoD thermal system for the detection of marine mammals without the addition of customized system-specific computer software to provide critical reliability (enhanced detection, cueing for an operator, reduced false positive, *etc.*)

Finally, current DoD thermal sensors are not always optimized for marine mammal detections versus object detection, nor do these systems have the automated marine mammal detection algorithms the Navy is testing via its ongoing research program. The combination of thermal technology and automated algorithms are still undergoing demonstration and validation under Navy funding.

Thermal detection systems specifically for marine mammal detection have not been sufficiently studied both in terms of their effectiveness within the environmental conditions found in the HSTT Study Area and their compatibility with Navy training and testing (*i.e.*, polar waters vs. temperate waters). The effectiveness of even the most advanced thermal detection systems with technological designs specific to marine mammal surveys is highly dependent on environmental conditions, animal characteristics, and animal behaviors. At this time, thermal detection systems have not been proven to be more effective than, or equally effective as, traditional techniques currently employed by the Navy to observe for marine mammals (*i.e.*, naked-eye scanning, hand-held binoculars, high-powered binoculars mounted on a ship deck). Focusing on thermal detection systems could also provide a distraction from and compromise to the Navy's ability to implement its established observation and mitigation requirements. Last, the Navy does not have available manpower to add Lookouts to use thermal detection systems in tandem with existing Lookouts who are using traditional observation techniques.

The Defense Advanced Research Projects Agency funded six initial studies to test and evaluate infrared-based thermal detection technologies and algorithms to automatically detect marine mammals on an unmanned surface vehicle. Based on the outcome of these initial studies, the Navy is pursuing additional follow-on research efforts.

The Office of Naval Research Marine Mammals and Biology program funded a project (2013–2019) to test the thermal limits of infrared-based automatic whale detection technology. That project focused on capturing whale spouts at two different locations featuring subtropical and tropical water temperatures, optimizing detector/classifier performance on the collected data, and testing system performance by comparing system detections with concurrent visual observations. Results indicated that thermal detection systems in subtropical and tropical waters can be a valuable addition to marine mammal surveys within a certain distance from the observation platform (e.g., during seismic surveys, vessel movements), but have challenges associated with false positive detections of waves and birds (Boebel, 2017). While Zitterbart *et al.* (2020) reported on the results of land-based thermal imaging of passing whales, their conclusion was that thermal technology under the right conditions and from land can detect a whale within 3 km although there could also be lots of false positives, especially if there are birds, boats, and breaking waves at sea.

The Navy's Living Marine Resources program is funding one ongoing thermal imaging project entitled "Thermal Imaging for Vessel Strike Mitigation on Autonomous Vessels Project 68". The project is focused on adapting and testing two thermal imaging-based whale detection systems to reduce the potential for vessel strike during navigation of unmanned Navy surface vessels. Phase one is planned for 2024 and 2025. The schedule for subsequent phases will be determined as work progresses. Project details are available at: https://exwc.navfac.navy.mil/Portals/88/Documents/EXWC/Environmental_Security/Living%20Marine%20Resources/LMRFactSheet_Project68.pdf.

The Navy plans to continue researching thermal detection systems for marine mammal detection to determine their effectiveness and compatibility with Navy applications. If the technology matures to the state where thermal detection is determined to be an effective mitigation tool during training and testing, NMFS and the Navy will assess the practicability of using the technology during training and testing events and retrofitting the Navy's observation platforms with thermal detection devices. The assessment will include an evaluation of the budget and acquisition process (including costs associated with designing, building, installing, maintaining, and manning the

equipment); logistical and physical considerations for device installment, repair, and replacement (e.g., conducting engineering studies to ensure there is no electronic or power interference with existing shipboard systems); manpower and resource considerations for training personnel to effectively operate the equipment; and considerations of potential security and classification issues. New system integration on Navy assets can entail up to 5 to 10 years of effort to account for acquisition, engineering studies, and development and execution of systems training. The Navy will provide information to NMFS about the status and findings of Navy-funded thermal detection studies and any associated practicability assessments at the annual adaptive management meetings.

Passive Acoustic Monitoring—Regarding the recommendation to utilize existing acoustic detection systems to track marine mammals in near real-time, the Navy does employ passive acoustic monitoring when practicable to do so (*i.e.*, when assets that have passive acoustic monitoring capabilities are already participating in the activity). For other explosive events, there are no platforms participating that have passive acoustic monitoring capabilities. Adding a passive acoustic monitoring capability (either by adding a passive acoustic monitoring device to a platform already participating in the activity, or by adding a platform with integrated passive acoustic monitoring capabilities to the activity, such as a sonobuoy) for mitigation is not practicable. As discussed in chapter 5 (Mitigation), section 5.5.3 (Active and Passive Acoustic Monitoring Devices) of the 2018 HSTT FEIS/OEIS, there are significant manpower and logistical constraints that make constructing and maintaining additional passive acoustic monitoring systems or platforms for each training and testing activity impracticable. Additionally, diverting platforms that have passive acoustic monitoring platforms would impact their ability to meet their Title 10 requirements for maintaining military readiness and reduce the service life of those systems.

The use of real-time PAM for mitigation at the Southern California Anti-submarine Warfare Range (SOAR) exceeds the capability of current technology. The Navy has a significant research investment in the Marine Mammal Monitoring on Navy Ranges (M3R) system at three ocean locations including SOAR. However, this system was designed and intended to support marine mammal research for select species, and not as a mitigation tool.

Marine mammal PAM using instrumented hydrophones is still under development and while it has produced meaningful results for marine species monitoring, abundance estimation, and research, it was not developed for, nor is it appropriate for, real-time mitigation. The ability to detect, classify, and develop an estimated position (and the associated area of uncertainty) differs across species, behavioral context, animal location vs. receiver geometry, source level, *etc.*

Based on current capabilities, and given adequate time, vocalizing animals within an indeterminate radius around a particular hydrophone are detected, but obtaining an estimated position for all individual animals passing through a predetermined area is not assured. Detecting vocalizations on a hydrophone does not determine whether vocalizing individuals would be within the established mitigation zone in the timeframes required for mitigation. Since detection ranges are generally larger than current mitigation zones for many activities, this would unnecessarily delay events due to uncertainty in the animal's location and put at risk event realism. If an event were to be moved based upon low-confidence localizations, it may inadvertently be moved to an area where non-vocalizing animals of undetermined species are present.

To develop an estimated position for an individual, it must be vocalizing and its vocalizations must be detected on at least three hydrophones. The hydrophones must have the required bandwidth, and dynamic range to capture the signal. In addition, calls must be sufficiently loud so as to provide the required signal to noise ratio on the surrounding hydrophones. Typically, small odontocetes echolocate with a directed beam that makes detection of the call on multiple hydrophones difficult. Developing an estimated position of selected species requires the presence of whistles which may or may not be produced depending on the behavioral state. Beaked whales at SOAR vocalize only during deep foraging dives which occur at a rate of approximately 10 per day. They produce highly directed echolocation clicks that are difficult to simultaneously detect on multiple hydrophones. Current real-time systems cannot follow individuals and at best produce sparse positions with multiple false locations. The position estimation process must occur in an area with hydrophones spaced to allow the detection of the same echolocation click on at least three hydrophones. Typically, a spacing of less than 4 km

in water depths of approximately 2 km is preferred. In the absence of detection, the analyst can only determine with confidence if a group of beaked whales is somewhere within 6 km of a hydrophone. Beaked whales produce stereotypic click trains during deep (500 m) foraging dives. The presence of a vocalizing group can be readily detected by an analyst by examining the click structure and repetition rate. However, estimating position is possible only if the same train of clicks is detected on multiple hydrophones which is often precluded by the animal's narrow beam pattern. Currently, this is not an automated routine.

In summary, the analytical and technical capabilities required to use PAM such as M3R at SOAR as a required mitigation tool are not sufficiently robust to rely upon due to limitations with near real-time classification and determining estimated positions. The level of uncertainty as to a species presence or absence and location are too high to provide the accuracy required for real-time mitigation. As discussed in chapter 5 (Mitigation) of the 2018 HSTT FEIS/OEIS, existing Navy visual mitigation procedures and measures, when performed by individual units at-sea, still remain the most effective and practical means of protection for marine species.

NMFS is not requiring drones to be used at this time and the commenters did not provide information supporting the recommendation that they be used when considering the extensive monitoring by Lookouts required.

4. The commenters neither offer a rationale for why a cap on the level of activities is needed nor do they suggest what an appropriate cap might be. The Navy is responsible under Title 10 of the U.S. Code for conducting the needed amount of testing and training to maintain military readiness, which is what they have proposed and NMFS has analyzed. Further, the MMPA states that NMFS shall issue MMPA authorizations if the necessary findings can be made, as they have been here. Importantly, as described in the Mitigation Measures section, the Navy has determined that it is practicable to limit activities (active sonar, explosive use, *etc.*) to varying degrees in five areas that are important to sensitive species or for important behaviors in order to minimize impacts that are more likely to lead to adverse effects on rates of recruitment or survival and is required by this final rule to do so.

5. During the promulgation of this rule, NMFS and the Navy fully explored the potential for the Navy to incorporate

WhaleSafe into its mitigation methods. However, the current WhaleSafe operational areas (Santa Barbara Channel and off the coast of San Francisco) do not overlap the HSTT Study Area. As such, while WhaleSafe can inform whale occurrence in other areas of Southern California, it is not an appropriate tool for determining mitigation actions in the HSTT Study Area, and NMFS has not required the Navy to halt training exercises when WhaleSafe indicates that whale presence in the area is "high" or "very high" as suggested by the commenter. However, NMFS has recommended to the Navy, including as a conservation recommendation in the 2024 reinitiated Biological and Conference Opinion, that it explore funding options and seek partnership opportunities for the development of a mapping and analysis tool that integrates acoustic and visual whale detections with model predictions to display near real-time whale presence data within the SOCAL and nearby surrounding areas. Information generated by such a tool could then be used by Navy, and potentially non-military, vessels to reduce the risk of large whale vessel strike in Southern California.

Comment 14: A commenter stated that NMFS must substantially strengthen mitigation measures, including requiring more effective measures to protect large whales from vessel strikes, before issuing any additional take authorizations to the Navy. The commenter stated that NMFS rejected other mitigation measures, such as requiring vessels used in the Navy's activities to slow to 10 kn (18.5 km per hour) or less in certain BIAs to reduce the risk of vessel strikes, by downplaying the risk of vessel strikes to endangered whales and other species impacted by the Navy's activities. The commenter stated that NMFS' proposed modifications to the mitigation measures fall short of meeting the least practicable adverse impact standard. Commenters provided several specific recommendations for mitigation measures.

1. The 2023 HSTT proposed rule included a revised mitigation measure that states "if marine mammals are observed, Navy personnel must maneuver (which may include reducing speed as the mission or circumstances allow) to maintain distance." The reference to reducing speed as the mission or circumstances allow is a revision from the measure in the 2020 HSTT final rule. The commenter stated that this measure should be mandatory in important whale habitat, where whales are known to occur, and where

vessel strikes have occurred or are expected to occur, and should be implemented in these areas even when whales have not been observed by Lookouts. Another commenter recommended focusing on vessel speeds and their impact on marine mammal safety to mitigate the risks associated with high-speed vessel travel and including revised protocols.

2. The 2023 HSTT proposed rule also requires that Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area. The commenter stated that NMFS should attach specific actions required of other vessels in the area, including a 10 kn (18.5 km per hour) ship speed, when a Navy vessel strike has been reported, in order to reduce the risk of further strikes. The commenter stated that these alerts should also go to non-Navy vessels in the vicinity that pose a risk to whales.

3. The 2023 HSTT proposed rule modified the requirement for awareness messages disseminated in Southern California. The commenter stated that it supports the use of more accurate seasonal information to inform large whale awareness messages, but expects awareness and alerts to be tied to more robust mitigation action, and recommends that if a marine mammal is spotted, NMFS should require a mandatory 10 kn (18.5 km per hour) ship speed limit.

4. The 2023 HSTT proposed rule also contains a new mitigation measure in which Navy personnel would issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in a select area of SOCAL (Of note, the four whales do not have to be the same species and do not have to be part of the same group (e.g., two whales of one species sighted at a distance off the port side at 500 yards (yd; 457.2 m) and two more whales of another species sighted off the starboard side at 500 yd (457.2 m) would be considered an aggregation under this measure)). The commenter recommended that (a) this should apply any time a whale is sighted (*i.e.*, Navy should not have to observe at least four whales to trigger this measure), (b) this should have no geographic limitation, and (c) this should trigger a mandatory 10 kn (18.5 km per hour) ship speed limit.

5. A commenter stated that the Navy will evaluate future revisions to online or DVD Marine Species Awareness Training (MSAT) video training to emphasize that when a protected species is spotted, this may be an indicator that additional marine

mammals are present and nearby, and the vessel should take this into consideration when transiting. The commenter stated that this purported mitigation measure should be more forceful; when a protected species is spotted, protective actions must result.

Response: Under the MMPA, NMFS' least practicable adverse impact determination for military readiness activities must include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (16 U.S.C. 1371(a)(5)(a)(iii)). The recommendation for NMFS to require, in some cases a reduction in speed, and in other cases a 10 kn (18.5 km per hour) speed limit, generally speaking, is impracticable because these speed reductions and further reductions to Navy vessel speeds negatively impact mission effectiveness. The Navy is unable to impose a 10 kn (18.5 km per hour) ship speed limit because it would not be practical to implement and would impact the effectiveness of Navy's activities by putting constraints on training and testing. The Navy requires flexibility in the use of variable ship speeds for training, testing, operational, safety, and engineering qualification requirements. Navy ships typically use the lowest speed practical given individual mission needs. NMFS has reviewed the Navy's analysis of these additional restrictions and the impacts they would have on military readiness and concurs with the Navy's assessment that they are impracticable. That said, NMFS has strengthened its mitigation requirement requiring Navy personnel to maneuver if marine mammals are observed to add "which may include reducing speed as the mission or circumstances allow" to emphasize that reduction of speeds should be considered where appropriate. Of note, current Navy Standard Operating Procedures and mitigations require a minimum of at least three Lookouts on duty on Navy cruisers and destroyers while underway and, so long as safety of navigation is maintained, to keep 500 yards away from large whales and 200 yards away from other marine mammals (except for bow-riding dolphins and pinnipeds hauled out on shore or man-made navigational structures, port structures, and vessels).

Previously, the Navy commissioned a vessel density and speed report based on an analysis of Navy ship traffic in the HSTT Study Area between 2011 and 2015. Median speed of all Navy vessels within the HSTT Study Area is typically already low, with median speeds between 5 and 12 kn (9.2 to 22.2 km per

hour). Further, the presence and transits of commercial and recreational vessels, annually numbering in the thousands, poses a more significant risk to large whales than the presence of Navy vessels. The *Vessel Strike* subsection of the *Estimated Take of Marine Mammals* section of the 2020 HSTT final rule and this rule and the 2018 HSTT FEIS/OEIS chapter 3 (Affected Environment and Environmental Consequences) section 3.7.3.4.1 (Impacts from Vessels and In-Water Devices) and Appendix K, section K.4.1.6.2 (San Diego (Arc) Blue Whale Feeding Area Mitigation Considerations), explain the important differences between most Navy vessels and their operation and commercial ships that make Navy vessels much less likely to strike a whale.

When developing Phase III mitigation measures, the Navy analyzed the potential for implementing additional types of mitigation, such as vessel speed restrictions within the HSTT Study Area. The Navy determined that based on how the training and testing activities will be conducted within the HSTT Study Area, vessel speed restrictions would be incompatible with practicability criteria for safety, sustainability, and training and testing missions, as described in chapter 5 (Mitigation), section 5.3.4.1 (Vessel Movement) of the 2018 HSTT FEIS/OEIS. NMFS fully reviewed this analysis and concurs with the Navy's conclusions. During the promulgation of this final rule, NMFS again discussed the potential for vessel speed restrictions, including during limited times and areas, and Navy continued to assert that such restrictions are not practicable. After thorough discussion, NMFS again concurs with the Navy's conclusions.

Regarding the recommendation for Navy to send alerts of increased risk of strike to non-Navy vessels (such as through the WhaleAlert app), Navy has informed NMFS that transmitting information between Navy and civilian vessels poses security risks that make sending alerts to non-Navy vessels impracticable.

Regarding the recommendations for the measure described in number 4 to be implemented when a single whale is sighted and in all areas, Navy asserts that doing so is not practicable as it would interfere with its mission success. Four whales was determined to be the appropriate trigger for this measure as it represents an increased strike risk without occurring so often that this measure becomes impracticable for the Navy to implement. Regarding the geographic limitations, this measure would apply to the area between 32–33

degrees North and 117.2–119.5 degrees West, which includes the locations where recent (2009, 2021, 2023) strikes occurred, and historic locations where strikes occurred when precise latitude and longitude were known. Given that this area includes the location where all known strikes have occurred, NMFS anticipates that this measure is of particular importance in this area, and Navy asserted that implementing this measure more broadly would be impracticable, as it could divert the attention of bridge personnel from other critical tasks.

As stated by the commenter, the Navy will evaluate future revisions to online or DVD MSAT video training to emphasize that when a protected species is spotted, this may be an indicator that additional marine mammals are present and nearby, and the vessel should take this into consideration when transiting. NMFS does not dictate exactly what measure must be taken, as different situations warrant different actions and may have different safety and practicability considerations.

The 2023 HSTT proposed rule and this final rule include two new mitigation measures beyond that required by the 2020 HSTT final rule and modification of two existing mitigation measures. Please see NMFS' response to Comment 15.

With the exception of the recommended mitigation measures discussed within this Comments and Responses section, the commenter has not demonstrated why NMFS has not met the least practicable adverse impact standard. As described in the Mitigation Measures section of this final rule, NMFS has included the mitigation requirements necessary to achieve the least practicable adverse impact on the affected species or stocks and their habitat.

Comment 15: Multiple commenters stated that, rather than authorizing additional take by serious injury or mortality by vessel strike, NMFS should require the Navy to implement additional mitigation measures to avoid harassment and future vessel strikes of large whales. Commenters specifically referenced the 2021 Royal Australian Navy vessel strikes of fin whales, with one commenter referencing what it describes as NMFS' acknowledgement of the susceptibility of fin whales to vessel strike year-round, and another stating that the Royal Australian Navy vessel strikes should be factored into the take calculation for the HSTT Study Area.

In a related comment, a commenter questioned whether the Navy can

continuously keep asking for more takes if they continue to reach their authorized number.

Response: Based on the available information at the time that the 2020 HSTT final rule was promulgated, NMFS' analysis suggested that three takes by serious injury or mortality by vessel strike over the 7-year duration of the HSTT rule could occur. To date, NMFS is aware of three confirmed vessel strikes of large whales by U.S. Navy vessels during the current regulatory period. While those three takes are within what NMFS anticipated could occur, given that three years remained of the effective period of the rule when the first two strikes occurred, the Navy reanalyzed the potential for take by mortality and serious injury by vessel strike over the duration of the rule, and that analysis suggested that additional takes could occur. NMFS' subsequent analysis also suggested that two additional takes could occur over the remainder of the regulatory period. NMFS requires the Navy to implement mitigation measures to reduce the potential for vessel strike; however, this mitigation is not quantitatively incorporated into NMFS' analysis, and therefore, does not reduce the number of takes that NMFS authorizes.

Regarding mitigation, the 2023 HSTT proposed rule and this final rule include two new mitigation measures beyond that required by the 2020 HSTT final rule and modification of two existing mitigation measures. The new measures include:

- Navy personnel must issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in a select area of SOCAL; and
- Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area.

Additionally, the 2020 HSTT final rule (85 FR 41780, July 10, 2020) requires Navy personnel to issue seasonal awareness notification messages to alert ships and aircraft to the possible presence of blue whales, humpback whales, gray whales, and fin whales in the seasons that they are most likely to occur in the HSTT Study Area. These messages assist in maintaining safety of navigation and in avoiding interactions with large whales during transits. This final rule requires the Navy to re-title the spring blue whale message (released in June) to a large whale awareness message inclusive of typical spring-summer large whales in southern California (mainly blue, fin, and humpback whales), as included in the 2023 HSTT proposed rule.

Furthermore, rather than tying the message release to a specific month, the message would be for a period based on predicted oceanographic conditions for a given year.

For vessel movement, the 2020 HSTT final rule (85 FR 41780, July 10, 2020) required that "when underway, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance." This measure has been updated to state that reducing speed may be an appropriate way to maneuver, as included in the 2023 HSTT proposed rule. Please see the Mitigation Measures section for a full discussion of these new and revised measures.

NMFS anticipates that additional vessel strike of large whales could still occur even in consideration of these additional and modified mitigation measures (noting that the mitigation measures are not quantitatively included in the vessel strike calculation). Therefore, NMFS is authorizing two additional takes of large whales by serious injury or mortality by vessel strike over the 7-year duration of the HSTT rule (two takes in addition to the three takes authorized in the current regulations). In the 2023 HSTT proposed rule and this final rule, NMFS describes factors that make fin whales particularly susceptible to vessel strike by the Navy in southern California (e.g., occurrence, Navy vessel strike history in SOCAL, year-round occurrence). As such, NMFS analysis suggests that of the five total takes by serious injury or mortality by vessel strike of large whales, up to four of those takes could be of the CA/OR/WA stock of fin whale. Regarding the suggestion that the Royal Australian Navy vessel strike of two fin whales should be factored into the take calculation for the HSTT Study Area, as explained in the 2023 HSTT proposed rule and in the Vessel Strike section of this final rule, according to the U.S. Navy, the May 2021 vessel strike of two fin whales by a Royal Australian Navy vessel did not occur while that vessel was participating in a U.S. Navy-led training exercise, and the strike of those two fin whales is not included in the estimated take by vessel strike calculation. Instead, NMFS considered the 2021 vessel strike by the Royal Australian Navy along with other strike information when determining which species could be among the estimated large whales struck.

Regarding a commenter's concern about whether the Navy can continuously keep asking for more takes if they continue to reach their authorized number, as stated in the

Background section of this final rule, an authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stocks and will not have an unmitigable adverse impact on the availability of the species or stocks for taking for subsistence uses (where relevant) (16 U.S.C. 1371(a)(5)(A)). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in this rule as "mitigation measures"); and requirements pertaining to the monitoring and reporting of such takings (16 U.S.C. 1371(a)(5)(A)). NMFS has made the required findings, and therefore, it must issue the requested incidental take authorization to the Navy.

Comment 16: The 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) states: "The 2021 NAVDORM requires the use of three Lookouts on Navy cruisers and destroyers as compared to the previous requirement of one Lookout when a vessel was underway and not engaged in sonar training or testing. However, as discussed in the Mitigation Measures section below, the Navy informed NMFS that requiring the additional Lookouts as mitigation is not practicable because this SOP may change in response to manning issues and national security needs." A commenter stated that NMFS should reject the Navy's explanation for why three lookouts on cruisers and destroyers are not practicable. In a related comment, a commenter stated that the 2023 HSTT proposed rule seeks to reduce the number of lookouts (the simplest and cheapest mitigation strategy) from three to one, and recommended increased numbers of lookouts as a mitigation measure. This commenter also recommended enhancing bridge resource management. A commenter also recommended training for Lookouts.

Response: Neither the 2023 HSTT proposed rule nor this final rule propose a reduction in the number of lookouts required on Navy vessels, and it is unclear what the commenter means by enhancing bridge resource management, though it is important to note that all bridge watchstanders including Lookouts take the Navy's Marine Species Awareness Training that NMFS has reviewed and approved. The

commenter did not suggest what additional training Lookouts should receive. As a general matter, NMFS' evaluation of least practicable adverse impact appropriately relies heavily on input from the applicant regarding the practicability of any given measure provided the explanation is reasonable and clear. Further, the 2004 NDAA amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of "least practicable adverse impact" shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity and consultation with the Department of Defense on these considerations (see 16 U.S.C. 1371(a)(5)(A)(iii)). The Navy has clearly indicated the need for flexibility to effectively carry out foreseeable military readiness activities, such that requiring additional Lookouts at all times would be impracticable, and we concur with that assessment.

Comment 17: A commenter stated that if the Navy is allowed a greater number of incidental takes on marine life, it must enforce strategies to avoid such incidents and suggested that the Navy expand its existing precautions to protect marine life and minimize takes of marine animals. The commenter encourages the Navy to (1) continue implementing state-of-the-art technology and best practices to reduce underwater noise and disturbance during training exercises, particularly in areas where marine mammals are known to inhabit, (2) collaborate with marine biologists and conservation experts to continually monitor the effects of Navy activities on marine life and suggest corrective actions when necessary, (3) consider adjusting the timing or location of training exercises to minimize their impact on critical marine habitats and migration paths, and (4) promote transparency and cooperation by engaging with environmental organizations and local communities to develop and assess mitigation strategies collaboratively. In a related comment, another commenter stated that advanced technologies should allow the United States military to maintain readiness standards and protect wildlife.

Response: NMFS worked closely with the Navy to investigate the recent vessel strikes and to identify ways to improve mitigation measures. This final rule includes revision to two existing mitigation measures and two new mitigation measures beyond that included in the 2020 HSTT final rule (85 FR 41780, July 10, 2020; described

further in response to Comment 15). Of note, this final rule authorizes additional take by serious injury or mortality by vessel strike beyond that authorized by the 2020 HSTT final rule. This final rule does not authorize additional take by Level A or Level B harassment. However, as discussed in the Mitigation Measures section of this final rule, elsewhere in this section, and in chapter 5 (Mitigation) of the 2018 HSTT FSEIS/OEIS, the Navy will implement extensive mitigation, both procedural mitigation and mitigation areas, to avoid or reduce potential impacts from the HSTT activities on marine mammals, including impacts from sonar and explosives. (Note that additional measures and revisions to some existing measures have been made since publication of this FEIS/OEIS). Specifically, the Navy would use a combination of delayed starts, powerdowns, and shutdowns to minimize the likelihood of M/SI, minimize the likelihood or severity of PTS or other injury, and reduce instances of TTS or more severe behavioral disruption caused by acoustic sources or explosives. The Navy will limit activities (active sonar, explosive use, major training exercises (MTEs), *etc.*) to varying degrees in multiple areas that are important to sensitive species or for critical behaviors in order to minimize impacts that are more likely to lead to adverse effects on rates of recruitment or survival. The mitigation measures would reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, vessel strike, and impacts to marine mammal habitat. Please see the Mitigation Measures section of this final rule for additional detail regarding required mitigation measures.

Regarding best practices to reduce underwater noise, most of the Navy's vessels already have state of the art quieting technologies employed to reduce their sound profile to assist them in avoiding detection by enemy forces, therefore, they are much quieter than commercial/recreational vessels of similar sizes.

Regarding monitoring the effects of Navy activities on marine life and the commenter's recommendation to take corrective actions when necessary, as required by this final rule, the Navy implements a robust monitoring program. Although the Navy has been conducting research and monitoring in the HSTT Study Area for over 20 years, it developed a formal marine species monitoring program in support of the MMPA and ESA authorizations for the Hawaii and Southern California range

complexes in 2009. This robust program has resulted in hundreds of technical reports and publications on marine mammals that have informed Navy and NMFS analyses in environmental planning documents, rules, and Biological Opinions. The reports are made available to the public on the Navy's marine species monitoring website (www.navy-marine-species-monitoring.us) and the data on the Ocean Biogeographic Information System Spatial Ecological Analysis of Megavertebrate Populations (OBIS-SEAMAP) (www.seamap.env.duke.edu). For additional information about the Navy's monitoring program, please see the Monitoring section herein and the websites listed above.

Further, the regulations governing the take of marine mammals incidental to Navy training activities in the HSTT Study Area contain an adaptive management component. Our understanding of the effects of Navy training and testing activities (*e.g.*, acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of 7-year regulations. Please see the Adaptive Management section of this final rule for additional information.

Regarding transparency and cooperation, the MMPA does not require an independent review of mitigation measures. It does require notice and opportunity for public comment (16 U.S.C. 1371(a)(5)(A)(i)). The public comment period is a means by which the public (*e.g.*, environmental organizations and local communities) are able to provide NMFS with mitigation measure recommendations supported by scientific evidence that NMFS takes into consideration when finalizing the rulemaking.

Comment 18: A commenter stated that measures should be taken to cease any more actions potentially impacting marine mammals. The 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) states that results of a study indicated that Navy Lookout Teams, which include lookouts and other crew members, have approximately an 80 percent chance of failing to detect a pod of large whales beyond 200 yd (182.9 m), compared with a 49 percent chance for trained marine mammal observers. The commenter recommended that the Navy hire trained marine mammal observers to keep the incidents of whale take to the original take numbers or less, and not need to have modifications to the LOA for additional animal take. The

commenter also recommended having experts that can accurately assess the physical and mental health of these animals. In a related comment, a commenter stated that the rule calls into question whether the three vessel strikes that have occurred were due to the crew not spotting the whales, not spotting them before the strike, or the Navy not emphasizing the importance of spotting and avoiding marine wildlife to its personnel.

Response: As described in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), a recent study by Oedekoven and Thomas (2022) was designed to evaluate the effectiveness of Navy Lookouts at detecting marine mammals before they entered a defined set of mitigation zones (*i.e.*, 200, 500, and 1,000 yd (182.9, 457.2, and 914.4 m)) during MFAS training activities. This study also compared Lookout effectiveness with that of trained marine mammal observers. Lookout teams were comprised of varying numbers of Lookouts depending on the type of ship and the training activity that was occurring (noting that the data was collected prior to the Navy's change in its SOPs to require the use of three Lookouts on Navy cruisers and destroyers). Marine mammal observer teams consisted of two dedicated observers. As noted by the commenter, results of this study indicate that Navy Lookout Teams, which include Lookouts and other crew members, have approximately an 80 percent chance of failing to detect a pod of large baleen whales (rorquals) before they come closer than a mitigation range of 200 yd (182.9 m), compared with a 49 percent chance for trained marine mammal observers. The probability of a pod remaining undetected by Lookouts was greater for larger mitigation zones (*i.e.*, 85 percent at 500 yd (457.2 m); 91 percent at 1,000 yd (914.4 m)). These values require some level of interpretation with regard to the numerical results. For instance, the study's statistical model assumed that Navy ships moved in a straight line at a set speed for the duration of the field trials, and that animals could not move in a direction perpendicular to a ship. Violation of this model assumption would underestimate Lookout effectiveness for some data points. The values for both Navy Lookouts and the Marine Mammal Observers include animals under the water that would not have been available for detection by a Lookout. This study suggests that detection of marine mammals is less certain than previously assumed at certain distances. While this study

suggests that trained marine mammal observers are more effective than Navy Lookouts, the Navy has asserted that it is impracticable to station independent marine mammal observers on Navy vessels. When making the least practicable adverse impact determination for military readiness activities, NMFS must consider personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activities and must consult with the Department of Defense on these considerations (16 U.S.C. 1371(a)(5)(A)(iii)). As described in section 5.5.5 (Third-Party Observers) of the 2018 HSTT FEIS/OEIS, use of third-party observers on Navy vessels or aircraft would result in safety and security clearance issues, berthing shortages or exceedance of other space limitations, impacts to Lookouts' abilities to complete their other mission-essential duties, and unsustainable costs, among other issues. Please see the 2018 HSTT FEIS/OEIS for additional detail.

Lookouts remain an important component of the Navy's mitigation strategy, especially as it relates to minimizing exposure to the more harmful impacts that may occur within closer proximity to the source, where Lookouts are most effective. Further, NMFS and the Navy are also considering, through the adaptive management process, whether there are additional measures that would be practicable to implement that would improve effectiveness of Lookouts, such as enhanced personnel training.

As described in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), the 2021 U.S. Navy vessel strikes were the first known U.S. Navy vessel strikes in the HSTT Study Area since 2009. Historically, military vessel strikes of large whales within the HSTT Study Area have been rare events with only seven such strikes occurring over the past 14 years, five U.S. Navy strikes, and two Royal Australian Navy strikes. Based on the Navy and NMFS' investigation of these recent strike incidents, NMFS found that the Navy was substantially following the required mitigation protocols, consistent with 16 U.S.C. 1371(a)(5)(B). These recent vessel strike reports (2021, 2023) appear to reflect the sporadic, episodic, or clustered nature of vessel strike or may reflect a trend of increased large whale presence in this area in the early summer months. Given the size of Navy vessels and the need to maintain specific speeds during certain activities, even if a whale is detected, a U.S. Navy vessel may not be able to avoid a strike.

Therefore, given the potential shift in factors contributing to vessel strike, and the challenges in avoiding potential strikes, it is important to ensure that the compliance process addresses the appropriate number of potential strikes and that they are considered in the negligible impact determination, which is why it was necessary to evaluate the authorization of an additional two takes by strike. The MMPA provides for the authorization of incidental take caused by specified activities, provided certain findings are made. The law directs NMFS to process adequate and complete applications for incidental take authorization, and issue the authorization provided all statutory findings and requirements, as well as all associated legal requirements, are met.

It is unclear how having experts that can accurately assess the physical and mental health of these animals, as suggested by the commenter, would assist in mitigating the effects of the Navy's activities, nor has the commenter provided detail explaining how. The required procedural mitigation measures are implemented within defined ranges based on established criteria, and implementation does not rely on a visual assessment of behavioral or physiological effects to animals. In its analysis, NMFS does consider the potential impacts of stress on marine mammals from exposure to the Navy's activities. Please see the Stress Response section of the 2018 HSTT Proposed Rule for a discussion of stress responses in marine mammals. Further, since that discussion, additional information about stress responses has become available (*e.g.*, Houser *et al.* (2020); Houser *et al.* (2021)). However, the additional studies do not change the expected potential impacts of stress on marine mammals from exposure to the Navy's activities.

NMFS thoroughly discussed each of the strikes with the Navy, and summarized the circumstances surrounding each strike in the *Estimated Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section of the 2023 HSTT proposed rule ((88 FR 68290, October 3, 2023) and the *Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section of this final rule. The circumstances surrounding whale detection ahead of each strike varied. However, of note, Navy vessels routinely successfully maneuver to avoid large whales. Between 2009 and 2021 (the most recent year for which data is available), U.S. Navy vessels in the SOCAL portion of the HSTT Study Area maneuvered 316 times to avoid large whales during MTEs. The years

2017 and 2021 had the highest number of maneuvers ($n = 64$ and $n = 82$, respectively). In all years for which data is available (2009 to 2021), Navy cruisers and destroyers account for 51 to 100 percent of maneuvers during MTEs to avoid whales.

Comment 19: A commenter, referencing two news articles, stated that new information indicates that the Navy is increasingly using unmanned systems, which cannot replace human monitoring, even if useful in addition to the lookouts and observers NMFS relies on to mitigate and monitor the impacts of the Navy's activities on marine mammals.

Response: As stated in the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023), the Navy's proposed activities have not changed from that analyzed in the 2018 final rule (83 FR 66846, December 27, 2018) or the 2020 final rule (85 FR 41780, July 10, 2020). Impacts from all unmanned systems that would be used in training and testing activities under this proposed rule have been accounted for in the analysis. Neither NMFS nor the Navy have proposed to replace human marine mammal monitoring with monitoring by unmanned systems.

Determinations

Comment 20: A commenter stated that NMFS has neither adequately evaluated nor met the negligible impact standard for the following reasons:

1. The negligible impact determination dismisses the important fact that vessel strikes already pose a substantial threat to large whales in the region, and several populations are already exceeding PBR. Endangered blue whales, threatened and endangered humpback whales, and endangered fin whales off the coast of Southern California are particularly vulnerable, with even one additional ship strike constituting a significant impact.

2. NMFS has failed to consider the impacts of the full scope of training exercises over 7 years on marine mammals, including joint training exercises with foreign fleets. The commenter further asserted that what is not unsaid in the rule, but is critically important, is that the Navy's activities over 7 years (in contrast to the five already authorized) has never been evaluated under the MMPA, ESA, or NEPA. The commenter stated that this underscores that NMFS has not taken the measures needed to ensure the Navy's activities in the HSTT Study Area will have no more than a negligible impact on endangered whales and other marine mammals in the Pacific Ocean over the full 7 years of the proposed

authorization. NMFS must reexamine the increased risk and incidence of vessel strikes in light of the Navy's full suite of impacts on large whales and other marine mammals (over this extended period of time) and decline to authorize this additional take.

Response: NMFS disagrees with the commenter's assertion that it has not adequately evaluated nor met the negligible impact standard. NMFS assessed all of the best available information about the relative risk of vessel strikes by commercial, recreational, and military vessels in the Vessel Strike section of this final rule. As explained in the Serious Injury or Mortality subsection of the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule, the 2020 HSTT final rule, and this final rule, NMFS may find the impact of the authorized take from a specified activity to be negligible even if total human-caused mortality exceeds PBR, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.*, other than the specified activities covered by the incidental take authorization in consideration, including vessel strike from other actions). When those considerations are applied in the section 101(a)(5)(A) context here, the authorized lethal take (0.14 annually) of humpback whales from the Mainland Mexico- CA/OR/WA stock, and blue whales from the Eastern North Pacific stock are less than 10 percent of PBR (less than 1 percent for humpback whales from the Mainland Mexico- CA/OR/WA stock and 3 percent for blue whales from the Eastern North Pacific stock). The authorized lethal take (0.57 annually) of fin whales from the CA/OR/WA stock is less than 10 percent of PBR also (less than 1 percent). There are management measures in place to address the mortality and serious injury from the activities other than those the Navy is conducting. For the complete discussion of how NMFS carefully considered potential mortalities from the Navy's activities in light of PBR levels, including an explanation for why mortality above PBR will not necessarily induce population-level non-negligible impacts, see the discussion in this rule, the 2020 HSTT final rule, and the 2018 HSTT final rule.

NMFS acknowledges that the removal of a reproductive female (or any female) could be more impactful to the status of a population than the removal of a male. However, the PBR framework that supports the negligible impact finding

inherently considers the likelihood that the human-caused mortalities being considered may consist of a random distribution of individuals of different sex in different life stages. Also, beyond the low likelihood of striking a whale at all, the likelihood of hitting a female is even lower.

It is important to note that the only change to the number of takes proposed by the 2023 HSTT proposed rule was to the take by vessel strike to account for new information since publication of the 2020 HSTT final rule. The 2020 HSTT final rule analyzed and authorized take of marine mammals over a 7-year period, not 5 years as noted by the commenter, and NMFS conducted the appropriate level of MMPA, ESA, and NEPA analysis to comply with both statutes during the promulgation of the 2020 HSTT final rule.

As stated in the Preliminary Analysis and Negligible Impact Determination section of the 2023 HSTT proposed rule (88 FR 68290, October 3, 2023) and the Analysis and Negligible Impact Determination section of this final rule, while this rule consists of a modification of take by M/SI by vessel strike, NMFS considers the impacts of the entire specified activity and the total taking in the negligible impact determination. In consideration of the total taking, including take by mortality, Level A harassment, and Level B harassment, NMFS finds that the incidental take from the specified activities will have a negligible impact on all affected marine mammal species and stocks. Consistent with 40 CFR 1502.9 and the information and analysis contained in this final rule, the Navy and NMFS as a cooperating agency made a determination that this final rule and the subsequent LOAs will not result in significant impacts that were not fully considered in the 2018 HSTT FEIS/OEIS. As indicated in the 2023 HSTT proposed rule, the Navy has made no substantial changes to the activities nor are there significant new circumstances or information relevant to environmental concerns or their impacts.

NMFS and the Navy reinitiated consultation under the ESA. NMFS issued a reinitiated Biological and Conference Opinion on June 3, 2024 concluding that the issuance of the 2024 HSTT final rule and subsequent LOAs are not likely to jeopardize the continued existence of the threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the HSTT Study Area. The opinion is

available at <https://doi.org/10.25923/7y9x-vw84>.

Please also see NMFS' response to Comment 7 regarding foreign vessels.

Comment 21: Commenters stated that they oppose this proposed promulgation of modified regulations and associated LOAs for the Navy because it is not consistent with MMPA mandates that require NMFS to ensure activities have no more than a negligible impact on marine mammal species or stocks and that they have the least practicable adverse impact on marine mammal species, stocks, and habitat. In a related comment, a commenter stated that this rule would disregard the previously established boundaries between the Navy and NMFS and would also disregard the push the United States claims to have for the protection of marine wildlife. The commenter stated that it perceives the request to be heavily hypocritical of the same government that implemented regulations to protect marine wildlife that teeter on the edge of the endangered species list, to reach for an exception for its military, and further that the proposed amendment is unethical, hypocritical, and unnecessary.

Response: The MMPA requires NMFS to authorize the incidental take of marine mammals by specified activities upon request if certain findings are made (16 U.S.C. 1371(a)(5)(A)). Here, the Navy submitted an application requesting two additional takes of large whales by serious injury or mortality by vessel strike through modification of the existing regulations and LOAs. As required by the MMPA, NMFS conducted the analysis described in the 2023 HSTT proposed rule and this final rule and made all required findings (preliminarily, in the case of the 2023 HSTT proposed rule), including finding that the Navy's activities will have a negligible impact on marine mammals and that the required mitigation measures will effect the least practicable adverse impact on marine mammals. Therefore, promulgation of this final rule is appropriate.

Please see the Mitigation Measures section of this final rule for additional discussion of the required mitigation measures and NMFS' least practicable adverse impact finding.

Other Regulatory Processes

Comment 22: A commenter stated that the Navy issued an EIS purporting to analyze the environmental impacts of its training and testing activities in the HSTT Study Area. NMFS was a cooperating agency for the 2018 HSTT FEIS/OEIS. The EIS considered only three alternatives in detail: the No

Action Alternative under which the Navy's training activities would not occur; Alternative 1 that considered fluctuations in training cycles, testing requirements, and deployment schedules based on global demand and other factors and included the Navy's entire suite of mitigation measures; and Alternative 2 that considered a higher number of training exercises and sonar hours than in Alternative 1 and included the Navy's entire suite of mitigation measures. Alternative 1 was the preferred and adopted alternative. The commenter stated that none of the Navy's alternatives considered in detail an alternative that would require mandatory speed limits to avoid collisions with endangered whales.

Response: While none of the Navy's alternatives considered in the 2018 HSTT FEIS/OEIS include mandatory vessel speed limits, the Navy conducted an operational analysis of potential mitigation throughout the entire Study Area to consider a wide range of mitigation options, including but not limited to vessel speed restrictions. As discussed in chapter 3, section 3.0.3.3.4.1 (Vessels and In-Water Devices) of the 2018 HSTT FEIS/OEIS, Navy ships transit at speeds that are optimal for fuel conservation or to meet operational requirements. Operational input indicated that implementing additional vessel speed restrictions beyond what is identified in chapter 5 (Mitigation), section 5.4 (Mitigation Areas to be Implemented) of the 2018 HSTT FEIS/OEIS would be impracticable to implement due to implications for safety and sustainability. In its assessment of potential mitigation, the Navy considered implementing additional vessel speed restrictions (e.g., expanding the 10 kn (18.5 km per hour) restriction to other activities). The Navy determined that implementing additional vessel speed restrictions beyond what is described in chapter 5 (Mitigation), section 5.5.2.2 (Restricting Vessel Speed) of the 2018 HSTT FEIS/OEIS would be impracticable due to implications for safety (the ability to avoid potential hazards), sustainability (maintain readiness), and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives.

Additionally, as described in chapter 5 (Mitigation), section 5.5.2.2 (Restricting Vessel Speed) of the 2018 HSTT FEIS/OEIS, any additional vessel speed restrictions would prevent vessel operators from gaining skill proficiency, would prevent the Navy from properly testing vessel capabilities, or would

increase the time on station during training or testing activities as required to achieve skill proficiency or properly test vessel capabilities, which would significantly increase fuel consumption. As discussed in chapter 5 (Mitigation), section 5.3.4.1 (Vessel Movement) of the 2018 HSTT FEIS/OEIS, the Navy implements mitigation to avoid vessel strikes throughout the Study Area. Additionally, this final rule includes two new mitigation measures beyond that required by the 2020 HSTT final rule and modification of two existing mitigation measures. These measures are described in response to Comment 15 and the Mitigation Measures section of this final rule.

Comment 23: A commenter stated that agencies must prepare supplemental EISs if: "(i) The agency makes substantial changes in 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" (40 CFR 1502.9(d)(1)). The commenter stated that because these triggers have been met, it urges NMFS to prepare a supplemental EIS on the basis of the new information that has come to light since 2018, including on the impacts of vessel strikes on large whales and on alternatives that reduce vessel strike impacts to marine mammals.

Response: NMFS disagrees with the commenter that supplemental NEPA evaluation is warranted. As described in the *National Environmental Policy Act* section herein, consistent with 40 CFR 1502.9(d) and the information and analysis contained in this rule, the Navy and NMFS as a cooperating agency have determined that this final rule and any subsequent LOAs would not result in significant impacts that were not fully considered in the 2018 HSTT FEIS/OEIS. As indicated in this final rule and a supplemental information report prepared by NMFS, the Navy has made no substantial changes to the activities that are relevant to environmental concerns; nor are there substantial new circumstances or information about the significance of adverse effects that bear on the analysis.

Comment 24: A commenter stated that despite the new 2020 authorization—and the additional extensive take and other impacts it enables—NMFS has not completed new ESA consultation or a supplemental NEPA evaluation. The Navy is operating under the 2018 BiOp and 2018 EIS. Since NMFS issued the 2018 BiOp and EIS, a slew of new information—in addition to the expanded scope of the Navy's

activities—indicates that the Navy’s activities in the HSTT Study Area are likely affecting ESA-listed species to an extent not previously considered.

In a related comment regarding ESA compliance, a commenter stated that the proposed rule states, “NMFS has also reinitiated consultation internally on the issuance of these proposed, revised regulations and LOAs under section 101(a)(5)(A) of the MMPA.” The commenter noted that when reinitiation is required, “the original opinion loses its validity, as does its accompanying incidental take statement, which then no longer shields the action agency from penalties for takings” (*Ctr. for Biological Diversity v. BLM*, 698 F.3d 1101, 1108 (9th Cir. 2012)). A commenter stated that it awaits the conclusion of this reinitiated consultation and expects a revised biological opinion that fully complies with the ESA’s standards.

Response: NMFS has fully complied with the ESA and NEPA. NMFS described the ESA section 7 consultation history for this action in the *Endangered Species Act* section of the 2023 HSTT proposed rule and this final rule. As described in that section, NMFS consulted internally on the issuance of the 2018 HSTT regulations and LOAs under section 101(a)(5)(A) of the MMPA.

NMFS issued a Biological Opinion on December 10, 2018 concluding that the issuance of the 2018 HSTT final rule and subsequent LOAs are not likely to jeopardize the continued existence of the threatened and endangered species under NMFS’ jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the HSTT Study Area. The 2018 Biological Opinion included specified conditions under which NMFS would be required to reinitiate section 7 consultation. NMFS reviewed these specified conditions for the 2020 HSTT rulemaking and determined that reinitiation of consultation was not warranted. The incidental take statement that accompanied the 2018 Biological Opinion was amended to cover the 7-year period of the 2020 HSTT rule. The 2018 Biological Opinion for this action is available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>.

The 2018 Biological Opinion reinitiation clause (2), states that formal consultation should be reinitiated if “new information reveals effects of the agency action that may affect ESA-listed species or critical habitat in a manner or to an extent not previously considered.” Given the new information regarding

the recent occurrence of large whale strikes by naval vessels in the southern California portion of the HSTT Study Area, as described herein, the Navy has reinitiated consultation with NMFS pursuant to section 7 of the ESA for HSTT Study Area activities, and NMFS has also reinitiated consultation internally on the issuance of the revised regulations and LOAs under section 101(a)(5)(A) of the MMPA. On June 3, 2024, NMFS issued a 2024 reinitiated Biological and Conference Opinion concluding that the issuance of the rule and subsequent LOAs is not likely to jeopardize the continued existence of the threatened and endangered species under NMFS’ jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the HSTT Study Area. The 2024 reinitiated Biological and Conference Opinion for this action is available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>.

NMFS is aware of the statement in *Ctr. for Biological Diversity v. BLM*, 698 F.3d 1101, 1108 (9th Cir. 2012) referenced by the commenter. NMFS’ position is that a biological opinion, including its Incidental Take Statement, for which formal consultation has been re-initiated remains valid and effective during the consultation and until a new biological opinion is issued. When the new biological opinion with a new ITS is issued, it supersedes and replaces the previous opinion and ITS.

Please see NMFS’ response to Comment 23 regarding NEPA compliance.

Changes From the Proposed Rule to the Final Rule

NMFS has added two additional reporting requirements since publication of the 2023 HSTT proposed rule. First, the Navy’s annual HSTT Training Exercise Report and Testing Activity Report must include information that tracks the Navy’s implementation of the new SOCAL large whale aggregation real-time reporting mitigation measure. The report must include the following information for each instance that an aggregation of large whales is reported: (1) the date, time and general location (e.g., approximately 10–12 nmi SE of San Clemente Island) of the whales when the aggregation was first sighted; (2) the total number of whales observed within 1 nmi of a Navy vessel that make up the aggregation; and (3) the approximate distance (or distances if more than one group of whales is sighted) of the vessel from the whales in the aggregation when

the whales were first sighted. To the extent practicable, this information should be provided in the Navy’s unclassified version of these reports.

Second, the Navy’s annual HSTT Training Exercise Report and Testing Activity Report must include a confirmation that foreign military use of sonar and explosives, when such militaries are participating in a U.S. Navy-led exercise or event, combined with the U.S. Navy’s use of sonar and explosives, would not cause exceedance of the analyzed levels (within each NAEMO modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of the acoustic impacts effects analysis used to estimate take in this final rule.

NMFS has also made a non-substantive name change in the final rule. *Ziphius cavirostris* has multiple common names. In the 2018 HSTT final rule, 2020 HSTT final rule, and 2023 HSTT proposed rule, NMFS used the common name Cuvier’s beaked whale. In this final rule, NMFS uses the common name goose-beaked whale instead.

Last, NMFS made several non-substantive changes to the regulations to add clarity and improve readability.

Description of Marine Mammals and Their Habitat in the Area of the Specified Activities

Marine mammal species and their associated stocks that have the potential to occur in the HSTT Study Area are presented in table 1 along with the best/minimum abundance estimate and associated coefficient of variation value. Consistent with the 2018 HSTT final rule and 2020 HSTT final rule, the Navy anticipates the take of individuals from 38 marine mammal species by Level A harassment and Level B harassment incidental to training and testing activities from the use of sonar and other transducers, in-water detonations, air guns, and impact pile driving/vibratory extraction activities. As described in detail later, serious injury or mortality of six species is also analyzed and authorized. Two marine mammal species, the Hawaiian monk seal and the Main Hawaiian Islands Insular DPS of false killer whale, have critical habitat designated under the ESA (16 U.S.C. 1531 *et seq.*) in the HSTT Study Area.

In the 2018 HSTT proposed rule and 2018 HSTT final rule, we presented a detailed discussion of marine mammals and their occurrence in the HSTT Study Area, inclusive of important marine mammal habitat (e.g., ESA-designated critical habitat), BIAs, national marine sanctuaries (NMSs), and unusual

mortality events (UMEs). Please see these rules and the 2017 and 2019 Navy applications for additional information beyond what is provided herein. While there have been some minor changes described here, there have been no changes to important marine mammal habitat, NMSs, or ESA-designated critical habitat since the issuance of the 2018 HSTT final rule that change our determination of which species or stocks have the potential to be affected by the Navy's activities or the information in the *Description of Marine Mammals and Their Habitat in the Area of the Specified Activities* section in the 2019 HSTT proposed rule and 2020 HSTT final rule. Therefore, the information presented in those sections of the 2019 HSTT proposed rule and 2020 HSTT final rule remains current and valid with the exception of the information about UMEs, BIAs, and revised humpback whale stock structures, discussed below.

On April 21, 2021, NMFS designated critical habitat for the endangered Western North Pacific DPS, the endangered Central America DPS, and the threatened Mexico DPS of humpback whales (86 FR 21082). Areas proposed as critical habitat include specific marine areas located off the coasts of California, Oregon, Washington, and Alaska. None of the designated critical habitat overlaps with the HSTT Study Area. One of the proposed areas, critical habitat Unit 19,

would have overlapped with the SOCAL range in the HSTT Study Area but was excluded after consideration of potential national security and economic impacts of designation. NMFS, in the final rule designating critical habitat for humpback whales, identified prey species, primarily euphausiids and small pelagic schooling fishes of sufficient quality, abundance, and accessibility within humpback whale feeding areas to support feeding and population growth, as an essential habitat feature. NMFS, through a critical habitat review team (CHRT), also considered inclusion of migratory corridors and passage features, as well as sound and the soundscape, as essential habitat features. NMFS did not include either in the final critical habitat, however, as the CHRT concluded that the best available science did not allow for identification of any consistently used migratory corridors or definition of any physical, essential migratory or passage conditions for whales transiting between or within habitats of the three DPSs. The best available science also currently does not enable NMFS to identify particular sound levels or to describe a certain soundscape feature that is essential to the conservation of humpback whales. Regardless of whether critical habitat is designated for a particular area, NMFS has considered all applicable information regarding marine mammals and their habitat in

the analysis supporting these final regulations.

NMFS has reviewed the 2023 SARs (Carretta *et al.* 2024, Young *et al.* 2024). For all species except humpback whale, NMFS determined that neither the SARs nor any other new information changes our determination in the 2020 HSTT final rule of which species or stocks have the potential to be affected by the Navy's activities. For humpback whale, the 2023 final SARs include a revision to the humpback whale stock structure in the Pacific Ocean. In the 2020 HSTT final rule, NMFS authorized take of the CA/OR/WA stock and Central North Pacific stock of humpback whale. Given the revised stock structure, in this final rule, NMFS has reanalyzed the potential for take of each stock of humpback whale and determined that the Central America/Southern Mexico-CA/OR/WA, Mainland Mexico-CA/OR/WA stock, and Hawaii stocks are likely to be taken by the Navy's activities. Please refer to the 2023 Alaska and Pacific Ocean SARs for additional information about these new stocks.

The species considered but not carried forward for analysis are two American Samoa stocks of spinner dolphins—(1) the Kure and Midway stock and (2) the Pearl and Hermes stock. There is no potential for overlap with any stressors from Navy activities and therefore there would be no incidental takes, therefore, these stocks are not considered further.

TABLE 1—MARINE MAMMAL OCCURRENCE WITHIN THE HSTT STUDY AREA

Common name	Scientific name	Stock	Status		Occurrence	Seasonal absence	Stock abundance (CV)/minimum population
			MMPA	ESA			
Blue whale	<i>Balaenoptera musculus</i>	Eastern North Pacific ...	Strategic, Depleted	Endangered	Southern California.	-	1,898 (0.085)/1,767.
		Central North Pacific ...	Strategic, Depleted	Endangered	Hawaii	Summer	133 (1.09)/63.
Bryde's whale	<i>Balaenoptera brydei/edeni</i> .	Eastern Tropical Pacific	-	-	Southern California.	-	unknown.
Fin whale	<i>Balaenoptera physalus</i>	Hawaii	-	-	Hawaii	-	791 (0.29)/623.
		CA/OR/WA	Strategic, Depleted	Endangered	Southern California.	-	11,065 (0.405)/7,970.
		Hawaii	Strategic, Depleted	Endangered	Hawaii	Summer	203 (0.99)/101.
Humpback whale	<i>Megaptera novaeangliae</i> .	Central America/Southern Mexico—CA/OR/WA.	Strategic	Endangered ¹	Southern California.	Winter	1,496 (0.171)/1,284.
		Mainland Mexico—CA/OR/WA.	Strategic	Threatened ¹	Southern California.	Winter	3,477 (0.101)/3,185.
		Hawai'i	-	- ¹	Hawaii	Summer	11,278 (0.56)/7,265.
Minke whale	<i>Balaenoptera acutorostrata</i> .	CA/OR/WA	-	-	Southern California.	-	915 (0.792)/509.
Sei whale	<i>Balaenoptera borealis</i> ..	Hawaii	-	-	Hawaii	Summer	438 (1.05)/212.
		Eastern North Pacific ...	Strategic, Depleted	Endangered	Southern California.	-	864 (0.40)/625.
Gray whale	<i>Eschrichtius robustus</i> ...	Hawaii	Strategic, Depleted	Endangered	Hawaii	Summer	391 (0.9)/204.
		Eastern North Pacific ...	-	-	Southern California.	-	26,960 (0.05)/25,849.
		Western North Pacific ..	Strategic, Depleted	Endangered	Southern California.	-	290 (NA)/271.

TABLE 1—MARINE MAMMAL OCCURRENCE WITHIN THE HSTT STUDY AREA—Continued

Common name	Scientific name	Stock	Status		Occurrence	Seasonal absence	Stock abundance (CV)/minimum population
			MMPA	ESA			
Sperm whale	<i>Physeter macrocephalus</i> .	CA/OR/WA	Strategic, Depleted	Endangered	Southern California.	-	2,606 (0.135)/2,011.
		Hawaii	Strategic, Depleted	Endangered	Hawaii	-	5,707 (0.23)/4,486.
Pygmy sperm whale	<i>Kogia breviceps</i>	CA/OR/WA	-	-	Southern California.	Winter and Fall	4,111 (1.12)/1,924.
		Hawaii	-	-	Hawaii	-	42,083 (0.64) 25,695.
Dwarf sperm whale	<i>Kogia sima</i>	CA/OR/WA	-	-	Southern California.	-	unknown.
		Hawaii	-	-	Hawaii	-	unknown.
Baird's beaked whale ...	<i>Berardius bairdii</i>	CA/OR/WA	-	-	Southern California.	-	1,363
Blainville's beaked whale.	<i>Mesoplodon densirostris</i>	Hawaii	-	-	Hawaii	-	(0.53)/894.
Goose-beaked whale ² ..	<i>Ziphius cavirostris</i>	CA/OR/WA	-	-	Hawaii	-	1,132 (0.99)/564.
		Hawaii	-	-	Southern California.	-	5,454 (0.27)/4,214.
Longman's beaked whale.	<i>Indopacetus pacificus</i> ...	Hawaii	-	-	Hawaii	-	4,431 0.41/3,180.
Mesoplodont beaked whales.	<i>Mesoplodon spp.</i>	Hawaii	-	-	Hawaii	-	2,550 (0.67)/1,527.
Common Bottlenose dolphin.	<i>Tursiops truncatus</i>	CA/OR/WA	-	-	Southern California.	-	3,044 (0.54)/1,967.
		California Coastal	-	-	Southern California.	-	453 (0.06)/346.
		CA/OR/WA Offshore	-	-	Southern California.	-	3,477 (0.696)/2,048.
		Hawaii Pelagic	-	-	Hawaii	-	unknown.
		Kauai and Niihau	-	-	Hawaii	-	112 (0.24)/92.
		Oahu	-	-	Hawaii	-	112 (0.17)/97.
		Maui Nui ³	-	-	Hawaii	-	64 (0.15)/56.
		Hawaii Island	-	-	Hawaii	-	136 (0.43)/96.
False killer whale	<i>Pseudorca crassidens</i> ..	Main Hawaiian Islands Insular ⁴ .	Strategic, Depleted	Endangered	Hawaii	-	167 (0.14)/149.
		Hawaii Pelagic	-	-	Hawaii	-	5,528 (0.35)/4,152.
		Northwestern Hawaiian Islands.	-	-	Hawaii	-	477 (1.71)/178.
Fraser's dolphin	<i>Lagenodelphis hosei</i>	Hawaii	-	-	Hawaii	-	40,960 (0.7)/24,068.
Killer whale	<i>Orcinus orca</i>	Eastern North Pacific Offshore.	-	-	Southern California.	-	300 (0.1)/276.
		West Coast Transient ...	-	-	Southern California.	-	349 (N/A)/349.
		Hawaii	-	-	Hawaii	-	161 (1.06)/78.
Long-beaked common dolphin.	<i>Delphinus capensis</i>	California	-	-	Southern California.	-	83,379 (0.216)/69,636.
Melon-headed whale	<i>Peponocephala electra</i>	Hawaiian Islands	-	-	Hawaii	-	40,647 (0.74)/23,301.
		Kohala Resident	-	-	Hawaii	-	unknown.
Northern right whale dolphin.	<i>Lissodelphis borealis</i>	CA/OR/WA	-	-	Southern California.	-	29,285 (0.72)/17,024.
Pacific white-sided dolphin.	<i>Lagenorhynchus obliquidens</i> .	CA/OR/WA	-	-	Southern California.	-	34,999 (0.222)/29,090.
Pantropical spotted dolphin.	<i>Stenella attenuata</i>	Oahu	-	-	Hawaii	-	unknown.
		Maui Nui ³	-	-	Hawaii	-	unknown.
		Hawaii Island	-	-	Hawaii	-	unknown.
		Hawaii Pelagic	-	-	Hawaii	-	67,313 (0.27)/53,839.
Pygmy killer whale	<i>Feresa attenuata</i>	Tropical	-	-	Southern California.	Winter & Spring	unknown.
		Hawaii	-	-	Hawaii	-	10,328 (0.75)/5,885.
Risso's dolphins	<i>Grampus griseus</i>	CA/OR/WA	-	-	Southern California.	-	6,336 (0.32)/4,817.
		Hawaii	-	-	Hawaii	-	6,979 (0.29)/5,283.
Rough-toothed dolphin	<i>Steno bredanensis</i>	NSD ⁵	-	-	Southern California.	-	unknown.
		Hawaii	-	-	Hawaii	-	83,915 (0.49)/56,782.
Short-beaked common dolphin.	<i>Delphinus delphis</i>	CA/OR/WA	-	-	Southern California.	-	1,056,308 (0.21)/888,971.
Short-finned pilot whale	<i>Globicephala macrorhynchus</i> .	CA/OR/WA	-	-	Southern California.	-	836 (0.79)/466.
		Hawaii	-	-	Hawaii	-	19,242 (0.23)/15,894.
Spinner dolphin	<i>Stenella longirostris</i>	Hawaii Pelagic	-	-	Hawaii	-	unknown.
		Hawaii Island	-	-	Hawaii	-	665 (0.09)/617.

TABLE 1—MARINE MAMMAL OCCURRENCE WITHIN THE HSTT STUDY AREA—Continued

Common name	Scientific name	Stock	Status		Occurrence	Seasonal absence	Stock abundance (CV)/minimum population
			MMPA	ESA			
Striped dolphin	<i>Stenella coeruleoalba</i> ...	Oahu and 4-Islands	-	-	Hawaii	-	unknown.
		Kauai and Niihau	-	-	Hawaii	-	unknown.
		Kure and Midway	-	-	Hawaii	-	unknown.
		Pearl and Hermes	-	-	Hawaii	-	unknown.
		CA/OR/WA	-	-	Southern California.	-	29,988 (0.3)/23,448.
Dall's porpoise	<i>Phocoenoides dalli</i>	Hawaii	-	-	Hawaii	-	64,343 (0.28)/51,055.
		CA/OR/WA	-	-	Southern California.	-	16,498 (0.61)/10,286.
Harbor seal	<i>Phoca vitulina</i>	California	-	-	Southern California.	-	30,968 (NA)/27,348.
Hawaiian monk seal	<i>Neomonachus schauinslandi</i> .	Hawaii	Strategic, Depleted	Endangered	Hawaii	-	1,564 (0.05)/1,444.
Northern elephant seal	<i>Mirounga angustirostris</i>	California	-	-	Southern California.	-	187,386 (NA)/85,369.
California sea lion	<i>Zalophus californianus</i>	U.S. Stock	-	-	Southern California.	-	257,606 (NA)/233,515.
Guadalupe fur seal	<i>Arctocephalus townsendi</i> .	Mexico to California	Strategic, Depleted	Threatened	Southern California.	-	34,187 (NA)/31,019.
Northern fur seal	<i>Callorhinus ursinus</i>	California	Depleted	-	Southern California.	-	14,050 (NA)/7,524.

Note: A “-” indicates that this column does not apply.

¹ The Mainland Mexico—CA/OR/WA stock and the Mexico—North Pacific stock (which does not occur in the HSTT Study Area) of humpback whale comprise the Mexico DPS. The Hawai'i stock comprises the Hawai'i DPS. The Central America/Southern Mexico—CA/OR/WA stock comprises the Central America DPS.

² *Ziphius cavirostris* has multiple common names. In the 2018 HSTT final rule, 2020 HSTT final rule, and 2023 HSTT proposed rule, NMFS used the common name Cuvier's beaked whale. In this final rule, NMFS uses the common name goose-beaked whale instead.

³ The “4-Islands” stocks of common bottlenose dolphin and pantropical spotted dolphin are now the “Maui Nui” stocks.

⁴ NMFS relied on the 2022 final SAR for this stock.

⁵ NSD—No stock designation. Rough-toothed dolphin has a range known to include the waters off Southern California, but there is no recognized stock or data available for the U.S. West Coast.

Unusual Mortality Events

An UME is defined under section 410(6) of the MMPA as a stranding that is unexpected, involves a significant die-off of any marine mammal population, and demands immediate response. From 1991 to the present, there have been 17 formally recognized UMEs affecting marine mammals in California and Hawaii and involving species under NMFS' jurisdiction.

At the time of publication of the 2023 HSTT proposed rule, there was an active UME for gray whales which NMFS fully considered in its analysis (88 FR 68290, October 3, 2023). This UME was closed on November 9, 2023. The UME involved 690 gray whale strandings, including 347 in the United States, 316 in Mexico, and 27 in Canada. Strandings occurred from Alaska to Mexico along the west coast of North America, including in the whale's wintering, migratory, and feeding areas. The Investigative Team concluded that the preliminary cause of the UME was localized ecosystem changes in the whale's Subarctic and Arctic feeding areas that led to changes in food, malnutrition, decreased birth rates, and increased mortality all documented during the UME. Please see <https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-eastern-north-pacific-gray-whale-ume-closed> for additional information on this UME.

Biologically Important Areas

Kratofil *et al.* (2023) identified updated BIAs in Hawaii. The HSTT Study Area overlaps the updated BIAs for small and resident populations of the following species in Hawaii: spinner dolphin, short-finned pilot whale, rough-toothed dolphin, pygmy killer whale, pantropical spotted dolphin, melon-headed whale, false killer whale, dwarf sperm whale, goose-beaked whale, common bottlenose dolphin, and Blainville's beaked whale. Further, the HSTT Study Area overlaps updated BIAs for humpback whale reproduction in Hawaii. The updated BIAs overlap critical Navy training and testing areas within the HSTT Study Area, including most of the internal Navy operating areas. Please see Kratofil *et al.* (2023) for additional details about the BIAs.

Since publication of the 2023 HSTT proposed rule, Calambokidis *et al.* (2024) identified updated BIAs on the West Coast of the U.S. The HSTT Study Area overlaps feeding BIAs for blue whale and fin whale in SOCAL. Additionally, it overlaps a reproductive BIA as well as northbound and southbound migratory BIAs for gray whale. Please see Calambokidis *et al.* (2024) for additional details about the BIAs.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Analysis and Negligible Impact Determination section considers the content of this section, the Estimated Take section, and the Mitigation Measures section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival. In the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section of the 2018 HSTT proposed and final rules, and as updated by the 2020 HSTT final rule, NMFS provided a description of the ways marine mammals may be affected by the same activities that the Navy will be conducting during the 7-year period analyzed in this rulemaking in the form of serious injury or mortality, physical trauma, sensory impairment (permanent and temporary threshold shifts and acoustic masking),

physiological responses (particularly stress responses), behavioral disturbance, or habitat effects. Further, in the 2023 HSTT proposed rule, we summarized any new relevant information from the scientific literature since publication of the 2020 HSTT final rule. We do not repeat the information here, all of which remains current and applicable, but refer the reader to those rules and the 2018 HSTT FEIS/OEIS (chapter 3, section 3.7 *Marine Mammals*), which NMFS participated in the development of via our cooperating agency status and adopted to meet our NEPA requirements.

In the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section of the 2018 HSTT final rule, we stated that it has been speculated for some time that beaked whales might have unusual sensitivities to sonar sound due to their likelihood of stranding in conjunction with MFAS use, although few definitive causal relationships between MFAS use and strandings have been documented, and no such findings have been documented with Navy use in Hawaii and southern California. On March 25, 2022, a beaked whale (species unknown) stranded in Honaunau Bay, Hawaii. The animal was observed swimming into shore and over rocks. Bystanders intervened to turn the animal off of the rocks, and it swam back out of the Bay on its own. Locals reported hearing a siren or alarm type of sound underwater on the same day, and a Navy vessel was observed from shore on the following day. The Navy confirmed it used CAS within 50 km (27 nmi) and 48 hours of the time of stranding, though the stranding has not been definitively linked to the Navy's CAS use.

An initial study of another deep diving odontocete, the sperm whale, found similar behavioral responses and reductions in foraging when whales were exposed to PAS and CAS at similar cumulative Sound Exposure Levels (SEL_{cum}), even though the CAS signal had a lower source level than the PAS signal. This may indicate that animals were, in this case, responding to the cumulative energy of a signal rather than the instantaneous amplitude (Cure *et al.* 2021, Isojunno *et al.* 2020). If a beaked whale were inshore of a Navy vessel using either PAS or CAS MFAS, and responded by moving away from the vessel, they could find themselves in shallow water and become disoriented, as may have happened in the case of Honaunau Bay. In addition, the animal was not seen after it returned to sea, so blood tissue samples could not be obtained. There has been a growing

body of literature about the impacts of new pathogens on the health and stranding of marine mammals, including beaked whales in Hawaii and other locations in the Pacific (e.g., Clifton *et al.* 2023 and West *et al.* 2013).

NMFS has reviewed new relevant information from the scientific literature since publication of the 2023 HSTT proposed rule. Further, in the 2023 HSTT proposed rule, we summarized any new relevant information from the scientific literature since publication of the 2020 HSTT final rule. Summaries of the new key scientific literature reviewed since publication of the 2023 HSTT proposed rule are presented below. The literature generally falls into the following topic areas: Vessel Strike; Hearing, Vocalization, and Masking; Hearing Loss (Temporary Threshold Shift (TTS) and Permanent Threshold Shift (PTS)); Behavioral Reactions; Stranding; Population Consequences of Disturbance and Cumulative Stressors; Methodology for Assessing Acoustic Impacts.

Vessel Strike

Dunlop (2024) studied migrating east Australian humpback whales' response to approaching vessels to determine if individuals exhibited an avoidance response. While some select groups did display changes in their movements, the sampled collective did not display any consistent vessel avoidance response. Furthermore, the degree of avoidance was lower as vessels approached at faster speeds. Overall, the results showed that humpbacks were generally unresponsive to approaching vessels regardless of the speed or noise level at which they approached. Female-calf pairs proved to be the biggest exception to this pattern; though this demographic did not exhibit a consistent response as a whole, these pairs were more likely to change their travel pattern more than any other group. Due to the lack of response from the population, the results suggest that implementation of vessel strike avoidance protocols is critical for successfully conserving large whale populations.

Redfern *et al.* (2024) developed a new metric for analyzing vessel strike risk reduction ("PLETHd") and applied it to North Atlantic right, humpback, fin, and sei whale distributions along the U.S. East Coast. The metric is calculated using three parameters: the relationship between vessel speed and the probability that a strike is lethal, vessel transit distance, and whale distributions. The authors compared the impact of a 14 kn (25.9 km/hr) vs. 10 kn (18.5 km/hr) speed restriction and found that only the 10 kn (18.5 km/hr)

reduction substantially reduced risk. The authors also found that applying a 10 kn (18.5 km/hr) speed restriction within multiple whale species' critical habitat zones was almost as effective as enacting the same speed restriction along the entire East Coast Exclusive Economic Zone (EEZ). The results suggest that 10 kn (18.5 km/hr) speed restrictions are a robust method for reducing vessel strike risk and that vessel restrictions within high-density core areas of a marine mammal's habitat can be highly impactful.

Hearing, Vocalization, and Masking

Parnell *et al.* (2024) studied the soundscapes of four underwater Hawaiian monk seal critical habitats, including measurement of ambient noise and characterization of detected sound sources. The authors observed diel patterns in both anthropogenic and biological sound sources that mask acoustic communication in Hawaiian monk seals. The measurements collected for this study provide a baseline for future research on impacts of anthropogenic activities on these soundscapes.

A multi-national team of scientists (U.S. and Norway) obtained the first hearing measurements of a mysticete species through auditory evoked potential (AEP) tests. During the 2023 field season, AEP tests were conducted on two adolescent female minke whales in Norway (Houser *et al.* 2024). Houser *et al.* (2024) indicate that the minke whale's upper-frequency limit of hearing occurs somewhere between 45 to 90 kHz. Minke whale's high-frequency sensitivity is hypothesized to support detection of the echolocation clicks of one their predators, the killer whale. The bandwidth of the tone-bursts used in the Houser *et al.* (2024) AEP testing was too broad to define the precise upper-frequency limit, but indicates this species is more sensitive to higher frequencies than previously predicted based on inner ear anatomy and vocalization data (Southall *et al.* 2019; NMFS 2024). Results from their final 2024 field season, which included further examination of the upper-frequency limit of hearing, are expected to be published in 2025, with preliminary data from two additional whales indicating that minke whale hearing is best around 32 kHz.

Hearing Loss (TTS and PTS)

Gransier and Kastelein (2024) examined TTS susceptibility in harbor porpoises and harbor seals based on exposures varying in frequency range and level. Specifically, exposures consisted of 100% duty cycle one-sixth-

octave noise bands at frequencies covering the entire hearing range of each species. Despite these species having different audiograms and regions of best sensitivity (*i.e.*, underwater pinnipeds are sensitive to sounds ranging from approximately 0.01 to 40–60 kHz, while most odontocetes are sensitive sounds ranging from approximately 0.25 to 80–125 kHz), the frequency-specific susceptibility to TTS was similar amongst both species, with the greatest susceptibility to TTS occurring at frequencies from 22.5 to 50 kHz and least susceptible to sounds below 10 kHz. The frequency of minimum TTS for the harbor seal aligns with its frequency of best hearing, while frequency of minimum TTS for the harbor porpoise is well below the frequency of best hearing. This study illustrates that the audiogram does not always serve as a good predictor of frequency-dependent susceptibility to TTS, with the pattern of susceptibility to TTS in these two species being more comparable than their audiograms.

Brewer *et al.* (2023) described 41 call types of Cook Inlet beluga vocal behavior and classified them into three categories: (1) whistles, (2) pulsed calls, and (3) combined calls. These are the first descriptions of vocal repertoire of this species in two critical habitat locations and across multiple seasons. Call types were then used to investigate the potential for masking from commercial ship noise. It was found that call types (0–12 kHz) were partially masked by distant ship noise and completely masked by close ship noise. This study provides evidence that ship noise can impact vocal communication of this population. Specifically Cook Inlet beluga vocalizations in the Susitna area, seven of the beluga's most common calls are either partially or fully masked by commercial ship traffic.

Kastelein *et al.* (2024) examined TTS in two California sea lions exposed to one-sixth-octave noise band centered at 32 kHz for 60-minutes of exposure, resulting in cumulative sound exposure levels (SEL_{cum}) ranging from 168 to 192 dB. Hearing after exposure was examined at the center frequency of the fatiguing sound (32 kHz) and at half an octave (44.8 kHz) and one octave above the center frequency (63 kHz). Higher SEL_{cum} resulted in greater threshold shifts. Furthermore, the greatest TTS occurred at half an octave above the center frequency, with TTS onset (6 dB threshold shift) measured at 44.8 kHz occurring at a 179 dB SEL_{cum} . TTS patterns and recovery was similar between the two individuals, with TTSs up to 6.7 dB recovering within 8 minutes of exposure, TTSs up to 12 dB

recovering within an hour, and only the highest TTS measured (12.9 dB) taking over an hour to recover. The results of this study were directly incorporated in the Navy's updated Phase IV AUD INJ/TTS criteria and indicate that California sea lions have lower AUD INJ/TTS onset than previously predicted (Southall *et al.* 2019).

Behavioral Reactions

Ceciarini *et al.* (2023) tested the efficacy of Acoustic Deterrent Devices for minimizing common bottlenose dolphin interactions with trammel nets in the Northern Tyrrhenian Sea. The authors used interactive pingers which emitted output signals “from 5 up to 500 kHz at 168 dB re 1 μ Pa at 1 m as random high-speed tones FM ranging from 100 μ s up to seconds”. The study found that catch damage from dolphins was significantly lower in nets where pingers were used.

Elmegaard *et al.* (2023) exposed six harbor porpoises to Acoustic Harassment Devices (AHDs), commonly referred to as “seal scarers”, to determine if they would exhibit any physiological or behavioral reactions. The AHDs pulsed at 14 kHz with a source level of 189 dB re 1 μ Pa (rms) or sound exposure level of 184 dB re 1 μ Pa²s, with porpoise RLs ranging from 98–132 dB re 1 μ Pa. All individuals sampled exhibited a mixture of behavioral or physiological responses, including startling, increased distance from the sound source, increased swim speed, diving, altered echolocation patterns, cardiac responses, or altered respiration patterns. Overall, responses were observed in every individual up to 7 km or down to an RL of 98 dB re 1 μ Pa.

Frankish *et al.* (2023) followed ten harbor porpoises for 5 to 10 days to observe their reactions to ship traffic around Denmark. The porpoises spent over half of the study period within 10 km of a ship, and a third of the study period exposed to noise levels above ambient. The porpoises responded by moving away from ships during the day, and diving deep during the night. They had a higher likelihood of altering their movements when louder ships were nearby (maximum probability of deterrence = 12.2 percent during the day and 14.9 percent at night), and moved an average of 3.2 km away from 13.6 different ships every day. Deeper dives occurred less frequently, at a rate of 5.7 different ships per individual per night. The porpoises also reacted to loud ships that were far away (>2 km at 93 $\pm$ 14 dB re 1 μ Pa²), though responses occurred less frequently (5 to 9 percent of the

time vs. up to 14.9 percent of the time at close range).

Southall *et al.* (2023) used control exposure experiments (CEEs) to provide the first results in examining the impact of mid-frequency navy sonar (3.5–4.1 kHz) or pseudorandom noise (similar frequency, duration and source and received level compared to mid-frequency sonar) on fin whale behavior in feeding habitats of the Southern California Bight. Of the 15 exposed fin whales, only five individuals demonstrated a mild to moderate behavioral changes (avoidance, changes in feeding, diving, or respiration), with no changes demonstrated for whales in the six control exposures. Compared to blue whales, fin whale behavioral responses were more limited in occurrence, severity and duration and were found to be less dependent upon contextual aspects of exposure, with received level as the primary factor associated with behavioral responses. Additionally, foraging success was not compromised by exposures from this study. The authors note that differences observed between behavioral response in fin whales in this study and blue whales in previously published studies may be attributed to the smaller sample size associated with this study. However, as seen in blue whales, fin whale behavior returned to baseline conditions after noise exposure ended.

Methodology for Assessing Acoustic Impacts

Indeck *et al.* (2024) assessed North Atlantic right whale, fin, and blue whale detectability by Slocum gliders near heavily used shipping lanes in the Gulf of St. Lawrence, Canada. The goal of the study was to evaluate the gliders' suitability as a passive acoustic monitoring platform for whale detection in areas with high anthropogenic noise levels. The authors found that shipping lane noise did not substantially impact whale detectability, as calls from the highly trafficked areas were not masked significantly more than calls in quieter areas nearby. The gliders were therefore identified as a viable PAM platform to use in and around busy shipping areas. These results suggest that gliders could be an important tool for monitoring mysticetes in highly industrialized areas and assisting in ongoing dynamic management initiatives.

Conclusion for New Pertinent Science Since Publication of the 2023 HSTT Proposed Rule

Having considered the best scientific information available, specifically new relevant information published since the 2023 HSTT proposed rule, we have

determined that there is no new information that substantively affects our analysis of impacts on marine mammals and their habitat that appeared in the 2020 HSTT final rule, all of which remains applicable and valid for our assessment of the effects of the Navy's activities during the 7-year period of this rulemaking.

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is authorizing, which are based on the amount of take that NMFS anticipates could occur or is likely to occur, depending on the type of take and the methods used to estimate it, as described below. NMFS coordinated closely with the Navy in the development of their incidental take application and agrees that the methods the Navy has put forth described herein, in the 2019 HSTT proposed rule, 2020 HSTT final rule, and in the 2018 HSTT proposed and final rules to estimate take (including the model, thresholds, and density estimates), and the resulting numbers are based on the best available science and appropriate for authorization, with the exception of that of humpback whales, discussed further below. The number and type of incidental takes that could occur or are likely to occur annually remain identical to those authorized in the 2018 HSTT regulations and 2020 HSTT regulations, with the exception of authorized takes by serious injury or mortality by vessel strike and harassment takes of humpback whale stocks in Southern California (due to the new stock structure).

Takes are predominantly in the form of harassment, but a small number of serious injuries or mortalities could occur. For military readiness activities, the MMPA defines "harassment" as (i) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B harassment).

Authorized takes will primarily be in the form of Level B harassment, as use of the acoustic and explosive sources (i.e., sonar, air guns, pile driving, explosives) is more likely to result in the disruption of natural behavior patterns to a point where they are abandoned or significantly altered (as defined specifically at the beginning of

this section but referred to generally as behavioral disturbance) or TTS for marine mammals. There is also the potential for Level A harassment in the form of auditory injury and/or tissue damage (the latter from explosives only) to result from exposure to the sound sources utilized in training and testing activities. Additionally, serious injuries or mortalities of mysticetes (except for sei whales, minke whales, Bryde's whales, Central North Pacific stock of blue whales, Hawaii stock of fin whales, Western North Pacific stock of gray whales, and sperm whales) could occur through vessel strike. Mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

Generally speaking, for acoustic impacts, NMFS estimates the amount and type of harassment by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals would experience behavioral disturbance or incur some degree of temporary or permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day or event; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) the number of days of activities or events.

Acoustic Thresholds

Using the best available science, NMFS, in coordination with the Navy, has established acoustic thresholds that identify the most appropriate received level of underwater sound above which marine mammals exposed to these sound sources could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered, either directly or via the effects of TTS (both equated to Level B harassment) or PTS of some degree (equated to Level A harassment). Thresholds have also been developed to identify the pressure levels above which animals may incur non-auditory injury from exposure to pressure waves from explosive detonation. We described the acoustic thresholds and the methods used to determine thresholds in detail in the *Acoustic Thresholds* section of the 2018 HSTT final rule; please see the 2018 HSTT final rule for detailed information. Further, in the 2020 HSTT final rule, and 2023 HSTT proposed rule, we described new relevant information from the scientific literature since publication of the 2018 HSTT final rule and 2020 HSTT final rule, respectively. Since publication of the 2023 HSTT proposed rule, NMFS has

updated our Technical Guidance (NMFS, 2024) containing updated acoustic criteria for auditory injury (89 FR 36762, October 24, 2024). The Technical Guidance provides updated auditory injury thresholds, where appropriate, as well as revised weighting functions, in some cases. For impulsive sources, the Updated Technical Guidance's auditory injury thresholds generally remain identical or are higher compared to our 2018 Technical Guidance, meaning that received levels would need to be higher in order for marine mammals to be expected to incur auditory injury. The exceptions are for phocid pinnipeds (PW), where the cumulative SEL threshold, in the Updated Technical Guidance, is 2 dB lower and for otariid pinnipeds (OW) where the peak sound pressure level threshold is 2 dB lower and the cumulative SEL threshold is 18 dB lower. As for the Updated Technical Guidance's weighting functions, for MF cetaceans (now called HF cetaceans in the updated document) and HF cetaceans (now called VHF cetaceans in the updated document), the weighting functions reflect a higher susceptibility to auditory injury at frequencies below 10 kHz, as compared to the 2018 Technical Guidance. Other minor changes/shifts to weighting functions (e.g., for LF cetaceans, PW pinnipeds, OW pinnipeds) were also included. This new information was not available in a timeframe in which NMFS could have incorporated it into the quantitative analysis supporting this final rulemaking; however, NMFS did consider the information qualitatively. While these changes in the auditory injury thresholds and weighting functions could result in minor increases in PTS exposure estimates for some species, given the conservative assumptions built into the take estimate methodology, they would not be expected to result in meaningful, if any, changes in take estimates and would not be expected to change any of the findings.

Navy's Acoustic Effects Model

The Navy proposed no changes to the Acoustic Effects Model as described in the 2018 HSTT final rule (and incorporated by reference in the 2020 HSTT final rule), and there is no new information that would affect the applicability or validity of the model. Please see the 2018 HSTT final and proposed rules and Appendix E of the 2018 HSTT FEIS/OEIS for detailed information, and see the discussion of the 2024 Technical Guidance in the *Acoustic Thresholds* section above.

Range to Effects

The Navy proposed no changes from the 2018 HSTT final rule (and subsequent 2020 HSTT final rule) to the type and nature of the specified activities to be conducted during the 7-year period analyzed in this final rule, including equipment and sources used and exercises conducted.

As described above in the *Acoustic Thresholds* section, since publication of the 2023 HSTT proposed rule, NMFS has updated our Technical Guidance (NMFS, 2024) containing updated acoustic criteria for auditory injury (89 FR 36762). Please see that section for a full discussion of the updates. This new information was not available in a timeframe in which NMFS could have incorporated it into the quantitative analysis supporting this final rulemaking; however, NMFS did consider the information qualitatively. While these changes in the auditory injury thresholds and weighting functions could result in minor increases in PTS exposure estimates for some species, given the conservative assumptions built into the take estimate methodology, they would not be expected to result in meaningful, if any, changes in take estimates and would not be expected to change any of the findings.

Therefore, the ranges to effects in this final rule are identical to those described and analyzed in the 2018 HSTT final rule and 2020 HSTT final rule, including received sound levels that may cause onset of significant behavioral response and TTS and PTS in hearing for each source type or explosives that may cause non-auditory injury. Please see the *Range to Effects* section and tables 24 through 40 of the 2018 HSTT final rule for detailed information.

Marine Mammal Density

The Navy proposed no changes to the methods used to estimate marine mammal density described in the 2018 HSTT final rule, and there is no new information that would affect the applicability or validity of these methods or change the results in a manner that would change the necessary determinations supporting the issuance of these regulations. The Navy's estimate of marine mammal density as described in the 2018 HSTT final rule remains valid, though, as described herein, NMFS has incorporated new information regarding humpback whale stock structure into its analysis. Please see the 2018 HSTT final rule, and below, for detailed information.

As noted above, NMFS regularly updates SARs, and in this rulemaking considers the 2023 final SARs (Carretta *et al.* 2024, Young *et al.* 2024). While these SARs contain updated information, the Navy's estimate of marine mammal density as described in the 2018 HSTT final rule remains valid for the following reasons. The Navy uses its Marine Species Density Database (NMSDD) for its analysis, which is derived from multiple sources, including but not limited to SARs. In contrast, for most cetacean species, the SAR is estimated using line-transect surveys or mark-recapture studies (*e.g.*, Barlow, 2010; Barlow and Forney, 2007; Calambokidis *et al.* 2008). The result provides one single abundance value for each species across broad geographic areas, but it does not provide information on the species density or concentrations within that area, and it does not estimate density for other timeframes or seasons that were not surveyed. A change in a stock's abundance indicated in a SAR does not necessarily indicate a change in that stock's density in any given area. Therefore, stocks in the HSTT Study Area with higher abundance estimates in the most recent SARs in comparison to the abundance estimates at the time that marine mammal densities were derived for the HSTT Study Area do not necessarily now occur in higher densities in the HSTT Study Area. For humpback whale, while the stock structure in the Pacific Ocean was revised in the 2022 final SARs (Carretta *et al.* 2023, Young *et al.* 2023), the discussion above remains true regarding density of humpback whales in the HSTT Study Area across all stocks.

Take Requests

As in the 2018 HSTT final rule and 2020 HSTT final rule, the Navy determined that the three stressors below could result in the incidental taking of marine mammals. NMFS has reviewed the Navy's data and analysis and determined that it is complete and accurate, and NMFS agrees that the following stressors have the potential to result in takes of marine mammals from the Navy's planned activities:

- Acoustics (sonar and other transducers; air guns; pile driving/extraction);
- Explosives (explosive shock wave and sound, assumed to encompass the risk due to fragmentation); and
- Physical Disturbance and Strike (vessel strike).

NMFS reviewed and agrees with the Navy's conclusion that acoustic and explosive sources have the potential to result in incidental takes of marine

mammals by harassment, serious injury, or mortality. NMFS carefully reviewed the Navy's analysis and conducted its own analysis of vessel strikes, determining that the likelihood of any particular species of large whale being struck is quite low. However, as noted previously, in 2021, two separate U.S. Navy vessels struck unidentified large whales on two separate occasions, one whale in June 2021 and one whale in July 2021. In May 2023, the U.S. Navy struck a large whale, which based on available photos and video, NMFS and the Navy have determined was either a fin whale or sei whale. NMFS agrees that vessel strikes have the potential to result in incidental take from serious injury or mortality for certain species of large whales, and the Navy has specifically requested coverage for these species. Therefore, the likelihood of vessel strikes, and later the effects of the incidental take that is being authorized, has been fully analyzed and is described below.

Regarding the quantification of expected takes from acoustic and explosive sources (by Level A and Level B harassment, as well as mortality resulting from exposure to explosives), the number of takes are based directly on the level of activities (days, hours, counts, *etc.*, of different activities and events) in a given year. In the 2020 HSTT final rule, take estimates across the 7 years were based on the Navy conducting 4 years of a representative level of activity and 3 years of maximum level of activity. As in the 2020 HSTT final rule, the Navy uses the maximum annual level to calculate annual takes (which would remain identical to what was determined in the 2020 HSTT final rule, with the exception of attribution of takes to humpback whale stocks), and the sum of all years (4 representative and 3 maximum) to calculate the 7-year totals for this rulemaking.

The quantitative analysis process used for the 2018 HSTT FEIS/OEIS and the 2017 and 2019 Navy applications to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors is detailed in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018). The Navy Acoustic Effects Model estimates acoustic and explosive effects without taking mitigation into account; therefore, the model overestimates predicted impacts on marine mammals within mitigation zones. To account for mitigation for marine species in the take estimates, the

Navy conducts a quantitative assessment of mitigation. The Navy conservatively quantifies the manner in which procedural mitigation is expected to reduce the risk for model-estimated PTS for exposures to sonars and for model-estimated mortality for exposures to explosives, based on species sightability, observation area, visibility, and the ability to exercise positive control over the sound source. Where the analysis indicates mitigation would effectively reduce risk, the model-estimated PTS are considered reduced to TTS and the model-estimated mortalities are considered reduced to injury. For a complete explanation of the process for assessing the effects of mitigation, see the 2017 Navy application and the *Take Requests* section of the 2018 HSTT final rule. The extent to which the mitigation areas reduce impacts on the affected species and stocks is addressed separately in the Analysis and Negligible Impact Determination section.

No changes have been made to the quantitative analysis process to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors and calculate take estimates, with the exception of take of humpback whales to account for the change in stock structure. Please see the documents described in the paragraph above, the 2018 HSTT proposed rule, the 2018 HSTT final rule, and below for detailed descriptions of these analyses. While Oedekoven and Thomas (2022) suggest that detection of marine mammals is less certain than previously assumed at certain distances, NMFS has independently evaluated the Navy's method for application of mitigation effectiveness in estimating take and agrees that it is appropriately applied to augment the model in the prediction and authorization of injury and mortality as described in the rule, including after consideration of Oedekoven and Thomas (2022). In summary, we believe the Navy's methods, including the method for incorporating mitigation and avoidance, are the most appropriate methods for predicting PTS, TTS, and behavioral disturbance. But even with the consideration of mitigation and avoidance, given some of the more conservative components of the methodology (e.g., the thresholds do not consider ear recovery between pulses), we would describe the application of these methods as identifying the maximum number of instances in which marine mammals would be reasonably expected to be taken through PTS, TTS, or behavioral disturbance.

Summary of Authorized Take From Training and Testing Activities

Based on the methods discussed in the previous sections and the Navy's model and quantitative assessment of mitigation, the Navy provided its take estimate and request for authorization of takes incidental to the use of acoustic and explosive sources for training and testing activities both annually (based on the maximum number of activities that could occur per 12-month period) and over the 7-year period in its 2019 rulemaking/LOA application. With the exception of changes to humpback whale take, described below, annual takes (based on the maximum number of activities that could occur per 12-month period) from the use of acoustic and explosive sources are identical to those presented in tables 41 and 42 and in the *Explosives* subsection of the *Take Requests* section of the 2018 HSTT final rule. The 2022 Navy application includes the Navy's updated take estimate and request for take by vessel strike due to vessel movement in the HSTT Study Area. NMFS reviewed the Navy's data, methodology, and analysis and determined that it was complete, but NMFS has reanalyzed the potential for vessel strike following the May 2023 strike, as described in the *Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section. NMFS agrees that the estimates for incidental takes by harassment from all sources as well as the incidental takes by serious injury or mortality from explosives requested for authorization are the maximum number of instances in which marine mammals are reasonably expected to be taken at the time of Navy's request, and continues to be for all stocks other than humpback whales, for which changes are described below. NMFS also agrees that the takes by serious injury or mortality as a result of vessel strikes could occur. Note that, consistent with the 2020 HSTT final rule, the total amount of estimated incidental take from acoustic and explosive sources over the total 7-year period covered by the 2019 Navy application is less than the annual total multiplied by seven. Although the annual estimates are based on the maximum number of activities per year and therefore, the maximum possible estimated takes, the 7-year total take estimates are based on the sum of 3 maximum years and 4 representative years, with the exception of humpback whale stocks that occur in SOCAL for which 7-year total take is conservatively estimated as the annual total multiplied by seven. Not all activities occur every year. Some activities would occur

multiple times within a year, and some activities would occur only a few times over the course of the 7-year period. Using 7 years of the maximum number of activities each year would vastly overestimate the amount of incidental take that would occur over the 7-year period where the Navy knows that it will not conduct the maximum number of activities each and every year for the 7 years.

As described above in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities section, the 2022 final SARs include a revision to the humpback whale stock structure in the Pacific Ocean. In the 2020 HSTT final rule, NMFS authorized take of the CA/OR/WA stock and Central North Pacific stock of humpback whale. Given the revised stock structure, in this final rule, NMFS has reanalyzed the potential for take of each stock of humpback whale and determined that the Central America/Southern Mexico-CA/OR/WA, Mainland Mexico-CA/OR/WA stock, and Hawaii stocks are likely to be taken by the Navy's activities.

Under the new stock structure, the Hawaii stock (Hawaii DPS) is the only stock that would occur in Hawaii. Therefore, the Hawaii stock of humpback whale is the only humpback whale stock anticipated to be taken by the Navy's activities in the HRC, and all takes of the Central North Pacific stock of humpback whale that were authorized in the 2020 HSTT final rule are anticipated to be of individuals from the new Hawaii stock. In SOCAL, the takes of individuals from the former CA/OR/WA stock that were authorized in the 2020 HSTT final rule are anticipated to be of individuals from the new Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stock.

Please see the Authorized Harassment Take from Testing Activities and Authorized Harassment Take from Training Activities sections below for the authorized annual and 7-year total number and type of Level A harassment and Level B harassment for each humpback whale stock.

Authorized Harassment Take From Training Activities

For training activities, table 11 of the 2020 HSTT final rule summarizes the Navy's take estimate and request in the 2019 Navy application and the maximum amount and type of Level A harassment and Level B harassment that NMFS concurred is reasonably expected to occur by species or stock and authorized in the 2020 HSTT LOA. In the 2022 Navy application, the Navy

requested no change to this authorized take, though as described above, NMFS has since published the 2023 final, which include a revision to humpback whale stock structure. For the estimated 7-year total amount and type of Level A harassment and Level B harassment, see table 11 of the 2020 HSTT final rule for all species other than humpback whale.

For the estimated amount and type of Level A harassment and Level B harassment annually, see table 41 in the 2018 HSTT final rule for all species other than humpback whale. Note that take by Level B harassment includes both behavioral disturbance and TTS. Navy figures 6–12 through 6–50 in section 6 of the 2017 Navy application

illustrate the comparative amounts of TTS and behavioral disturbance for each species annually, noting that if a modeled marine mammal was “taken” through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS.

TABLE 2—HUMPBACK WHALE TAKE FROM ACOUSTIC AND EXPLOSIVE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE HSTT STUDY AREA

Species	Stock	Annual		7-year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
Humpback whale ^a	Hawaii	5,604	1	34,437	12
	Central America/Southern Mexico-CA/OR/WA (Central America DPS).	585	0	^b 4,095	0
	Mainland Mexico—CA/OR/WA (Mexico DPS).	669	1	^b 4,683	7

^a Combined takes from the Central America/Southern Mexico- CA/OR/WA stock and the Mainland Mexico CA/OR/WA stock are equal to takes of the CA/OR/WA stock authorized in the 2020 HSTT final rule.

^b Unlike other species and stocks, for the Central America/Southern Mexico-CA/OR/WA stock and Mainland Mexico-CA/OR/WA stock, NMFS estimated the 7-year take by Level B harassment by multiplying the annual estimated take by seven. However, between the two stocks, NMFS does not anticipate that the total number of takes by Level B harassment across all 7 years would exceed the 7,962 takes by Level B harassment from training activities that were authorized for the CA/OR/WA stock of humpback whales in the 2020 HSTT final rule.

Authorized Harassment Take From Testing Activities

For testing activities, table 12 of the 2020 HSTT final rule summarizes the Navy’s take estimate and request in the 2019 Navy application and the maximum amount and type of Level A harassment and Level B harassment that NMFS concurred is reasonably expected to occur by species or stock and

authorized in the 2020 HSTT LOA. In the 2022 Navy application, the Navy requested no change to this authorized take. For the estimated 7-year total amount and type of Level A harassment and Level B harassment, see table 12 of the 2020 HSTT final rule. For the estimated amount and type of Level A harassment and Level B harassment annually, see table 42 in the 2018 HSTT final rule. Note that take by Level B

harassment includes both behavioral disturbance and TTS. Navy figures 6–12 through 6–50 in section 6 of the 2017 Navy application illustrate the comparative amounts of TTS and behavioral disturbance for each species annually, noting that if a modeled marine mammal was “taken” through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS.

TABLE 3—HUMPBACK WHALE TAKE FROM ACOUSTIC AND EXPLOSIVE EFFECTS FOR ALL TESTING ACTIVITIES IN THE HSTT STUDY AREA

Species	Stock	Annual		7-year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
Humpback whale ^a	Hawaii	3,522	2	23,750	19
	Central America/Southern Mexico-CA/OR/WA.	291	0	^b 2,037	0
	Mainland Mexico—CA/OR/WA	449	0	^b 3,143	0

^a Combined takes from the Central America/Southern Mexico- CA/OR/WA stock and the Mainland Mexico CA/OR/WA stock are equal to takes of the CA/OR/WA stock authorized in the 2020 HSTT final rule.

^b Unlike other species and stocks, for the Central America/Southern Mexico-CA/OR/WA stock and Mainland Mexico-CA/OR/WA stock, NMFS estimated the 7-year take by Level B harassment by multiplying the annual estimated take by seven. However, between the two stocks, NMFS does not anticipate that the total number of takes by Level B harassment across all 7 years would exceed the 4,961 takes by Level B harassment from testing activities that were authorized for the CA/OR/WA stock of humpback whales in the 2020 HSTT final rule.

Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality

Vessel Strike

Vessel strikes from commercial, recreational, and military vessels are known to affect large whales and have resulted in serious injury and fatalities

to cetaceans (Abramson *et al.* 2011; Berman-Kowalewski *et al.* 2010; Calambokidis, 2012; Douglas *et al.* 2008; Laggner, 2009; Lammers *et al.* 2003; Van der Hoop *et al.* 2012; Van der Hoop *et al.* 2013; Crum *et al.* 2019). Records of collisions date back to the early 17th century, and the worldwide number of collisions appears to have increased

steadily during recent decades (Laist *et al.* 2001; Ritter 2012) due to increases in the number and speed of large vessels, increased reporting of strikes, and increased abundance of some large whales (Ransome *et al.* 2021), among other factors.

Numerous studies of interactions between surface vessels and marine

mammals have demonstrated that free-ranging marine mammals often, but not always (*e.g.*, McKenna *et al.* 2015; Smultea *et al.* 2022; Szesciorka *et al.* 2019), engage in avoidance behavior when surface vessels move toward them. It is not clear whether these responses are caused by the physical presence of a surface vessel, the underwater noise generated by the vessel, or an interaction between the two (Amaral and Carlson, 2005; Au and Green, 2000; Bain *et al.* 2006; Bauer 1986; Bejder *et al.* 1999; Bejder and Lusseau, 2008; Bejder *et al.* 2009; Bryant *et al.* 1984; Corkeron, 1995; Erbe, 2002; Félix, 2001; Goodwin and Cotton, 2004; Lemon *et al.* 2006; Lusseau, 2003; Lusseau, 2006; Magalhaes *et al.* 2002; Nowacek *et al.* 2001; Richter *et al.* 2003; Scheidat *et al.* 2004; Simmonds, 2005; Watkins, 1986; Williams *et al.* 2002; Wursig *et al.* 1998). Several authors suggest that the noise generated during vessel movement is probably an important factor (Blane and Jackson, 1994; Evans *et al.* 1992; Evans *et al.* 1994). Water disturbance may also be a factor. These studies suggest that the behavioral responses of marine mammals to surface vessels are similar to their behavioral responses to predators. Avoidance behavior is expected to be even stronger in the subset of instances during which the Navy is conducting training or testing activities using active sonar or explosives.

The marine mammals most vulnerable to vessel strikes are those that spend extended periods of time at the surface to restore oxygen levels within their tissues after deep dives (*e.g.*, sperm whales). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.* 2004). These species are primarily large whales.

Some researchers have suggested the relative risk of a vessel strike can be assessed as a function of animal density and the magnitude of vessel traffic (*e.g.*, Fonnesebeck *et al.* 2008; Vanderlaan *et al.* 2008). Differences among vessel types also influence the probability of a vessel strike. The ability of any ship to detect a marine mammal and avoid a collision depends on a variety of factors, including environmental conditions, ship design, size, speed, and ability and number of personnel observing, as well as the behavior of the animal. Vessel speed, size, and mass are all important factors in determining if injury or death of a marine mammal is likely due to a vessel strike. For large vessels, speed and angle of approach can influence the severity of a strike. For example,

Vanderlaan and Taggart (2007) found that between vessel speeds of 8.6 and 15 kn (15.9 and 27.8 km per hour), the probability that a vessel strike is lethal increases from 0.21 to 0.79. Large whales also do not have to be at the water's surface to be struck. Silber *et al.* (2010) found when a whale is below the surface (about one to two times the vessel draft), there is likely to be a pronounced propeller suction effect. This suction effect may draw the whale into the hull of the ship, increasing the probability of propeller strikes.

There are some key differences between the operation of military and non-military vessels, which make the likelihood of a military vessel striking a whale lower than some other vessels (*e.g.*, commercial merchant vessels). Key differences include:

- Many military ships have their bridges positioned closer to the bow, offering better visibility ahead of the ship (compared to a commercial merchant vessel);
- There are often aircraft associated with the training or testing activity (which can serve as Lookouts), which can more readily detect cetaceans in the vicinity of a vessel or ahead of a vessel's present course before crew on the vessel would be able to detect them;
- Military ships are generally more maneuverable than commercial merchant vessels, and if cetaceans are spotted in the path of the ship, could be capable of changing course more quickly;
- The crew size on military vessels is generally larger than merchant ships, allowing for stationing more trained Lookouts on the bridge. At all times when vessels are underway, trained Lookouts and bridge navigation teams are used to detect objects on the surface of the water ahead of the ship, including cetaceans. Additional Lookouts, beyond those already stationed on the bridge and on navigation teams, are positioned as Lookouts during some training events; and
- When submerged, submarines are generally slow moving (to avoid detection), and therefore, marine mammals at depth with a submarine are likely able to avoid collision with the submarine. When a submarine is transiting on the surface, there are Lookouts serving the same function as they do on surface ships.

Vessel strike to marine mammals is not associated with any specific training or testing activity but is rather a limited and sporadic, but possible, accidental result of Navy vessel movement within the HSTT Study Area or while in transit.

In 2009, the Navy began implementing additional mitigation measures to further reduce the likelihood of vessel strikes. Prior to the recent strikes in 2021 and 2023, there were two recorded U.S. Navy vessel strikes of large whales in the HSTT Study Area between 2009 and April 2021, a period of approximately 12 years.

Since 2021 there have been five strikes of large whales in SOCAL attributed to naval vessels, three by the U.S. Navy and two by the Royal Australian Navy. As stated previously, the U.S. Navy struck a large whale in waters off Southern California in May 2023. Based on available photos and video, NMFS and the Navy have determined this whale was either a fin whale or sei whale. The U.S. Navy struck two unidentified large whales during the months of June and July 2021, and prior to that, on May 7, 2021, the Royal Australian Navy HMAS Sydney, a 147.5 m (161.3 yd) Hobart Class Destroyer, struck and killed two fin whales (a mother and her calf) while operating within SOCAL. In the case of the Royal Australian Navy strike, the carcasses were first sighted under the bow of the vessel while it was approaching the Naval Base in San Diego. The whales had been pinned to a sonar dome in the front of the vessel due to the force of water as the ship was underway. Based on interviews with HMAS Sydney personnel, the most likely time of impact with the two whales would have been around 6:25 a.m. when the vessel was located near Cortes Bank, and visibility was poor. The reported vessel speed at the estimated time of strike was 9 kn (16.7 km per hour). One minute before the estimated strike time a lookout reported whales off the starboard bow. The officer on-watch verbally acknowledged the report, slowed speed, and visually tracked the whales passing clear down the starboard side until they were clear of the ship. The morning of the strike, the HMAS Sydney was getting into position to participate in a U.S. Navy-led exercise later that day. Of note, throughout the remainder of the day visibility was poor and the vessel had implemented mitigation measures in multiple instances due to whale occurrence. In addition to being the only documented occurrence of a foreign military vessel strike of a large whale within the HSTT Study Area, the HMAS Sydney vessel strike was also somewhat unique, as compared to other reported military vessel strikes, in that two whales were apparently struck at one time, and both remained pinned to

the front of the vessel until the vessel approached the port.

On June 29, 2021, a U.S. Navy cruiser struck an unknown whale species approximately 95 nmi (176 km) west of San Diego. The ship was returning from Hawaii, heading to a rendezvous with a fuel replenishment vessel (oiler) for an Underway Replenishment. Off-duty sailors noticed a group of whales approaching the ship from the port quarter (*i.e.*, left rear of the ship), an area unique to cruisers with some equipment structures blocking close aboard sight. The first indication of a whale within the 500-yd mitigation zone immediately prior to the strike was when an off-duty sailor on the flight deck witnessed the whale briefly surface on the aft port quarter before diving. Shortly after this occurred blood was noticed in the wake, and a floating whale body was eventually observed behind the ship. The ship's speed was 25 kn (46.3 km per hour) at the estimated time the strike occurred. The Navy also noted that, on the morning before the strike occurred, the ship had maneuvered several times to avoid whale blows beyond the 500-yd (457.2 m) mitigation zone, closer to 1,000 yd (914.4 m).

On July 11, 2021, a U.S. Navy cruiser struck an unknown whale species approximately 90 nmi (166.7 km) south-southwest of San Diego. The vessel was a participant in a MTE (Large Integrated Anti-Submarine Warfare—Composite Unit Training Exercise) within the SOCAL portion of the action area. The vessel was maneuvering for pending flight operations to receive an inbound helicopter. At 2:27 p.m., the starboard lookout sighted what they believed to be a whale crossing immediately under the vessel's bow. The conning officer attempted to maneuver the vessel by turning to port but internal watchstanders subsequently felt the ship shudder aft. The vessel's combat center observed a red slick 600 yd (548.6 m) astern on a flight deck camera and a brief surfacing of the whale itself, but no carcass was observed. There had not been any sightings of large whales off the bow leading up to the incident. Although the ship was traveling at 25–30 kn (46.3–55.6 km per hour) 1 hour before the estimated strike time, at 10 minutes before, the vessel changed course and reduced its speed to 17 kn (31.5 km per hour). These 2021 incidents were the first known U.S. Navy vessel strikes in the HSTT Study Area since 2009.

On May 20, 2023, a U.S. Navy aircraft carrier was at sea conducting independent, unit-level flight training for the embarked airwing approximately 70 nmi (129.6 km) west of San Diego.

Training exercises concluded for the day at approximately 7:44 p.m. local time. Navy personnel discovered a whale impinged on the bow of the vessel at approximately 8:00 p.m. local time. The vessel was traveling at approximately 5 kn (9.3 km per hour) and had recently made a turn to reset position for the evening when the Navy personnel discovered the whale. Navy personnel captured video and photos of the carcass, and based on those images, NMFS and the Navy have determined this whale was either a fin whale or sei whale; the two species are very similar morphologically and are difficult to distinguish from one another at sea. Navy personnel stopped the vessel to allow lack of momentum to dislodge the carcass from the bow, and based on lack of further observations after the carcass dislodged, it is believed to have sunk around 9:30 p.m. local time. Navy personnel on board the vessel reported that they did not feel an impact from striking the whale. Prior to the strike, between 6:45 p.m. and 7:45 p.m., the forward Lookouts on the vessel observed two whales crossing the vessel's bow but did not provide a distance between the vessel and the whales. One Lookout reported seeing the blow and the other reported seeing 'humps' (presumably the dorsal of the animal). Both whales were sighted past the ship's course to the northwest. Within the same time window, one of the aft Lookouts observed a single whale swimming parallel to the ship and soon passed astern of the ship. During the same time, independent of the sightings and for general movement reasons, the ship changed speed from 17 kn (31.5 km per hour) to 10 kn (18.5 km per hour) at 7:22 p.m.

While in this incident a whale was discovered impinged on the bow of a Navy vessel, this incident is very different from the discovery of two fin whales discovered impinged on the sonar dome of a Royal Australian Navy vessel in 2021 when the vessel came to port at Naval Base San Diego. While U.S. Navy cannot speculate on the configurations of other ships bows and even sonar dome specifications (that may be at the bow), the Navy believes it would be implausible for a marine mammal to become lodged on the sonar dome of a U.S. Navy ship and remain undetected due to a technological standard operating procedure. Sonar domes on U.S. Navy ships have a pressurized rubber window that maintains 150 pound-force per square inch (PSI) through the ship's fire main. If anything affects the pressure, an alarm sounds in the sonar control room. In the

event of a whale strike in that location, this alarm would alert personnel that something hit the sonar dome. Further, the shape, hydrodynamic design, construction using a non-abrasive material, and regular hull cleaning procedures to remove barnacles and other growth on U.S. Navy ships also make it unlikely that a whale would become lodged and remain undetected on a U.S. Navy ship's bow or even sonar dome. While in the case of the May 2023 strike, described above, a whale also became lodged on the ship's bow, the aircraft carrier that struck the whale does not have active or passive sonar capabilities (*i.e.*, no sonar dome), nor does it have a bulbous bow, and the whale was more quickly discovered by Navy personnel.

In March 2024 a dead fin whale was discovered off of Pier 10 in Naval Station San Diego within the Navy's security barrier. The security barrier, which consists of a series of connected floating sections, is intended to discourage unauthorized boat entry to the piers. The necropsy indicated that vessel strike was the most likely cause of death. Given the location the whale was discovered, this could have been the result of a military vessel strike. However, the Navy reviewed its vessel activity during that time frame and available observations of those vessels coming and going to port, as well as at port, and determined it was unlikely that the whale was carried into port by a Navy vessel. Based on this and other information from Navy's investigation, we cannot determine whether this whale was struck by a Navy vessel during HSTT activities or was struck by a commercial or other vessel and drifted into the Navy pier area.

For the same reasons listed above describing why the likelihood of a military vessel striking a whale is lower than that of some other vessels striking whales, it is also highly unlikely that a Navy vessel would strike a whale, dolphin, porpoise, or pinniped without detecting it. Specifically, Navy vessels have Lookouts, including on the forward part of the ship that can visually detect a hit animal in the event ship personnel do not feel the strike (which has occurred). Accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis. The Navy has strict internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Navy's discipline, extensive training (not only for detecting marine mammals, but for detecting and reporting any potential navigational obstruction), and strict

chain of command give NMFS a high level of confidence that all strikes are reported.

In order to better account for the accidental nature of vessel strikes to large whales in general and the potential risk from U.S. Navy vessel movement within the HSTT Study Area during the remaining period of the HSTT rule in particular, the Navy requested the HSTT rule be modified to authorize additional incidental takes by vessel strike based on probabilities derived from a Poisson distribution using vessel strike data between 2009–2021 in the HSTT Study Area (the time period from when current mitigations were instituted until the Navy conducted the analysis for the 2022 Navy application), as well as historical at-sea days in the HSTT Study Area from 2009–2015 and estimated at-sea days for the period from 2016 to 2025 covered by the current regulations. This distribution predicted the probabilities of a specific number of strikes ($n = 0, 1, 2, \text{etc.}$) over the remaining period of the regulations at the time of the Navy's analysis (2022–2025).

The Navy used the two fin whale strikes (2009) and two unidentified large whale strikes (2021) in their calculations to determine the number of strikes likely to result from its activities over the remaining 3 years of the rule (2023–2025, although worldwide strike information from all Navy activities and other sources was used to inform the species that may be struck). The Navy

evaluated data beginning in 2009 as that was the start of the Navy's Marine Species Awareness Training and adoption of additional mitigation measures to address vessel strike, which will remain in place along with additional and modified mitigation measures during the 7 years of this rulemaking. From this analysis, the Navy concluded that there was a 27 percent chance that zero whales would be struck by Navy vessels over the remaining period of the rule (which, at the time that the application was submitted, was 4 years), and a 35, 23, and 10 percent chance that one, two, or three whales, respectively, would be struck over the remaining 4 years of the rule. Therefore, the Navy estimated that there was some probability that the Navy could strike, and take by serious injury or mortality, up to three large whales incidental to training and testing activities within the HSTT Study Area over what would have been the remaining 4 years of the current authorization, and the Navy requested authorization of two additional takes of large whales by serious injury or mortality by vessel strike, beyond the three takes authorized by the 2020 HSTT final rule (85 FR 41780, July 10, 2020).

NMFS has since updated this analysis to reflect that an additional strike of an unidentified large whale occurred in May 2023 (either a fin whale or sei whale, as stated above) and that additional time has passed since the

Navy submitted the 2022 Navy application. Based on further discussions with the Navy, NMFS has also updated the way it calculated at-sea days. This is a different manner of calculating at-sea days for the purposes of the strike analysis rather than a change in Navy's activity levels. For 2010–2015, the at-sea days used in NMFS' calculation reflected historic at-sea days in the HSTT action area based on positional vessel data records (Mintz, 2016). While the actual annual at-sea days from 2016–present are currently classified, NMFS' updated calculation reflects an extrapolation of the 2010–2015 at-sea days (using the formula $y = -64x + 131555$) to estimate the number of at-sea days in 2016 (Navy, 2022). The number of at-sea days derived for 2016 was 2,056 at-sea days, which reflects the downward trend in HSTT vessel activity from 2010–2015. Since we do not have sufficient information to say whether or not this downward trend continued for the years 2017–2023, we conservatively estimate the average over these years was the same as the 2016 extrapolated value of 2,056 at-sea days. This analysis only included at-sea days for Navy warships greater than 65 feet (*i.e.*, destroyers are the smallest ship class included). Navy vessels smaller than 65 feet have never reported a whale strike in the Pacific, and therefore, we consider it unlikely that this would occur in the remaining period of the regulations.

TABLE 4—HSTT 2009 THROUGH MID-2023 AT-SEA DAYS USED FOR THE VESSEL STRIKE PROBABILITY CALCULATION

Year	At-Sea days	Derivation
2009	4,233	Estimated average based on 2010–2015 data.
2010	5,207	Based on positional vessel data.
2011	4,483	Based on positional vessel data.
2012	4,081	Based on positional vessel data.
2013	4,041	Based on positional vessel data.
2014	4,272	Based on positional vessel data.
2015	3,311	Based on positional vessel data.
2016	2,056	Extrapolated from 2010–2015 regression.
2017	2,056	Extrapolated from 2010–2015 regression.
2018	2,056	Extrapolated from 2010–2015 regression.
2019	2,056	Extrapolated from 2010–2015 regression.
2020	2,056	Extrapolated from 2010–2015 regression.
2021	2,056	Extrapolated from 2010–2015 regression.
2022	2,056	Extrapolated from 2010–2015 regression.
2023 (first half of year)	1,028	Extrapolated from 2010–2015 regression, then reduced by half.
2009– Mid-2023 total	45,048	

NMFS then used the number of past Navy vessel strikes and the at-sea days to calculate a vessel strike rate for 2009 through mid-2023. The estimated total number of Navy at-sea days (for vessels greater than 65 feet) for 2009 through mid-2023 was 45,048 days. Dividing the five known strikes during that period by

the at-sea days (*i.e.*, 5 strikes/45,048 at-sea days) results in a strike rate of 0.000111 strikes per day.

As described above, NMFS conservatively assumed that the average number of at-sea days from mid-2023 through 2025 (the remaining period of the regulations at the time that the

analysis was conducted) will be the same as the 2016 extrapolated value of 2,056. Therefore, the estimated at-sea days within the action area for the period from mid-2023 through 2025 is 5,140 days. NMFS multiplied the historic daily strike rate by the estimated at-sea days from mid-2023

through 2025 (0.000111 strikes per day $\times$ 5,140 days) to estimate the number of whale strikes anticipated during that period. This calculation predicts an estimated 0.57 strikes over the remaining 2.5 years of the regulations at the time the analysis was conducted (mid-2023 through 2025).

As explained above, according to the U.S. Navy, the May 2021 vessel strike of two fin whales by a Royal Australian Navy vessel did not occur while that vessel was participating in a U.S. Navy-led training exercise, and the strike of those two fin whales is not included in the estimated take by vessel strike calculation. Instead, as noted below, NMFS considered the 2021 vessel strike by the Royal Australian Navy along with other strike information when determining which species could be among the estimated large whales struck.

NMFS used a Poisson distribution to derive the probabilities of a specific number of strikes ($n=0, 1, 2, \text{etc.}$) from mid-2023 through 2025, given the estimated 0.57 strikes during that period. NMFS' probability analysis concluded that there is a 57 percent chance that zero whales would be struck by U.S. Navy vessels from mid-2023 through 2025, and a 32, 9, and 2 percent chance that one, two, or three whales, respectively, would be struck over that period. Further, there is an estimated 11 percent chance that the Navy would strike more than one large whale from mid-2023 through 2025. We have assessed these probabilities and determined that the strike of up to two large whales could occur over the remaining duration of the regulations, for a total of five takes by serious injury or mortality of large whales by vessel strike total over the 7-year duration of the regulations (three takes authorized in the 2020 HSTT final rule (85 FR 41780, July 10, 2020) which have occurred, plus two additional takes).

In addition to the reasons listed above that make it unlikely that the Navy will hit a large whale (more maneuverable ships, larger crew, *etc.*), vessel strike of dolphins, small whales, porpoises, and pinnipeds is considered very unlikely. Dating back more than 20 years and for as long as it has kept records, the Navy has no records of any pinnipeds being struck by a vessel as a result of Navy activities. Over the same time period, NMFS and the Navy have only one record of a dolphin, porpoise, or small whale being struck by a vessel as a result of Navy activities. A dolphin was accidentally struck by a Navy small boat in fall 2021 in Saint Andrew's Pass, Florida. The smaller size and maneuverability of dolphins, small

whales, and pinnipeds generally make such strikes very unlikely. Other than this one reported strike of a dolphin in 2021, NMFS has never received any reports from other LOA or Incidental Harassment Authorization holders indicating that these species have been struck by vessels. In addition, worldwide vessel strike records show little evidence of strikes of these groups from the shipping sector and larger vessels, and the majority of the Navy's activities involving faster-moving vessels (that could be considered more likely to hit a marine mammal) are located in offshore areas where smaller delphinid, porpoise, and pinniped densities are lower. Based on this information, NMFS concurs with the Navy's assessment and recognizes the potential for (and is authorizing) incidental take by vessel strike of large whales only (*i.e.*, no dolphins, small whales, porpoises, or pinnipeds) over the course of the 7-year regulations from training and testing activities as discussed below.

Next, after determining that take of up to five large whales could occur, NMFS considered which species could be among the five large whales struck. As noted in the 2018 HSTT proposed and final rules, the 2019 HSTT proposed rule, 2020 HSTT final rule, and 2023 HSTT proposed rule, in the 2017 Navy rulemaking/LOA application, the Navy initially considered a weight of evidence approach that considered relative abundance, historical strike data over many years, and the overlap of Navy activities with the stock distribution in their request. NMFS updated this analysis to consider several factors, in addition to the overlap of Navy activities with stock distribution: (1) The relative likelihood of striking one stock versus another based on available strike data from all vessel types as denoted in the Carretta *et al.* (2021; referenced in the Pacific SARs), the Pacific and Alaska SARs (Carretta *et al.* 2024 and Young *et al.* 2024), and unpublished NMFS vessel strike data for 2019–2021; and (2) whether the Navy has ever struck an individual from a particular species or stock in the HSTT Study Area, and if so, how many times. (Note that since publication of the 2023 HSTT proposed rule, Carretta *et al.* (2023), which includes vessel strike data through 2021 has published, but NMFS included this data in its analysis through the unpublished NMFS vessel strike data for 2019–2021, referenced above). NMFS did not consider relative abundance, as was considered in previous analyses, given that the relative abundance of a stock does not necessarily inform its

occurrence in a specific area. Further, NMFS did not consider the historical strike data from older years (prior to 2015), given that more recent data is more relevant to determining occurrence of, and strike risk to, various stocks. NMFS updated the analysis with NMFS' vessel strike probability analysis for the remaining period of the rule (2.5 years at the time of the analysis) and included new/updated vessel strike data from the SARs and NMFS records for California and Hawaii.

To address number (1) above, for SOCAL, NMFS compiled information from Carretta *et al.* (2021) and unpublished NMFS vessel strike data for 2020–2021 (since published in Carretta *et al.* (2023)) for California on known annual rates of large whale serious injury or mortality from vessel collisions (this data includes the strike of two fin whales by the Royal Australian Navy in 2021, but does not include Navy strikes in 2021 and 2023 because the species struck is not known). Use of Carretta *et al.* (2021) rather than the Pacific SAR allows NMFS to separate strikes that occurred in California from strikes to the same stocks that occurred in other locations. For the HRC, NMFS compiled information from the Pacific and Alaska SARs and unpublished NMFS vessel strike data for 2019–2021 for Hawaii on known annual rates of large whale serious injury or mortality from vessel collisions. The annual rates of large whale serious injury or mortality from vessel collisions from those sources help inform the relative susceptibility of large whale species to vessel strike in SOCAL and the HRC; therefore, we considered only reported strikes where the species struck was identified with sufficient certainty (*i.e.*, “known strikes”). Additionally, the M/SI in the 2023 SAR considers modeled takes for some, but not most species and stocks (*i.e.*, M/SI for humpback whale includes modeled takes from Rockwood *et al.* (2017)). Using known strike data for all species and stocks allows us to consider-like metrics for this comparative analysis. (Note we rely on the M/SI estimates from the 2023 SAR (or draft 2023 SAR, where relevant) in our negligible impact analysis. We also consider modeled takes of species from Rockwood *et al.* (2017) in table 7). We summed the annual rates of serious injury or mortality from vessel collisions in California and Hawaii as calculated above and then divided each species' annual rate by this sum to get the proportion of strikes for each species/stock (table 5).

TABLE 5—ANNUAL RATES OF SERIOUS INJURY AND MORTALITY FROM VESSEL STRIKE AND PERCENTAGE OF TOTAL STRIKES BY SPECIES IN SOCIAL AND THE HRC

ESA status	Species	Stock	SOCAL annual known strikes (2015–2021)	HRC annual known strikes (2015–2021)	Percentage of total annual strikes
Listed	Blue whale	Central North Pacific	0	0	0.0
		Eastern North Pacific	0.57		6.5
	Fin whale ^a	California, Oregon, & Washington	1.57		17.8
		Hawaiian		0	0.0
	Humpback whale	Central America/Southern Mexico-CA/OR/WA (Central America DPS).	1 ^b		11.3
		Mainland Mexico- CA/OR/WA (Mexico DPS).			
	Sei whale	Eastern North Pacific	0.14		1.6
		Hawaiian		0	0.0
	Gray whale	Western North Pacific	0		0.0
	Sperm whale	California, Oregon, & Washington	0		0.0
Not listed		Hawaiian		0	0.0
	Gray whale	Eastern North Pacific	2.14		24.3
	Bryde's whale	ETP stock	0		0.0
		Hawaiian		0	0.0
	Minke whale	CA/OR/WA	0		0.0
		Hawaii		0	0.0
Total	Humpback whale	Hawaii (Hawaii DPS)		3.4	38.5
			8.82		

^a This includes the two fin whales struck by the Royal Australian Navy in May 2021.

^b This strike occurred to an individual of the CA/OR/WA stock under the previous stock structure. As such, in its analysis, NMFS assumed that this strike could have been of either stock.

To inform the likelihood of striking a particular species of large whale, we multiplied the percent of total annual strikes for a given species in table 5, by the total percent likelihood of striking at least one whale during the remaining period of the rule (2023–2025 at the time of the analysis; *i.e.*, 43 percent, as described by the probability analysis above). We also calculated the percent

likelihood of striking a particular species of large whale twice during the remaining period of the rule by squaring the value estimated for the probability of striking a particular species of whale once (*i.e.*, to calculate the probability of an event occurring twice, multiply the probability of the first event by the second). The results of these calculations are reflected in the last two

columns of table 6. We note that these probabilities vary from year to year as the average annual mortality changes depending on the specific range of time considered; however, over the years and through updated data in the SARs and unpublished NMFS records, stocks tend to consistently maintain a relatively higher or relatively lower likelihood of being struck.

TABLE 6—PERCENT LIKELIHOOD OF STRIKING EACH STOCK ONE OR TWO TIMES OVER 2.5 YEARS AND TOTAL KNOWN U.S. NAVY STRIKES IN THE HSTT STUDY AREA

Species	Stock	Total known U.S. Navy strikes in HSTT study area	Percent likelihood of 1 strike over 2.5 years	Percent likelihood of 2 strikes over 2.5 years
Blue whale	Central North Pacific	0	0.00	0.00
	Eastern North Pacific	1 in SOCAL (2004)	2.81	0.08
Fin whale	CA/OR/WA	3 in SOCAL (2009, 2023 ^a)	7.74 ^b	0.60 ^b
	Hawaiian	0	0.00	0.00
Humpback whale	Central America/Southern Mexico-CA/OR/WA (Central America DPS).	0	4.93	0.24
	Mainland Mexico- CA/OR/WA (Mexico DPS).			
Sei whale	Eastern North Pacific	1 in SOCAL (2023 ^a)	0.69	0.00
	Hawaiian	0	0.00	0.00
Gray whale	Western North Pacific	0	0.00	0.00
Sperm whale	CA/OR/WA	0.00	0.00	
	Hawaiian	1 in HRC (2007)	0.00	0.00
Gray whale	Eastern North Pacific	3 in SOCAL (1993, 1998)	10.55	1.11
Bryde's whale	ETP stock	0	0.00	0.00
	Hawaiian	0	0.00	0.00
Minke whale	CA/OR/WA	0	0.00	0.00
	Hawaii	0	0.00	0.00

TABLE 6—PERCENT LIKELIHOOD OF STRIKING EACH STOCK ONE OR TWO TIMES OVER 2.5 YEARS AND TOTAL KNOWN U.S. NAVY STRIKES IN THE HSTT STUDY AREA—Continued

Species	Stock	Total known U.S. Navy strikes in HSTT study area	Percent likelihood of 1 strike over 2.5 years	Percent likelihood of 2 strikes over 2.5 years
Humpback whale	Hawaii (Hawaii DPS)	2 in HRC (2003)	16.76	2.81

^aBased on available photos and video, NMFS and the Navy have determined the May 2023 strike was of either a fin whale or sei whale. In the analysis herein, NMFS has assumed that this strike could have been of either species, and has therefore, accounted for it in both the fin whale and sei whale strike totals. Given that we are unable to identify the species of the whales struck by the U.S. Navy in 2021, NMFS did not include the two 2021 strikes in this part of the analysis.

^bThis includes the two fin whales struck by the Royal Australian Navy in May 2021.

The percent likelihood calculated as described above are then considered in combination with the information indicating the known species that the Navy has hit in the HSTT Study Area since 1991 (since they started tracking consistently; table 6). We note that for the lethal take of species specifically denoted in table 7 below, 47 percent of those struck by the Navy (8 of 17 in the Pacific) remained unidentified (including the May 2023 strike, which as stated above, NMFS and the Navy have determined was of either a fin

whale or sei whale). However, given the information on known stocks struck, the analysis below remains appropriate. We also note that Rockwood *et al.* (2017) modeled the likelihood of vessel strike of blue whales, fin whales, and humpback whales on the U.S. West Coast (discussed in more detail in the *Serious Injury or Mortality* subsection of the Analysis and Negligible Impact Determination section), and those numbers help inform the relative likelihood that the Navy could hit those stocks.

For each indicated stock, table 7 includes the percent likelihood of striking an individual whale from a particular stock during the remaining 2.5 years of the rule once based on SAR data, Carretta *et al.* (2021), and unpublished NMFS vessel strike data from 2019–2021 for Hawaii; total strikes from Navy vessels in the HSTT Study Area, and modeled vessel strikes from Rockwood *et al.* (2017). The last column indicates the authorized annual mortality.

TABLE 7—SUMMARY OF FACTORS CONSIDERED IN DETERMINING THE NUMBER OF INDIVIDUALS IN EACH STOCK POTENTIALLY STRUCK BY A VESSEL

ESA status	Species	Stock	Percent likelihood of one strike over 2.5 years	Total known U.S. Navy strikes in HSTT study area (1993–2009)	Rockwood <i>et al.</i> 2017 modeled vessel strikes ¹	Annual authorized take from 2020 HSTT final rule	Annual authorized take
Listed	Blue whale	Central North Pacific	0.00	0			0
		Eastern North Pacific	2.81	1 in SOCAL (2004)	18	0.14	0.14
	Fin whale	CA/OR/WA	7.74 ²	3 in SOCAL (2009, 2023 ³)	43	0.29	0.57
		Hawaii	0.00	0			0
	Humpback whale ⁴	Central America/Southern Mexico- CA/OR/WA (Central America DPS).	4.93	0	22	0.14	0
		Mainland Mexico-CA/OR/WA (Mexico DPS).					0.14
		Eastern North Pacific	0.69	1 in SOCAL(2023) ³			0.14
	Sei whale	Hawaii	0.00	0			0
	Gray whale	Western North Pacific	0.00	0			0
	Sperm whale	CA/OR/WA	0.00	0			0
Not listed	Gray whale	Hawaii	0.00	1 in HRC (2007)		0.14	0
		Eastern North Pacific	10.55	3 in SOCAL (1993, 1998) ...		0.29	0.57
	Bryde's whale	Eastern Tropical Pacific	0.00	0			0
		Hawaii	0.00	0			0
	Minke whale	CA/OR/WA	0.00	0			0
		Hawaii	0.00	0			0
	Humpback whale	Hawaii (Hawaii DPS) ⁵	16.76	2 in HRC (2003)		0.29	0.29

¹ Rockwood *et al.* modeled likely annual vessel strikes off the West Coast for these three species only.

² This includes the two fin whales struck by the Royal Australian Navy in May 2021.

³ Based on available photos and video, NMFS and the Navy have determined the May 2023 strike was of either a fin whale or sei whale. In the analysis herein, NMFS has assumed that this strike could have been of either species, and has therefore, accounted for it in both the fin whale and sei whale strike totals.

⁴ In the 2020 HSTT final rule, take of humpback whale by serious injury and mortality by vessel strike in SOCAL was attributed to the former CA/OR/WA stock and the Mexico DPS. Text explains why takes in SOCAL come from the Mexico DPS, and therefore the Mainland Mexico-CA/OR/WA stock.

⁵ The 2023 final SAR reports vessel strike data for the Hawaii stock of humpback whales in Alaska, Washington, and Hawaii. Only vessel strike data from Hawaii was incorporated into our analysis as Alaska and Washington are outside of the HSTT Study Area.

Accordingly, stocks that have no record of ever having been struck by any vessel are considered to have a zero percent likelihood of being struck by the Navy in the 7-year period of the rule. Stocks that have never been struck by the Navy, have rarely been struck by

other vessels, and have a low percent likelihood based on the historical vessel strike calculation are also considered to have a zero percent likelihood to be struck by the Navy during the 7-year rule. We note that while vessel strike records have not differentiated between

Eastern North Pacific and Western North Pacific gray whales, given their small population size and the comparative rarity with which individuals from the Western North Pacific stock are detected off the U.S. West Coast, it is highly unlikely that

they would be encountered, much less struck. This rules out all but seven stocks. Further, it is unlikely that the Hawaii stock of sperm whale would be struck given the zero percent likelihood of striking a sperm whale as indicated by the quantitative analysis above, the fact that the last U.S. Navy strike of a Hawaii stock sperm whale was in 2007, before the mitigation updates discussed above, and that, with the exception of humpback whales, vessel strikes (both military and non-military) of other large whale species in the HRC are extremely rare events (Carretta 2021b; Carretta 2022). (The 2020 HSTT final rule authorized one take (0.14 annual take) by mortality of the Hawaii stock of sperm whale.)

As stated previously, based on available photos and video of the whale struck by the U.S. Navy in Southern California in 2023, NMFS and the Navy have determined this whale was either a fin whale or sei whale. While the species of the two whales struck by the U.S. Navy in 2021 are unknown, given the following factors, NMFS expects these strikes may have been CA/OR/WA fin whales or Eastern North Pacific (ENP) gray whales, or some combination of these two stocks. These species have the highest annual rates of M/SI from vessel collision in California (1.57, 2.14, respectively, as noted above; which is approximately one and a half to two times higher than the species with the next highest strike rate, humpback whale, and approximately two to four times higher than the strike rate of blue whale). Additionally, gray whale and fin whale have the most recorded vessel strike incidents by military vessels in SOCAL and are the only stocks known to have been hit more than one time by naval vessels in the SOCAL portion of the HSTT Study Area (three gray whale strikes by the U.S. Navy (1993, 1998), two or three fin whale strikes by the U.S. Navy (2009, potentially 2023), and two fin whale strikes by the Royal Australian Navy (2021)). Further, accounting for undocumented vessel strikes, Rockwood *et al.* (2021) estimated that in their study area off Southern California from 2012–2018, on average 8.9 blue, 4.6 humpback, and 9.7 fin whales were killed by civilian vessel strikes from June to November each year. In addition, they estimated that, on average, 5.7 humpback whales were killed by civilian vessel strike from January–April per year (Rockwood *et al.* 2021). For fin whales in particular, model-predicted densities of large whales in the Southern California Bight from May to July 2021 (the time period during which the 2021 strikes of two

unidentified whales by the U.S. Navy occurred) estimated fin whale abundance as being nearly an order of magnitude higher than either blue or humpback whale abundance during this time period (Becker *et al.* 2020; Zickel *et al.* 2021). Ship-whale encounter models for the U.S. West Coast Exclusive Economic Zone also indicated that vessel strike mortality estimates for fin whales were significantly higher than for blue whales and humpback whales (Rockwood *et al.* 2017). The comparatively higher modeled vessel strike rates for fin whales result from both the larger population as well as the more offshore distribution that overlaps significantly with several major shipping routes for a much greater spatial extent (Rockwood *et al.* 2017). Based on 1,243 visual boat-based sightings of 2,638 fin whales from 1991–2011, Calambokidis *et al.* (2015) found fin whale concentration areas included the San Clemente Basin where the 2021 Navy vessel strikes occurred (Tanner and Cortez Banks area and the shelf edge west of San Nicolas Island were also reported as fin whale concentration areas). There are two different populations of fin whales that occur in the Southern California Bight: a seasonal population, and a population that occurs year-round with offshore/inshore movements (Campbell *et al.* 2015; Falcone *et al.* 2022). This would likely make fin whales more susceptible to vessel strike year-round, as compared to other large whale species that may occur seasonally within SOCAL. Based on all of these factors, there is a reasonable likelihood that the CA/OR/WA stock of fin whales or ENP stock of gray whales could be struck twice during the remaining period of the rule. Therefore, we find that, of the five total takes by serious injury or mortality by vessel strike of large whales authorized over the course of the 7-year rule, up to four of those takes could be of the CA/OR/WA stock of fin whale or the ENP stock of gray whale given that the two strikes of unidentified large whales in 2021 could have been of either stock. Further, consistent with the 2020 HSTT final rule, we expect that, of the five total takes by serious injury or mortality by vessel strike of large whales authorized, up to two of those takes could occur in Hawaii, and therefore be of individuals of the Hawaii stock of humpback whale.

Based on the information summarized in table 7 and the fact that there is the potential for up to two large whales to be struck over the remaining period of the rule (five strikes over the full 7-year rule period), one individual from the

Eastern North Pacific stock of blue whale, Mainland Mexico-CA/OR/WA stock of humpback whale, or Eastern North Pacific stock of sei whale could be among the two whales struck during the remaining effective period of the regulations (2023–2025 at the time of the analysis). The total strikes of Eastern North Pacific blue whales and the percent likelihood of striking one based on the historic strike calculation above can both be considered moderate compared to other stocks, and the Navy struck a blue whale in 2004 (based on the historic strike calculation, the likelihood of striking two blue whales is well below one percent (table 6)). Therefore, we consider it reasonably likely that the Navy could strike one individual over the course of the 7-year rule, and given that we do not expect that the 2023 strike nor either of the 2021 U.S. Navy strikes of unidentified large whales were blue whales, we expect that this strike could occur during the remaining period of the rule. The total strikes of Eastern North Pacific sei whales are low compared to other stocks, but NMFS and the Navy think it is possible that the Navy may have struck a sei whale in SOCAL in 2023. Therefore, we consider it reasonably likely that the Navy could strike a sei whale over the remaining period of the rule. The Navy has not hit a humpback whale in the SOCAL portion of the HSTT Study Area. However, in 2016 a U.S. Coast Guard vessel participating in a Navy event struck a humpback whale in Hood Canal, and as a species, humpbacks have a moderate to high number of total strikes and percent likelihood of being struck. Although the likelihood of Central America/Southern Mexico- CA/OR/WA (Central America DPS) or Mainland Mexico-CA/OR/WA (Mexico DPS) humpback whales being struck by any vessel type is moderate to high relative to other stocks, the distribution of the Mexico DPS versus the Central America DPS, as well as the distribution of overall vessel strikes inside versus outside of the SOCAL area (the majority are outside), supports the reasonable likelihood that the Navy could strike one individual humpback whale from the Mainland Mexico-CA/OR/WA stock (Mexico DPS) over the 7-year duration of the rule, as described below.

Regarding the likelihood of striking a humpback whale from a particular DPS, we evaluated the relative abundance of each of these DPS in California waters. Curtis *et al.* (2022) estimated the abundance of the Central America DPS to be 1,496 whales. From Wade *et al.* (2017), about 93 percent (or 1,391

whales) of these humpbacks that winter in Central America will move to Oregon/California in the summer months. While there is currently no abundance estimate for the Mexico DPS, an estimated 3,477 whales from the Mexico DPS feed off the U.S. West Coast (Calambokidis and Barlow 2020; Curtis 2022). Based on this information, we estimate that approximately 30 percent of the humpback whales off the coast of California may be from the Central America DPS with the remaining 70 percent expected to be from the Mexico DPS. Therefore, we anticipate that if a Navy vessel strike of a humpback whale were to occur within SOCAL, it would likely be from the Mexico DPS. Last, Rockwood *et al.* (2017) supports a relative likelihood of 1:1:2 for striking blue whales, humpback whales, and fin whales off the U.S. West Coast (though as noted above, more recent data suggests that the relative likelihood of striking a fin whale is higher and suggests that the two 2021 U.S. Navy vessel strikes of unidentified large whales may have been fin whales), which, in consideration of more recent data also supports the authorized take included in this rule, which is 1, 1, and 4, respectively over the 7-year period. For these reasons, one lethal take of a Mainland Mexico-CA/OR/WA humpback whale (Mexico DPS) could occur and is authorized.

For Hawaii stocks, given that all known vessel strikes between 2015 and 2021 were of humpback whales, we anticipate that any vessel strike of a large whale in Hawaii would be of the Hawaii stock of humpback whale. Given that this stock has the highest percentage of total annual strikes (38.5 percent) and a 2.81 percent chance of being struck twice over the remaining period of the rule (more than twice that of the species with the next highest percentage, gray whale), NMFS authorizes two lethal takes of Hawaii humpback whales.

As described above, the Navy's analysis suggests and NMFS' analysis concurs that the likelihood of vessel strikes to the stocks below is discountable due to the stocks' relatively low occurrence in the HSTT Study Area, particularly in core HSTT training and testing subareas, and the fact that the stocks have not been struck by the Navy and are rarely, if ever, recorded struck by other vessels. Therefore, NMFS is not authorizing lethal take for the following stocks: Blue whale (Central North Pacific stock), Bryde's whale (Eastern Tropical Pacific stock and Hawaii stock), fin whale (Hawaii stock), gray whale (Western North Pacific stock), humpback whale

(Central America/Southern Mexico-CA/OR/WA stock, Central America DPS), minke whale (CA/OR/WA stock and Hawaii stock), sei whale (Hawaii stock), and sperm whale (CA/OR/WA stock and Hawaii stock).

Also of note, while information on past Navy vessel strikes can serve as a reasonable indicator of future vessel strike risk, future conditions may differ from the past in ways that could influence the likelihood of a large whale vessel strike occurring. In general, the magnitude of vessel strike risk may be increasing over time as many whale populations are gradually recovering from centuries of commercial whaling (Redfern *et al.* 2020). Increased vessel strike risk off California in recent decades has been associated with increases in the abundance of fin and humpback whale populations in the North Pacific (Redfern *et al.* 2020). It has also been suggested that the blue whale population in the Eastern North Pacific, inclusive of the SOCAL portion of the HSTT Study Area, is at carrying capacity and recovered to pre-whaling levels (Monnahan *et al.* 2014). In addition, the magnitude of risk may also be affected by shifts in whale distributions over time in response to environmental factors including climate change, marine heatwaves, and associated changes in prey distribution.

Historically, military vessel strikes of large whales within the HSTT Study Area have been rare events with only seven such strikes occurring over the past 14 years, five U.S. Navy strikes, and two Royal Australian Navy strikes. However, the fact that four of these strikes occurred within a 3-month period (May-July) in 2021, and two occurred within a 4-month period (February-May) in 2009, suggests that military vessel strikes in SOCAL can be both highly episodic and clustered. The four large whale strikes in 2021 (two strikes of unidentified large whales by the U.S. Navy and two fin whale strikes by the Royal Australian Navy) appear to be outliers in the time series of military vessel strikes in SOCAL for that period. However, particularly in consideration of the 2023 U.S. Navy strike, these strikes could also represent an early indicator of an increased military vessel strike risk within SOCAL based on the factors discussed above. Results from a survey of whale watching vessel operators and crew in Southern California, combined with remote sensing data in the area, suggest that the number of large whales may have been greater in May through July of 2021 compared with previous years in certain high military vessel traffic and "core" use HSTT areas off southern California,

particularly farther offshore as well as closer to shore off San Diego Bay (Zickel MJ *et al.* 2021).

In conclusion, while take by vessel strike across any given year is sporadic, based on the information and analysis above, including consideration of the 2021 and 2023 strikes by the U.S. Navy, NMFS anticipates no more than five takes of large whales by M/SI could occur over the 7-year period of the rule. Of those five whales over the 7-years, no more than four may come from the following stocks: gray whale (Eastern North Pacific stock) and fin whale (CA/OR/WA stock). No more than two may come from the Hawaii stock of humpback whales. No more than one may come from the following stocks: blue whale (Eastern North Pacific stock), sei whale (Eastern North Pacific), and humpback whale (Mexico-North Pacific stock or Mainland Mexico-CA/OR/WA, Mexico DPS). Accordingly, NMFS has evaluated under the negligible impact standard the M/SI of 0.14, 0.29, or 0.57 whales annually from each of these species or stocks (*i.e.*, one, two, or four takes, respectively, divided by 7 years to get the annual number), along with the expected incidental takes by harassment.

Explosives

The Navy's model and quantitative analysis process used for the 2018 HSTT FEIS/OEIS and in the Navy's 2017 and 2019 applications to estimate potential exposures of marine mammals to explosive stressors is detailed in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing report* (U.S. Department of the Navy, 2018). Specifically, over the course of a modeled maximum year of training and testing, the Navy's model and quantitative analysis process estimates M/SI of two short-beaked common dolphin and one California sea lion as a result of exposure to explosive training and testing activities (please see section 6 of the 2017 Navy application where it is explained how maximum annual estimates are calculated). Over the 7-year period of the 2020 HSTT regulations, M/SI of 8 short-beaked common dolphins and 5 California sea lions (13 marine mammals in total) is estimated as a result of exposure to explosive training and testing activities. NMFS makes no changes to the authorization of take by M/SI as a result of explosive use as the Navy made no changes to its activities from that described in the 2018 HSTT final rule, and after reviewing all new information,

we find that our previous analyses remain applicable. Please refer to the 2018 HSTT final rule and 2020 HSTT final rule for additional information.

Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable adverse impact on the species or stock(s) and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock(s) for subsistence uses (“least practicable adverse impact”). NMFS does not have a regulatory definition for least practicable adverse impact. The 2004 NDAA amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of “least practicable adverse impact” shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. For the full discussion of how NMFS interprets least practicable adverse impact, including how it relates to the negligible-impact standard, see the Mitigation Measures section in the 2018 HSTT final rule.

Section 101(a)(5)(A)(i)(II) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions (in the form of regulations) setting forth how the activity must be conducted, thus ensuring the activity has the “least practicable adverse impact” on the affected species or stocks. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(A)(i)(II) also provides a mechanism for ensuring compliance with the “negligible impact” requirement. Finally, the least practicable adverse impact standard also requires consideration of measures for marine mammal habitat, with particular attention to rookeries, mating grounds, and other areas of similar significance, and for subsistence impacts, whereas the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.¹ In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the Specified Activities, the availability of measures to minimize those potential

impacts, and the practicability of implementing those measures, as we describe below. This final rule includes all mitigation measures required by the 2020 HSTT final rule (though two have been modified in this final rule), and our discussion in that rule remains complete and accurate (including reference to the 2018 HSTT final rule), except as described below.

Implementation of Least Practicable Adverse Impact Standard

Our evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (where relevant). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation; and

(2) The practicability of the measure(s) for applicant implementation. Practicability of implementation may consider such things as cost, impact on activities, and, in the case of a military readiness activity, specifically considers personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS’ analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals that are likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or

degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the environment, and the affected species or stocks—and the best available science has been used here. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks. We also acknowledge that there is always the potential that new information, or a new recommendation could become available in the future and necessitate reevaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species, consideration of personnel safety, practicality of implementation, and consideration of the impact on effectiveness of military readiness activities are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability in terms of these considerations, can vary widely. For example, a time/area restriction could be of very high value for decreasing population-level impacts (e.g., avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (e.g., decreased disturbance in an area of high productivity but of less firmly established biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the Navy’s ability to certify a strike group (higher impact on mission effectiveness), or it could mean delaying a small in-port training event by 30 minutes to avoid exposure of a marine mammal to injurious levels of sound (lower impact). A responsible evaluation of “least practicable adverse impact” will consider the factors along these realistic scales. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the

¹ Outside of the military readiness context, mitigation may also be appropriate to ensure compliance with the “small numbers” language in MMPA sections 101(a)(5)(A) and (D).

species or stock or its habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and will be carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. For more detail on how we apply these factors, see the discussion in the Mitigation Measures section of the 2018 HSTT final rule.

Assessment of Mitigation Measures for HSTT Rule

NMFS fully reviewed the Navy's specified activities and the mitigation measures for the 2020 HSTT final rule and determined, with the addition of the new and modified measures discussed herein, and after consideration of the new information and studies described above, that the mitigation measures would result in the least practicable adverse impact on marine mammals (see the 2019 Navy application and the 2018 HSTT final rule for detailed information on the Navy's mitigation measures, with the exception of the new and modified measures described herein). NMFS worked with the Navy in the development of the Navy's mitigation measures, which were informed by years of implementation and monitoring. A complete discussion of the Navy's evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in chapter 5 (*Mitigation*) of the 2018 HSTT FEIS/OEIS. The process described in chapter 5 (*Mitigation*) of the 2018 HSTT FEIS/OEIS robustly supports NMFS' independent evaluation of whether the mitigation measures would meet the least practicable adverse impact standard. The Navy has implemented the mitigation measures under the 2020 HSTT regulations and will be required to continue implementation of the mitigation measures identified in this rulemaking for the full 7 years it covers to avoid or reduce potential impacts from acoustic, explosive, and physical disturbance and vessel strike stressors.

The Navy also evaluated numerous measures in the 2018 HSTT FEIS/OEIS that were not included in the 2017 Navy application, and NMFS independently reviewed and considered all new information, and continues to concur

with Navy's analysis that their inclusion was not appropriate under the least practicable adverse impact standard. The Navy considered these additional potential mitigation measures in two groups. First, chapter 5 (*Mitigation*) of the 2018 HSTT FEIS/OEIS, in the Measures Considered but Eliminated section, includes an analysis of an array of different types of mitigation that have been recommended over the years by NGOs or the public, through scoping or public comment on environmental compliance documents. Appendix K (Geographic Mitigation Assessment) of the 2018 HSTT FEIS/OEIS includes an in-depth analysis of time/area restrictions that have been recommended over time or previously implemented as a result of litigation.

Below, we summarize the mitigation measures (organized into procedural measures and mitigation areas) that NMFS has determined will ensure the least practicable adverse impact on all affected species and stocks and their habitat, including the specific considerations for military readiness activities, and including several measures that are new or modified since publication of the 2020 HSTT final rule.

In its 2022 application, the Navy proposed no changes to the procedural or geographic mitigation measures in the 2020 HSTT final rule. NMFS reviewed new information potentially pertinent to mitigation of the Navy's training and testing activities. While Lookouts are essential to detecting the potential for and potentially avoiding a vessel strike of a marine mammal, NMFS and the Navy have always acknowledged that Lookouts cannot prevent all vessel strikes. The recent U.S. Navy and Royal Australian Navy vessel strikes appear to confirm this, as these strikes occurred when Lookouts were posted. As acknowledged above, these recent incidents may represent an early indicator of an increased military vessel strike risk within SOCAL. Recent reports appear to reflect the sporadic, episodic, or clustered nature of vessel strike or may reflect a trend of increased large whale presence in this area in the early summer months. NMFS and the Navy have discussed the circumstances of each of the recent strikes, including the Royal Australian Navy strike, and discussed ways of improving strike mitigation. In these further conversations, NMFS and the Navy developed several new and modified mitigation measures in comparison to those included in the 2020 HSTT final rule.

For vessel movement, the 2020 HSTT final rule required that "When underway Navy personnel must observe

the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance." This measure has been updated to state that reducing speed may be an appropriate way to maneuver. The revised measure states that "When underway, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver (which may include reducing speed as the mission or circumstances allow) to maintain distance." Of note, between 2009 and 2021 (the most recent year for which data is available), U.S. Navy vessels in the SOCAL portion of the HSTT Study Area maneuvered 316 times to avoid large whales during MTEs. The years 2017 and 2021 had the highest number of maneuvers (n=64 and n=82, respectively). In all years for which data is available (2009 to 2021), Navy cruisers and destroyers account for 51 to 100 percent of maneuvers during MTEs. With this modified measure, NMFS is emphasizing that Navy personnel should consider reducing speed (as mission or circumstances allow) when maneuvering to avoid marine mammals, though this modified measure does not require reduction of vessel speed for reasons explained in chapter 5 (*Mitigation*) of the 2018 HSTT FEIS/OEIS, in the Measures Considered but Eliminated section (*i.e.*, requirements to reduce vessel speeds would have significant direct negative effects on mission effectiveness).

This final rule also requires that Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area.

Further, the 2020 HSTT final rule included a requirement for Navy personnel to issue seasonal awareness notification messages to alert ships and aircraft to the possible presence of blue whales (June–October), humpback whales (November–April), gray whales (November–March), or fin whales (November–May). These messages assist in maintaining safety of navigation and in avoiding interactions with large whales during transits. Platforms must use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation. This final rule requires the Navy to re-title the spring blue whale message (released in June) to a large whale awareness message inclusive of typical spring-summer large whales in southern California (mainly blue, fin,

and humpback whales). Furthermore, rather than tying the message release to a specific month, the message would be for a period based on predicted oceanographic conditions for a given year (e.g., May–November, April–November, *etc.*). The Navy will also evaluate information obtained from NMFS' Southwest Fisheries Science Center scientists, recently published West Coast BIAs (Calambokidis *et al.* 2024), and other oceanographic or predictive models for guiding message text descriptions of whale occurrence in Southern California. The improvement will emphasize that when a marine mammal is spotted, this may be an indicator that additional marine mammals are present and nearby, and increased vigilance and awareness of Navy personnel is warranted.

This final rule also contains a new mitigation measure in which Navy personnel would issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in a select area of SOCAL (Of note, the four whales do not have to be the same species and do not have to be part of the same group (e.g., two whales of one species sighted at a distance off the port side at 500 yd (457.2 m) and two more whales of another species sighted off the starboard side at 500 yd (457.2 m) will be considered an aggregation under this measure)). This measure will apply to the area between 32–33 degrees North and 117.2–119.5 degrees West, which includes the locations where recent (2009, 2021, 2023) strikes occurred, and historic locations where strikes occurred when precise latitude and longitude were known.

Of note, in order to improve mitigation effectiveness, in fall 2022 the Navy made several changes to its Lookout training. The Navy revised its basic Lookout training materials to improve marine mammal awareness and spotting techniques through updates to the Marine Mammal chapter of the Navy's September 2022 Lookout Training Handbook. Further, the Navy integrated improved Lookout training into a new generation of a shipboard simulator at its recruit training center in the Great Lakes. This simulator enhances new sailor knowledge and skill under realistic training scenarios. Last, the Navy will evaluate future revisions to online or DVD Marine Species Awareness Training video training to emphasize that when a protected species is spotted, this may be an indicator that additional marine mammals are present and nearby, and

the vessel should take this into consideration when transiting.

In addition to Lookouts required under this rule, the Navy mandates the number of Lookouts on underway vessels per internal policy documents, including the Surface Ship NAVDORM. As described in the *Standard Operating Procedures* section, in 2021, NAVDORM policy changed to require three Lookouts on most classes of surface ship, including destroyers and cruisers. However, the Navy asserts that always including three Lookouts on these vessels in the future as a required mitigation measure is not practicable because lookout numbers are subject to change based on national security needs, including manning and staffing requirements. As such, although the Navy describes these additional Lookouts in its application under the mitigation section, NMFS has not considered the potential presence of two additional lookouts when considering Navy's mitigation effectiveness. Please see the Reporting section for additional detail on this requirement.

With the exception of Oedekoven and Thomas (2022) described above, there is no new information that affects NMFS' assessment of the applicability or effectiveness of the measures included in the 2018 HSTT final rule over the remainder of the 7-year period. As stated above in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, while (Oedekoven and Thomas, 2022) suggests that detection of marine mammals is less certain than previously assumed at certain distances, model assumptions may still underestimate Lookout effectiveness in some cases. Additionally, maneuvering data summarized above demonstrates that Navy vessels are successfully maneuvering to avoid striking sighted marine mammals in most cases, despite the Oedekoven and Thomas (2022) results. Further, as described above, Navy and NMFS have developed modified or new mitigation in this final rule which are anticipated to further reduce the risk of vessel strike of large whales.

In summary, and as described in more detail above regarding vessel strike, the Navy has agreed to procedural mitigation measures that will reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, vessel strike, and impacts to marine mammal habitat. Specifically, the Navy will use a combination of delayed starts, powerdowns, and shutdowns to minimize or avoid M/SI and minimize the likelihood or severity of PTS or

other injury, and reduce instances of TTS or more severe behavioral disturbance caused by acoustic sources or explosives. The Navy will also implement multiple time/area restrictions (several of which were added in the 2018 HSTT final rule since the previous HSTT MMPA incidental take rule) that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors, such as feeding or calving, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts. Table 8 provides the Navy's required procedural mitigation measures for environmental awareness and education and vessel movement as well as summaries of the Navy's procedural mitigation measures for other activities. Table 9 provides summaries of mitigation areas for the HSTT Study Area.

NMFS and the Navy considered additional mitigation areas (beyond those already identified with associated measures to reduce impacts to marine mammals) to further protect marine mammals, including odontocetes with small or resident populations in the HSTT Study Area, and large whales with feeding, reproductive, and migratory BIAs in the HSTT Study Area. This includes consideration of new mitigation areas that could be based on newly identified BIAs in Hawaii (Kratofil *et al.* 2023) and on the West Coast (Calambokidis *et al.* 2024). The HRC overlaps BIAs identified in Kratofil *et al.* (2023) for humpback whale, spinner dolphin, short-finned pilot whale, rough-toothed dolphin, pygmy killer whale, pantropical spotted dolphin, melon-headed whale, false killer whale, dwarf sperm whale, goose-beaked whale, common bottlenose dolphin, and Blainville's beaked whale. All of the BIAs that overlap the HRC are small and resident population BIAs, with the exception of the humpback whale reproductive BIA. SOCAL overlaps BIAs identified in Calambokidis *et al.* (2024) for blue whale (feeding area), fin whale (feeding area), and gray whale (migratory route).

Additional restrictions in mitigation areas beyond those restrictions and areas included in the 2020 HSTT final rule (including mitigation to reduce vessel strike risk such as vessel speed restrictions, and in consideration of the newly identified BIAs (Kratofil *et al.* 2023 and Calambokidis *et al.* 2024)) is impracticable given overlap with critical Navy training areas in the HRC and SOCAL. However, many of the BIAs

identified in Kratofil *et al.* 2023 and Calambokidis *et al.* (2024) partially or fully overlap the mitigation areas included in the 2020 HSTT final rule and this final rule and are aimed at reducing impacts to the same species for which Kratofil *et al.* 2023 and Calambokidis *et al.* (2024) identified BIAs. In the HRC, the existing mitigation areas are targeted and expected to reduce impacts to humpback whales, false killer whales, dwarf sperm whales, pygmy killer whales, short-finned pilot whales,

melon-headed whales, bottlenose dolphins, spotted dolphins, spinner dolphins, rough-toothed dolphins, goose-beaked whales, and Blainville's beaked whales (*i.e.*, all species for which Kratofil *et al.* (2023) identified BIAs). In SOCAL, the existing mitigation areas are aimed at reducing impacts to blue whales, fin whales, and gray whales (*i.e.*, all species for which Calambokidis *et al.* (2024) identified BIAs). Further, as included in the 2023 HSTT proposed rule, this final rule requires that Navy personnel must issue

real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in a select area of SOCAL, and that Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area. Last, this final rule includes modification of two mitigation measures from the 2020 HSTT final rule (85 FR 41780; July 10, 2020) to further reduce the potential for vessel strike.

TABLE 8—SUMMARY OF PROCEDURAL MITIGATION

Stressor or activity	Mitigation zone sizes and other requirements
Environmental Awareness and Education	- This mitigation applies to all training and testing activities, as applicable. - Mitigation Requirements: - Appropriate Navy personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specific activities must complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: - Introduction to the U.S. Navy Afloat Environmental Compliance Training Series. The introductory module provides information on environmental laws (<i>e.g.</i>, ESA, MMPA) and the corresponding responsibilities that are relevant to Navy training and testing activities. The material explains why environmental compliance is important in supporting the Navy's commitment to environmental stewardship. - Marine Species Awareness Training. All bridge watch personnel, Commanding Officers, Executive Officers, maritime patrol aircraft aircrews, anti-submarine warfare and mine warfare rotary-wing aircrews, Lookouts, and equivalent civilian personnel must successfully complete the Marine Species Awareness Training prior to standing watch or serving as a Lookout. The Marine Species Awareness Training provides information on sighting cues, visual observation tools and techniques, and sighting notification procedures. Navy biologists developed Marine Species Awareness Training to improve the effectiveness of visual observations for biological resources, focusing on marine mammals and sea turtles, and including floating vegetation, jellyfish aggregations, and flocks of seabirds. - U.S. Navy Protective Measures Assessment Protocol. This module provides the necessary instruction for accessing mitigation requirements during the event planning phase using the Protective Measures Assessment Protocol software tool. - U.S. Navy Sonar Positional Reporting System and Marine Mammal Incident Reporting. This module provides instruction on the procedures and activity reporting requirements for the Sonar Positional Reporting System and marine mammal incident reporting.
Active Sonar	Depending on sonar source: 1,000 yd (914.4 m) power down, 500 yd (457.2 m) power down, and 200 yd (182.9 m) shut down. 200 yd (182.9 m) shut down.
Air Guns	150 yd (137.2 m).
Pile Driving	100 yd (91.4 m).
Weapons Firing Noise	30 degrees on either side of the firing line out to 70 yd (64 m).
Explosive Sonobuoys	600 yd (548.6 m).
Explosive Torpedoes	2,100 yd (1,920.2 m).
Explosive Medium-Caliber and Large-Caliber Projectiles.	1,000 yd (914.4 m; large-caliber projectiles). 600 yd (548.6 m; medium-caliber projectiles during surface-to-surface activities). 200 yd (182.9 m; medium-caliber projectiles during air-to-surface activities).
Explosive Missiles and Rockets	2,000 yd (1,828.8 m; 21–500 lb. net explosive weight). 900 yd (823 m; 0.6–20 lb. net explosive weight). 2,500 yd (2,286 m). 2.5 nmi (4.6 km).
Explosive Bombs	2,100 yd (1,929.2 m; 6–650 lb net explosive weight).
Sinking Exercises	600 yd (548.6 m; 0.1–5 lb net explosive weight).
Explosive Mine Countermeasure and Neutralization Activities.	1,000 yd (914.4 m; 21–60 lb net explosive weight for positive control charges and charges using time-delay fuses).
Explosive Mine Neutralization Activities Involving Navy Divers.	500 yd (457.2 m; 0.1–20 lb net explosive weight for positive control charges).
Underwater Demolition Multiple Charge—Mat Weave and Obstacle Loading.	700 yd (640.1 m).
Maritime Security Operations—Anti-Swimmer Grenades.	200 yd (182.9 m).
Vessel Movement	- The mitigation must not be applied if: (1) The vessel's safety is threatened, (2) the vessel is restricted in its ability to maneuver (<i>e.g.</i>, during launching and recovery of aircraft or landing craft, during towing activities, when mooring), (3) the vessel is operated autonomously, or (4) when impractical based on mission requirements (<i>e.g.</i>, during Amphibious Assault—Battalion Landing exercises). - Number of Lookouts and Observation Platform: - Lookout must be on the vessel that is underway.¹ - Mitigation Requirements: - Mitigation zones:—500 yd (457.2 m) around whales.—200 yd (182.9 m) around other marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). - When a vessel is underway, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver (which may include reducing speed as the mission or circumstances allow) to maintain distance. - Additional requirements: - If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures. Navy personnel must also send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area.

TABLE 8—SUMMARY OF PROCEDURAL MITIGATION—Continued

Stressor or activity	Mitigation zone sizes and other requirements
Towed In-Water Devices	○ Navy personnel must issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in the area between 32–33 degrees North and 117.2–119.5 degrees West. These notifications would be issued to Navy vessels within this boundary only.
Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions.	• 250 yd (228.6 m; marine mammals). • 200 yd (182.9 m).
Non-Explosive Missiles and Rockets	• 900 yd (823 m).
Non-Explosive Bombs and Mine Shapes	• 1,000 yd (914.4 m).

Note: lb: pounds; nmi: nautical miles; yd: yards; m: meters.

¹ Underway vessels will maintain at least one Lookout. For ship classes required to maintain more than one Lookout, the specific requirement is subject to change over time in accordance with Navy navigation instruction (e.g., the Surface Ship NAVDORM). Navy personnel will notify NMFS as soon as practicable should its Lookout policies change, including in the NAVDORM.

TABLE 9—SUMMARY OF MITIGATION AREAS FOR MARINE MAMMALS

Summary of mitigation area requirements
Hawaii Island Mitigation Area (year-round) • Navy personnel must not conduct more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of MF4 dipping sonar, or use explosives that could potentially result in takes of marine mammals during training and testing.¹ 4-Islands Region Mitigation Area (November 15–April 15 for active sonar; year-round for explosives) • Navy personnel must not use MF1 surface ship hull-mounted mid-frequency active sonar or explosives that could potentially result in takes of marine mammals during training and testing.¹ Humpback Whale Special Reporting Areas (December 15–April 15) • Navy personnel must report the total hours of surface ship hull-mounted mid-frequency active sonar used in the special reporting areas in its annual training and testing activity reports submitted to NMFS. San Diego Arc, San Nicolas Island, and Santa Monica/Long Beach Mitigation Areas (June 1–October 31) • Navy personnel must not conduct more than a total of 200 hours of MF1 surface ship hull-mounted mid-frequency active sonar in the combined areas, excluding normal maintenance and systems checks, during training and testing.¹ • Within the San Diego Arc Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during large-caliber gunnery, torpedo, bombing, and missile (including 2.75" rockets) activities during training and testing.¹ • Within the San Nicolas Island Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery, torpedo, bombing, and missile (including 2.75" rockets) activities during training.¹ • Within the Santa Monica/Long Beach Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery, torpedo, bombing, and missile (including 2.75" rockets) activities during training and testing.¹ Santa Barbara Island Mitigation Area (year-round) • Navy personnel must not use MF1 surface ship hull-mounted mid-frequency active sonar during training and testing, or explosives that could potentially result in the take of marine mammals during medium-caliber or large-caliber gunnery, torpedo, bombing, and missile (including 2.75" rockets) activities during training.¹ Awareness Notification Message Areas (seasonal according to species) • Navy personnel must issue spring awareness notification messages to alert ships and aircraft to the possible presence of large whales during a period based on predicted oceanographic conditions for a given year. The message must emphasize to personnel on vessels that when a marine mammal is spotted, this may be an indicator that additional marine mammals are present and nearby, and increased vigilance and awareness of Navy personnel is warranted. Navy personnel must also issue awareness notification messages to alert ships and aircraft to the possible presence of gray whales (November–March) and fin whales (November–May).

¹ If Naval units need to conduct more than the specified amount of training or testing, they will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include the information in its annual activity reports submitted to NMFS.

Mitigation Conclusions

NMFS has carefully evaluated the Navy's mitigation measures from the 2020 rule—many of which were developed with NMFS' input during the previous phases of Navy training and testing authorizations and none of which have changed since our evaluation during the 2018 HSTT rulemaking, with the exception of the changes described herein—and considered a broad range of other measures (*i.e.*, the measures considered but eliminated in the 2018 HSTT FEIS/OEIS, which reflect many of the comments that have arisen via NMFS or public input in past years) in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included

consideration of the following factors in relation to one another: the manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts to marine mammal species and stocks and their habitat; the proven or likely efficacy of the measures; and the practicability of the measures for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. After considering all new information, including consideration of new information regarding vessel strike, NMFS is requiring two additional mitigation measures and revision of two existing mitigation measures as described above.

Based on our evaluation of the Navy's current mitigation measures (which are being implemented under the 2020 HSTT regulations), as well as modified and new measures described above, NMFS has determined that the mitigation measures are appropriate means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. Additionally, as described in more detail below, the 2020 HSTT final rule includes an adaptive management provision, which NMFS has included in this final rule, which ensures that mitigation is regularly assessed and

provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate.

Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to authorize incidental take for an activity, NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present.

In its 2022 application, the Navy proposed no changes to the monitoring described in the 2018 HSTT final rule and 2020 HSTT final rule. They would continue implementation of the robust Integrated Comprehensive Monitoring Program and Strategic Planning Process described in the 2018 HSTT final rule. The Navy's monitoring strategy, currently required by the 2018 HSTT regulations, is well-designed to work across Navy ranges to help better understand the impacts of the Navy's activities on marine mammals and their habitat by focusing on learning more about marine mammal occurrence in different areas and exposure to Navy stressors, marine mammal responses to different sound sources, and the consequences of those exposures and responses on marine mammal populations. Similarly, these modified regulations would include identical adaptive management provisions and reporting requirements as the 2018 HSTT regulations. There is no new information that would indicate that the monitoring measures put in place under the 2018 HSTT final rule would not remain applicable and appropriate for the 7-year period of this rule. See the *Monitoring* section of the 2018 HSTT final rule for more details on the monitoring program that would be required under this rule. In addition, please see the 2019 Navy application, which references chapter 13 of the 2017 Navy application for full details on the monitoring and reporting proposed by the Navy.

Within the SOCAL portion of HSTT, the Navy has been primarily focused on beaked whale monitoring since 2018 through two separate ongoing projects that are expected to continue until 2025. These projects use passive acoustic devices, visual surveys, satellite tagging, genetic analysis, photoID, and response

to anthropogenic sounds to refine population status of beaked whales in SOCAL. There is also one concurrent project with fin whales using visual surveys, satellite tagging, and photoID to gather additional data on fin whale populations in Southern California. Finally, the Navy continues to fund marine mammal sighting data collected during California Cooperative Oceanic Fisheries Investigations (CALCOFI) <https://calcofi.org/>. These data are collected on a much more frequent basis than NMFS' West Coast visual survey which typically occur once every 5 years in the summer. CALCOFI surveys occur quarterly every year to include winter and spring seasons NMFS does not survey. Sufficient marine mammal sightings have been accumulated since the Navy started funding in 2004 for the data to be incorporated into ongoing NMFS spatial habitat models, including new models for select species. The Navy also annually funds continued NMFS spatial habitat model improvements as new data and techniques become available. These models benefit the Navy and other Federal partners such as the Bureau of Ocean Energy Management and NMFS, for use in future regional marine mammal density derivation. For additional information, please see the Navy's Marine Species Monitoring program website, <https://www.navy.marin-speciesmonitoring.us/regions/pacific/current-projects/>.

Adaptive Management

The 2020 HSTT regulations governing the take of marine mammals incidental to Navy training and testing activities in the HSTT Study Area contain an adaptive management component. Our understanding of the effects of Navy training and testing activities (e.g., acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of 7-year regulations. The 2022 Navy application proposed no changes to the adaptive management component included in the 2020 HSTT final rule.

The reporting requirements associated with this rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes to existing mitigation and monitoring requirements are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or

deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring and if the measures are practicable. If the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of the planned LOA in the **Federal Register** and solicit public comment.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) results from monitoring and exercises reports, as required by MMPA authorizations; (2) compiled results of Navy funded R&D studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs. The results from monitoring reports and other studies may be viewed at <https://www.navy.marin-speciesmonitoring.us>.

Reporting

In order to issue incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal: <http://www.navy.marin-speciesmonitoring.us>. The 2019 Navy application and 2022 Navy application proposed no changes to the reporting requirements, though as noted above, the Navy has since proposed to report changes to Lookout SOPs to NMFS. Except as discussed below, reporting requirements would remain identical to those described in the 2018 HSTT final rule and 2020 HSTT final rule, and there is no new information that would indicate that the reporting requirements put in place under the 2020 HSTT final rule would not remain applicable and appropriate for the remaining duration of the 7-year period of this rule. See the *Reporting* section of the 2018 HSTT final rule for more details on the reporting that would be required under this rulemaking. In addition, the 2018 HSTT proposed and final rules unintentionally failed to

include the requirement for the Navy to submit a final activity “close out” report at the end of the regulatory period. That oversight was corrected through the 2020 HSTT final rule. Please see the 2020 HSTT final rule for the detailed requirements for that report.

In addition to the reporting requirements included in the 2020 HSTT final rule, in 2023, we proposed requiring the Navy to report changes in its Lookout policies to NMFS as soon as practicable after a change is made. This final rule requires the Navy to implement that reporting measure, as well as two new measures that were not included in the 2023 HSTT proposed rule, described below.

The Navy’s annual HSTT Training Exercise Report and Testing Activity Report must include information that tracks the Navy’s implementation of the new SOCAL large whale aggregation real-time reporting mitigation measure. The report must include the following information for each instance that an aggregation of large whales is reported: (1) the date, time and general location (*e.g.*, approximately 10–12 nmi (18.5 to 22.2 km) SE of San Clemente Island) of the whales when the aggregation was first sighted; (2) the total number of whales observed within 1 nmi (1.8 km) of a Navy vessel that make up the aggregation; and (3) the approximate distance (or distances if more than one group of whales is sighted) of the vessel from the whales in the aggregation when the whales were first sighted. To the extent practicable, this information should be provided in the Navy’s unclassified version of these reports.

The Navy’s annual HSTT Training Exercise Report and Testing Activity Report must include a confirmation that foreign military use of sonar and explosives, when such militaries are participating in a U.S. Navy-led exercise or event, combined with the U.S. Navy’s use of sonar and explosives, would not cause exceedance of the analyzed levels (within each NAEMO modeled sonar and explosive bin) used for estimating predicted impacts, which formed the basis of the acoustic impacts effects analysis used to estimate take in this final rule. The purpose of this new reporting measure is for the Navy to confirm annually that the Navy has accounted for foreign military participation in its annual report, without requiring the Navy to quantitatively account for foreign military activity. The Navy informed NMFS that it would be difficult for the Navy to quantify foreign military activities as a subset of its total activities because the Navy does not track activities conducted by foreign vessels

in this manner. Furthermore, the annual reported takes from Navy activities are calculated the same regardless of whether the activity was conducted by a foreign military or not.

Analysis and Negligible Impact Determination

NMFS has defined negligible impact 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 (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). While this final rule consists of a modification of take by M/SI by vessel strike, NMFS considers the impacts of the entire specified activity and the total taking in the negligible impact determination. An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be taken through mortality, serious injury, and Level A or Level B harassment (as presented in tables 11 and 12 of the 2020 HSTT final rule), NMFS considers other factors, such as the likely nature of any responses (*e.g.*, intensity, duration), the context of any responses (*e.g.*, critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS’ implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities (including foreign military activities) are incorporated into this analysis via their impacts on the environmental baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, other ongoing sources of human-caused mortality, ambient noise levels, and specific consideration of take by Level A harassment or M/SI previously authorized for other NMFS activities).

In the Estimated Take of Marine Mammals sections of this final rule and the 2020 HSTT final rule (where the activities, species and stocks, potential effects, and mitigation measures (except as modified above) are the same as for this rulemaking), we identified the subset of potential effects that would be expected to rise to the level of takes

both annually and over the 7-year period covered by this rulemaking and then identified the number of each of those mortality takes that we believe could occur or the maximum number of harassment takes that are reasonably expected to occur based on the methods described. The impact that any given take will have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.*, the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts to individuals, *etc.*). For this final rule, we evaluated the likely impacts of the enumerated maximum number of harassment takes that were reasonably expected to occur and are authorized, in the context of the specific circumstances surrounding these predicted takes. We also assessed M/SI takes that could occur, as well as considering the traits and statuses of the affected species and stocks. Last, we collectively evaluated this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific assessments that support our negligible impact conclusions for each stock or species. Because all of the Navy’s specified activities would occur within the ranges of the marine mammal stocks identified in the rule, all negligible impact analyses and determinations are at the stock level (*i.e.*, additional species-level determinations are not needed).

The Navy proposed no changes to the nature or level of the specified activities or the boundaries of the HSTT Study Area, and therefore, the training and testing activities (*e.g.*, equipment and sources used, exercises conducted) are the same as those analyzed in the 2020 HSTT final rule. In addition, the mitigation, monitoring, and nearly all reporting measures are identical to those described and analyzed in the 2018 HSTT final rule with the exception of changes to mitigation measures and the additional reporting requirements described previously. There is no new information since the publication of the 2020 HSTT final rule regarding the impacts of the specified activities on marine mammals, the status and distribution of any of the affected marine mammal species or stocks, or the effectiveness of the mitigation and monitoring measures that would change the content of our analyses, with the exception of that described below. First, naval vessel strikes have occurred in the HSTT and Atlantic Fleet Training and Testing (AFTT) Study Areas since

publication of the 2020 HSTT final rule (one fin or sei whale struck by the U.S. Navy in the HSTT Study Area (2023), two unidentified large whales struck by the U.S. Navy in the HSTT Study Area (2021), two fin whales struck by a foreign navy in the HSTT Study Area (2021), and one dolphin struck by the U.S. Navy in the AFTT Study Area (2021)). Second, for gray whales, we have considered the latest effects of the recently closed UME on the west coast of North America along with the effects of the Navy's activities in the negligible impact analysis. Third, a new study suggests that Lookout detection of marine mammals is less certain than previously assumed (Oedekoven and Thomas, 2022). Fourth, stock assessments have been updated for multiple stocks in the 2023 Pacific and Alaska SARs (Carretta *et al.* 2024; Young *et al.* 2024).

As described above, since publication of the 2023 HSTT proposed rule, NMFS has updated our Technical Guidance (NMFS, 2024) containing updated acoustic criteria for auditory injury (89 FR 36762, October 24, 2024). The Technical Guidance provides updated auditory injury thresholds, where appropriate, as well as revised weighting functions, in some cases. For impulsive sources, the Updated Technical Guidance's auditory injury thresholds generally remain identical or are higher compared to our 2018 Technical Guidance, meaning that received levels would need to be higher in order for marine mammals to be expected to incur auditory injury. The exceptions are for phocid pinnipeds (PW), where the cumulative SEL threshold, in the Updated Technical Guidance, is 2 dB lower and for otariid pinnipeds (OW) where the peak sound pressure level threshold is 2 dB lower and the cumulative SEL threshold is 18 dB lower. As for the Updated Technical Guidance's weighting functions, for MF cetaceans (now called HF cetaceans in

the updated document) and HF cetaceans (now called VHF cetaceans in the updated document), the weighting functions reflect a higher susceptibility to auditory injury at frequencies below 10 kHz, as compared to the 2018 Technical Guidance. Other minor changes/shifts to weighting functions (e.g., for LF cetaceans, PW pinnipeds, OW pinnipeds) were also included. This new information was not available in a timeframe in which NMFS could have incorporated it into the quantitative analysis supporting this final rulemaking; however, NMFS did consider the information qualitatively. While these changes in the auditory injury thresholds and weighting functions could result in minor increases in PTS exposure estimates for some species, given the conservative assumptions built into the take estimate methodology, they would not be expected to result in meaningful, if any, changes in take estimates and would not be expected to change any of the findings.

Harassment

As described in the Estimated Take of Marine Mammals section, the annual number of takes authorized and reasonably expected to occur by Level A harassment and Level B harassment (based on the maximum number of activities per 12-month period) are identical to those presented in tables 41 and 42 in the *Take Requests* section of the 2018 HSTT final rule, with the exception of humpback whale, which are presented in tables 2 and 3 herein. As such, the negligible impact analyses and determinations of the effects of the estimated Level A harassment and Level B harassment takes on annual rates of recruitment or survival for each species and stock are nearly identical to and substantively unchanged from those presented in the 2020 HSTT final rule. The differences in the analysis is our removal of consideration of California Sea Lion UME and gray whale UME,

which have been closed since publication of the 2020 HSTT final rule and 2023 HSTT proposed rule, respectively, and incorporation of the revised stock structure for humpback whales. This does not affect the results of the analyses or our determinations. For detailed discussion of the impacts that affected individuals may experience given the specific characteristics of the specified activities and required mitigation (e.g., from behavioral disruption, masking, and temporary or permanent threshold shift), along with the effects of the expected Level A harassment and Level B harassment take on reproduction and survival, see the applicable subsections in the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule (83 FR 66977–67018; also incorporated by reference in the 2020 HSTT final rule).

Serious Injury or Mortality

Based on the information and methods discussed in the Estimated Take of Marine Mammals section (which are identical to those used in the 2018 HSTT final rule for explosives and revised for vessel strike), NMFS is authorizing five mortalities of large whales due to vessel strike over the 7-year period of this rulemaking, two more strikes than what was authorized in the 2018 HSTT final rule and 2020 HSTT final rule. Across the 7-year duration of the rule, take of an annual average of 0.57 gray whales (Eastern North Pacific stock) and fin whales (CA/OR/WA stock), an annual average of 0.29 humpback whales (Hawaii stock) and an annual average of 0.14 blue whales (Eastern North Pacific stock), sei whales (Eastern North Pacific stock) and humpback whales (Mainland Mexico-CA/OR/WA stock, Mexico DPS), as described in table 7 (*i.e.*, one, two, or four take(s) over 7 years divided by seven to get the annual number) could occur and are authorized.

TABLE 10—SUMMARY INFORMATION RELATED TO MORTALITIES REQUESTED FOR VESSEL STRIKE, 2018–2025

Species (stock)	Stock abundance (Nbest) *	Annual authorized take by serious injury or mortality ¹	Total annual M/ SI * ²	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	Annual rate of M/SI from vessel collision *	PBR *	Residual PBR (PBR minus annual M/SI) ³	Stock trend * ⁴	Recent UME (Y/N); number and year (since 2007)
Fin whale (CA/OR/WA stock).	11,065	0.57	≥43.4	Y; ≥0.41	Y, 43	80	36.6	↑	N
Gray whale (Eastern North Pacific stock).	26,960	0.57	131	Y, 9.3	Y, 1.8	801	670	⁵ ↑	Y; 690; 2019
Humpback whale (Mainland Mexico-CA/OR/WA stock, Mexico DPS).	3,477	0.14	22	Y; 11.4	⁶ Y, 10.15	65	⁷ 43	Unknown	N
Humpback whale (Hawaii stock).	11,278	0.29	27.09	Y; 8.39	⁸ Y, 10.59	127	99.91	Unknown	Y; 52; 2015

TABLE 10—SUMMARY INFORMATION RELATED TO MORTALITIES REQUESTED FOR VESSEL STRIKE, 2018–2025—Continued

Species (stock)	Stock abundance (nbest) *	Annual authorized take by serious injury or mortality ¹	Total annual M/ SI * ²	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	Annual rate of M/SI from vessel collision *	PBR *	Residual PBR (PBR minus annual M/SI) ³	Stock trend * ⁴	Recent UME (Y/N); number and year (since 2007)
Blue whale (Eastern North Pacific Stock).	1,898	0.14	≥18.6	Y; ≥0.61	Y, 18	4.1	–14.5	Unknown	Y; 3, 2007
Sei whale (Eastern North Pacific Stock).	864	0.14	≥0	N; 0	Y, 0	1.25	1.25	Unknown	N

* Presented in the 2023 final SARs.

¹ This column represents the annual take by serious injury or mortality (M/SI) by vessel collision and was calculated by the number of mortalities authorized divided by 7 years (the length of the rule and LOAs).

² This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either Navy strikes or NMFS' Southwest Fisheries Science Center (SWFSC) takes in the SARs to ensure not double-counted against PBR. However, for these species, there were no takes from either other Navy activities or SWFSC in the SARs to deduct that would be considered double-counting.

³ This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.*, total annual human-caused M/SI, which is presented in the SARs).

⁴ See relevant SARs for more information regarding stock status and trends.

⁵ The Pacific 2023 SAR indicates that the stock trend is increasing. However, recent (2023–2024) surveys conducted by NMFS' Southwest Fisheries Science Center indicated that the estimated total abundance of gray whales during the 2023–2024 southbound migration was 19,260, though the authors note that this stock has historically shown a pattern of population growth and decline that has not impacted the population in the long term (Eguchi *et al.* 2024).

⁶ Vessel strike of the Mainland Mexico-CA/OR/WA stock was calculated by applying a prorated portion of humpback whale strikes modeled by Rockwood *et al.* (2017) to this stock.

⁷ For this stock, PBR is currently set at 43 for U.S. waters and 65 for the stock's entire range. As the HSTT Study Area extends beyond U.S. waters and activities have the potential to impact the entire stock, we present the analysis using the PBR for the stock's entire range.

⁸ Annual vessel strike for this stock reported in the 2023 final SAR was calculated by summing vessel strike data from Hawaii, Alaska, and Washington. All observed strikes in Hawaii were assigned to the Hawaii stock, and a portion of observed strikes in Alaska were assigned to the Hawaii stock. Vessel strike of the Hawaii stock in Washington waters was calculated by applying a prorated portion of humpback whale strikes modeled by Rockwood *et al.* (2017) to the Hawaii stock.

The Navy also requested a small number of takes by M/SI from explosives in the 2017 Navy application. To calculate the annual average of mortalities for explosives in table 11, we used the same method as described for vessel strikes. The annual average is the total number of takes over 7 years divided by seven. Specifically,

NMFS is authorizing the following M/SI takes from explosives: five California sea lions and eight short-beaked common dolphins over the 7-year period (therefore 0.71 mortalities annually for California sea lions and 1.14 mortalities annually for short-beaked common dolphin), as described in table 11. As this annual number is the

same as that analyzed and authorized in the 2020 HSTT final rule, and no other relevant information about the status, abundance, or effects of mortality on each species or stock has changed, the analysis of the effects of explosives is identical to that presented in the 2020 HSTT final rule.

TABLE 11—SUMMARY INFORMATION RELATED TO MORTALITIES FROM EXPLOSIVES, 2018–2025

Species (stock)	Stock abundance (nbest) *	Annual authorized take by serious injury or mortality ¹	Total annual M/SI * ²	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	PBR *	SWFSC authorized take (annual) ³	Residual PBR-PBR minus annual M/SI and SWFSC ⁴	Stock trend * ⁵	UME (Y/N); number and year
California sea lion (U.S. stock)	257,606	0.71	≥321	Y; ≥197	14,011	6	13,684	↑	N
Short-beaked common dolphin (CA/OR/WA stock).	1,056,308	1.14	≥30.5	Y; ≥30.5	8,889	2.8	8,855.7	unknown	N

* Presented in the 2023 SARs.

¹ This column represents the annual take by serious injury or mortality (M/SI) during explosive detonations and was calculated by the number of mortalities planned for authorization divided by 7 years (the length of the rule and LOAs).

² This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR.

³ This column represents annual take authorized through NMFS' SWFSC rulemaking/LOAs (86 FR 3840, January 15, 2021).

⁴ This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.*, total annual human-caused M/SI column and the annual authorized take from the SWFSC column. In the case of California sea lion the M/SI column (321) and the annual authorized take from the SWFSC (6) were subtracted from the calculated PBR of 14,011. In the case of short-beaked common dolphin the M/SI column (30.5) and the annual authorized take from the SWFSC (2.8) were subtracted from the calculated PBR of 8,889.

⁵ See relevant SARs for more information regarding stock status and trends.

See the *Serious Injury or Mortality* subsection in the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule (83 FR 66985–66993, December 27, 2018) for detailed discussions of the impacts of M/SI, including a description of how the agency uses the PBR metric and other factors to inform our analysis and an analysis of the impacts on each species and stock for which M/SI is

authorized, including the relationship of potential mortality for each species to the insignificance threshold and residual PBR, except as updated below.

Stocks With M/SI Below the Insignificance Threshold

As noted in the *Serious Injury or Mortality* subsection of the *Analysis and Negligible Impact Determination* section in the 2018 HSTT final rule and 2020

HSTT final rule, for a species or stock with incidental M/SI less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.*, in the absence of any other take and barring any other unusual circumstances) will clearly not adversely affect annual rates of recruitment and survival. In this case, as

shown in table 10 and table 11, the following species or stocks have potential or estimated M/SI from vessel strike and explosive takes, respectively, and authorized below their insignificance threshold: fin whale (CA/OR/WA stock), gray whale (Eastern North Pacific stock), humpback whale (Hawaii stock and Mainland Mexico-CA/OR/WA stock), California sea lion (U.S stock), and short-beaked common dolphin (CA/OR/WA stock). While the authorized M/SI of gray whales (Eastern North Pacific stock) is below the insignificance threshold, because of the recent UME, we further address how the authorized M/SI and the UME inform the negligible impact determination immediately below. For the other five stocks with authorized M/SI below the insignificance threshold, there are no other known factors, information, or unusual circumstances that indicate anticipated M/SI below the insignificance threshold could have adverse effects on annual rates of recruitment or survival and they are not discussed further. For the remaining stocks with anticipated potential M/SI above the insignificance threshold, how that M/SI compares to residual PBR, as well as additional factors, as appropriate, are discussed below as well.

Gray Whales (Eastern North Pacific Stock)

The estimated and authorized lethal take of gray whale (Eastern North Pacific stock) is well below the insignificance threshold (0.57 as compared to a residual PBR of 670). Nonetheless, we consider here how the 2019–2023 West Coast Gray Whale UME informs our negligible impact determination. Strandings of eastern North Pacific gray whales occurred in the United States, Canada and Mexico along the west coast of North America. They occurred in wintering, migratory, and feeding areas. Stranding rates have returned back to normal and expected levels, and the prevalence of thin live or thin dead whales has also decreased. The Investigative Team concluded localized ecosystem changes, including both access to and quality of prey, in the northern Bering and Chukchi seas caused the UME. These changes contributed to the poor nutritional condition observed in live whales in the wintering areas of Mexico and dead stranded gray whales in all three countries. This malnutrition led to increased mortality during the whales' annual northward migration (from Mexico to Alaska) and decreased production of calves. This resulted in an overall decline in population

abundance. Because of the abundance and residual PBR of this stock, as well as the fact that the UME is closed and increased mortality stopped in late 2023 (with peak strandings ending in December 2020), this UME is not expected to have any impacts on individuals during the period of this final rule, nor is it thought to have had impacts on the population rate when it was occurring that would influence our evaluation of the effects of the mortality authorized on the stock.

Stocks with M/SI Above the Insignificance Threshold

Blue Whale (Eastern North Pacific Stock)

For blue whales (Eastern North Pacific stock), PBR is currently set at 4.1 and the total annual M/SI is estimated at greater than or equal to 18.6, yielding a residual PBR of – 14.5. This is slightly higher than the 2020 HSTT final rule (– 16.7) and 2023 HSTT proposed rule (– 15.4). NMFS authorizes one M/SI for the Navy over the 7-year duration of the rule (indicated as 0.14 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which means that residual PBR is exceeded by 14.5. However, as described in the 2018 and 2020 rules, given that the negligible impact determination is based on the assessment of take of the activity being analyzed, when total annual mortality from human activities is higher, but the impacts from the specific activity being analyzed are very small, NMFS may still find the impact of the authorized take from a specified activity to be negligible even if total human-caused mortality exceeds PBR if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.*, other than the specified activities covered by the incidental take authorization in consideration). When those considerations are applied here, the authorized lethal take (0.14 annually) of blue whales from the Eastern North Pacific stock is less than 10 percent of PBR (which is 4.1), and there are management measures in place to address M/SI from activities other than those the Navy is conducting (as discussed below). Perhaps more importantly, the available data suggests that the current number of vessel strikes is not likely to have an adverse impact on the population, despite the fact that it exceeds PBR, with the Navy's minimal additional mortality of one

whale in the 7 years not creating the likelihood of adverse impact. Immediately below, we explain the information that supports our finding that the Navy's authorized M/SI is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.*, harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the stock-specific conclusion sections.

As discussed in the 2018 HSTT final rule and the 2020 HSTT final rule, the 2018 draft SAR and the more recent SARs rely on a new method to estimate annual deaths by vessel strike utilizing an encounter theory model that combined species distribution models of whale density, vessel traffic characteristics, and whale movement patterns obtained from satellite-tagged animals in the region to estimate encounters that would result in mortality (Rockwood *et al.* 2017). The model predicts 18 annual mortalities of blue whales from vessel strikes, which, with the additional M/SI of 1.54 from fisheries interactions, results in the current estimate of residual PBR being – 15.4. Although NMFS' Permits and Conservation Division in the Office of Protected Resources has independently reviewed the vessel strike model and its results and agrees that it is appropriate for estimating blue whale mortality by vessel strike on the U.S. West Coast, for analytical purposes we also note that if the historical method were used to predict vessel strike (*i.e.*, using observed mortality by vessel strike, or 0.6, instead of 18), then total human-caused mortality including the Navy's potential take would not exceed PBR. We further note that the authors (Rockwood *et al.* 2017) do not suggest that vessel strike suddenly increased to 18 recently. In fact, the model is not specific to a year, but rather offers a generalized prediction of vessel strike off the U.S. West Coast. Therefore, if the Rockwood *et al.* (2017) model is an accurate representation of vessel strike, then similar levels of vessel strike have been occurring in past years as well. Put another way, if the model is correct, for some number of years total-human-caused mortality has been significantly underestimated and PBR has been similarly exceeded by a notable amount, and yet, the Eastern North Pacific stock of blue whales remains stable nevertheless.

NMFS' 2023 SAR states that the current population trend is unknown, though there may be evidence of a population size increase since the 1990s. The SAR further cites to Monnahan *et al.* (2015), which used a population dynamics model to estimate that the Eastern North Pacific blue whale population was at 97 percent of carrying capacity in 2013 and to suggest that the observed lack of a population increase since the early 1990s was explained by density dependence, not impacts from vessel strike. This would mean that this stock of blue whales shows signs of stability and is not increasing in population size because the population size is at or nearing carrying capacity for its available habitat. In fact, we note that this population has maintained this status throughout the years that the Navy has consistently tested and trained at similar levels (with similar vessel traffic) in areas that overlap with blue whale occurrence, which would be another indicator of population stability.

Monnahan *et al.* (2015) modeled vessel numbers, vessel strikes, and the population of the Eastern North Pacific blue whale population from 1905 out to 2050 using a Bayesian framework to incorporate informative biological information and assign probability distributions to parameters and derived quantities of interest. The authors tested multiple scenarios with differing assumptions, incorporated uncertainty, and further tested the sensitivity of multiple variables. Their results indicated that there is no immediate threat (*i.e.*, through 2050) to the population from any of the scenarios tested, which included models with 10 and 35 strike mortalities per year. Broadly, the authors concluded that, unlike other blue whale stocks, the Eastern North Pacific blue whales have recovered from 70 years of whaling and are in no immediate threat from vessel strikes. They further noted that their conclusion conflicts with the depleted and strategic designation under the MMPA as well as PBR specifically.

As discussed, we also take into consideration management measures in place to address M/SI caused by other activities. The Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around the Vessel Speed Reduction (VSR) zones and the Channel Islands NMS region. Redfern *et al.* (2013) note that the most risky area for blue whales is the Santa Barbara Channel, where shipping lanes intersect with common feeding areas. The seasonally established Southern California VSR zone spans from Point

Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from May 1 through December 15, 2023 are recommended to exercise caution and voluntarily reduce speed to 10 kn (18.5 km per hour) or less for blue, humpback, and fin whales. (Note this is an expanded timeframe from the Whale Advisory Zone discussed in the 2020 HSTT final rule, which spanned June through November, though the effective period could change in future years.) Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and U.S. Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS Office of Protected Resources, U.S. Coast Guard, California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database.

In this case, 0.14 M/SI means one mortality in 1 of the 7 years and zero mortalities in 6 of those 7 years. Therefore, the Navy would not be contributing to the total human-caused mortality at all in 6 of the 7, or 85.7 percent, of the years covered by this rulemaking. That means that even if a blue whale were to be struck, in 6 of the 7 years there could be no effect on annual rates of recruitment or survival from Navy-caused M/SI. Additionally, the loss of a male would have far less, if any, effect on population rates and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that the single strike authorized by this rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of M/SI in 6 of the 7 years and the fact that the single strike could be a male. Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. This is especially important given the minor difference between zero and one across the 7-year period covered by this

rulemaking, which is the smallest distinction possible when considering mortality. As noted above, Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that "Estimating incidental mortality in 1 year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated." The information included here indicates that the current population trend of this blue whale stock is unknown but likely approaching carrying capacity and has leveled off because of density-dependence, not human-caused mortality, in spite of what might be otherwise indicated from the calculated PBR. Further, potential (and authorized) M/SI is below 10 percent of PBR and management actions are in place to minimize vessel strike from other vessel activity in one of the highest-risk areas for strikes. Based on the presence of the factors described above, we do not expect lethal take from Navy activities, alone, to adversely affect Eastern North Pacific blue whales through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality exceeds PBR necessitates close attention to the remainder of the impacts (*i.e.*, harassment) on the Eastern North Pacific stock of blue whales from the Navy's activities to ensure that the total authorized takes have a negligible impact on the species or stock. Therefore, this information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Sei Whale (Eastern North Pacific Stock)

For sei whales (Eastern North Pacific stock), PBR is currently set at 1.25. The total annual M/SI is estimated at greater than or equal to 0 in the 2023 SAR, yielding a residual PBR of 1.25. NMFS authorizes one M/SI for the Navy over the 7-year duration of the rule (indicated as 0.14 annually for the purposes of comparing to PBR and evaluating overall effects on annual rates of recruitment and survival), which means that residual PBR is 1.11.

We acknowledge that the 2023 vessel strike by the U.S. Navy could have been of a sei whale or a CA/OR/WA fin whale, and this strike is not quantitatively included in this PBR analysis (nor is it quantitatively included in the PBR analysis for CA/

OR/WA fin whale if both of the 2021 U.S. Navy strikes were fin whales) which relies on the 2023 SARs. However, consideration of the 2023 strike would not change the total M/SI which NMFS compares to PBR, as the 2023 U.S. Navy strike occurred outside of the time period considered in the vessel strike analysis in the 2023 SAR. Therefore, while we acknowledge the 2023 U.S. Navy strike, in the quantitative analysis it is treated the same as other non-U.S. Navy strikes that occurred outside of the timeframe reflected in the total M/SI.

Immediately below, we explain the information that supports our finding that the Navy's authorized M/SI is not expected to result in more than a negligible impact on this stock. As described previously, NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.*, harassment) do not combine with the impacts from mortality to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which occurs further below in the stock-specific conclusion sections.

Of note, management measures are in place to address M/SI caused by other activities. The Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around the VSR zones and the Channel Islands NMS region. The seasonally established Southern California VSR zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from May 1 through December 15, 2023 are recommended to exercise caution and voluntarily reduce speed to 10 kn (18.5 km per hour) or less. While the VSR zone is aimed at reducing risk of fatal vessel strike of blue, humpback, and fin whales, this measure is also anticipated to reduce risk to sei whales (note, this is an expanded timeframe from the Whale Advisory Zone discussed in the 2020 HSTT final rule, which spanned June through November, though the effective period could change in future years). Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and U.S. Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS Office of Protected Resources, U.S. Coast Guard, California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of

Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database.

Further, as stated in the 2023 SAR, the California swordfish drift gillnet fishery is the most likely U.S. fishery to interact with Eastern North Pacific sei whales, though there are zero estimated annual takes from this fishery given no observed entanglements from 1990–2021 across 9,246 observed fishing sets (Carretta *et al.* (2022)). NMFS established the Pacific Offshore Cetacean Take Reduction Team in 1996 and prepared an associated Plan (PCTRP) to reduce the risk of M/SI via fisheries interactions. In 1997, NMFS published final regulations formalizing the requirements of the PCTRP, including the use of pingers following several specific provisions and the employment of Skipper education workshops.

In this case, 0.14 M/SI means one authorized mortality in 1 of the 7 years and zero authorized mortalities in 6 of those 7 years. Therefore, the Navy's authorized take would not be contributing to the total human-caused mortality at all in 6 of the 7, or 85.7 percent, of the years covered by this rulemaking. That means that even if a sei whale were to be struck, in 6 of the 7 years there could be no effect on annual rates of recruitment or survival from Navy-caused M/SI. Additionally, the loss of a male would have far less, if any, effect on population rates and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that the single strike authorized by this rulemaking would be a male, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of M/SI in 6 of the 7 years and the fact that the single strike could be a male.

Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. This is especially important given the minor difference between zero and one across the 7-year period covered by this rulemaking, which is the smallest distinction possible when considering mortality. As noted above, Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that “Estimating incidental

mortality in 1 year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.” Even after qualitatively considering the possibility that the whale struck by Navy in 2023 was a sei whale, and based on the presence of the factors described above, we do not expect one authorized lethal take from Navy activities, alone, to adversely affect Eastern North Pacific sei whales through effects on annual rates of recruitment or survival. This information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Group and Species-Specific Analyses

In addition to broader analyses of the impacts of the Navy's activities on mysticetes, odontocetes, and pinnipeds, the 2018 HSTT final rule contained detailed analyses of the effects of the Navy's activities in the HSTT Study Area on each affected species and stock and was updated, as appropriate, in the 2020 HSTT final rule. All of that information and analyses remain applicable and valid for our analyses of the effects of the same Navy activities on the same species and stocks, with the exception of humpback whale, for which the stock structure has been revised, and NMFS has updated its analyses accordingly for this final rule. See the *Group and Species-Specific Analyses* subsection in the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule (83 FR 66993–67018). In addition, apart from the additional authorized incidental take by vessel strike of two large whales, the resulting changes to the average annual mortality estimates discussed above, and the revised humpback whale stock structure, no new information has been received since the publication of the 2020 HSTT final rule that significantly changes the analyses of the effects of the Navy's activities on each species and stock presented in the 2020 HSTT final rule (new information regarding vessel strike, the potential impact of the gray whale UME (now closed), and the revised humpback whale stock structure were discussed earlier in the rule).

In the discussions below, the estimated Level B harassment takes represent instances of take, not the number of individuals taken (the much lower and less frequent Level A harassment takes are far more likely to

be associated with separate individuals), and in many cases, some individuals are expected to be taken more than one time while in other cases, a portion of individuals will not be taken at all. Below, we compare the total take numbers (including PTS, TTS, and behavioral disturbance) for species or stocks to their associated abundance estimates to evaluate the magnitude of impacts across the species or stock and to individuals. Specifically, when an abundance percentage comparison is below 100, it means that percentage or less of the individuals in the stock will be affected (*i.e.*, some individuals will not be taken at all), that the average for those taken is 1 day per year, and that we would not expect any individuals to be taken more than a few times in a year. When it is more than 100 percent, it means there will definitely be some number of repeated takes of individuals. For example, if the percentage is 300, the average would be each individual is taken on 3 days in a year if all were taken, but it is more likely that some number of individuals will be taken more than three times and some number of individuals fewer times or not at all. While it is not possible to know the maximum number of days across which individuals of a stock might be taken, in acknowledgement of the fact that it is more than the average, for the purposes of this analysis, we assume a number approaching twice the average. For example, if the percentage of take compared to the abundance is 800, we estimate that some individuals might be taken as many as 16 times. Those comparisons are included in the sections below. For some stocks, these numbers have been adjusted slightly (with these adjustments being in the single digits) so as to more consistently apply this approach, but these minor changes did not change the analysis or findings.

To assist in understanding what this analysis means, we clarify a few issues related to estimated takes and the

analysis here. An individual that incurs a PTS or TTS take may sometimes, for example, also be subject to behavioral disturbance at the same time. As described in the *Harassment* subsection of the *Analysis and Negligible Impact Determination* section of the 2018 HSTT final rule, the degree of PTS, and the degree and duration of TTS, expected to be incurred from the Navy's activities are not expected to impact marine mammals such that their reproduction or survival could be affected. Similarly, data do not suggest that a single instance in which an animal accrues PTS or TTS and is also subjected to behavioral disturbance would result in impacts to reproduction or survival. Alternately, we recognize that if an individual is subjected to behavioral disturbance repeatedly for a longer duration and on consecutive days, effects could accrue to the point that reproductive success is jeopardized (as discussed below in the stock-specific summaries). Accordingly, in analyzing the number of takes and the likelihood of repeated and sequential takes (which could result in reproductive impacts), we consider the total takes, not just the Level B harassment takes by behavioral disturbance, so that individuals potentially exposed to both threshold shift and behavioral disturbance are appropriately considered. We note that the same reasoning applies with the potential addition of behavioral disturbance to tissue damage from explosives, the difference being that we do already consider the likelihood of reproductive impacts whenever tissue damage occurs. Further, the number of Level A harassment takes by either PTS or tissue damage are so low compared to abundance numbers that it is considered highly unlikely that any individual would be taken at those levels more than once.

Having considered all of the information and analyses previously presented in the 2018 HSTT final rule, including the *Group and Species-*

Specific Analyses discussions organized by the different groups and species, below we present tables showing instances of total take as a percentage of stock abundance for each group, updated with the new vessel strike calculations and humpback stock structure. We then summarize the information for each species or stock, considering the analysis from the 2018 HSTT final rule, 2020 HSTT final rule, and any new analysis. The analyses below in some cases address species collectively if they occupy the same functional hearing group (*i.e.*, low, mid, and high-frequency cetaceans and pinnipeds in water), share similar life history strategies, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these groups or species share characteristics that inform the impact analysis similarly, it would be duplicative to repeat the same analysis for each species or stock. In addition, animals belonging to each stock within a species typically have the same hearing capabilities and behaviorally respond in the same manner as animals in other stocks within the species.

Mysticetes

In tables 12 and 13 below for mysticetes, we indicate the total annual mortality, Level A harassment, and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Tables 12 and 13 have been updated from tables 18 and 19 in the 2020 HSTT final rule, as appropriate, with the 2023 final SARs and updated information on mortality, as discussed above. For additional information and analysis supporting the negligible-impact analysis, see the *Mysticetes* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 12—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR MYSTICETES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)				Total takes ^a		Abundance		Instance of total take as percent of abundance		
		Level B harassment		Level A harassment		Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside of EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of Navy EEZ abundance (HRC)	
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							Mortality ^b
Blue whale	Central North Pacific	15	33	0	0	0	48	40	43	33	112	121

TABLE 12—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR MYSTICETES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes ^a		Abundance		Instance of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality ^b	Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside of EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of Navy EEZ abundance (HRC)
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							
Bryde's whale.	Hawaii	40	106	0	0	0	146	123	108	89	135	138
Fin whale	Hawaii	21	27	0	0	0	48	41	52	40	92	103
Humpback whale.	Hawaii	2,837	6,289	3	0	0.29	9,129	7,389	5,078	4,595	180	161
Minke whale.	Hawaii	1,233	3,697	2	0	0	4,932	4,030	3,652	2,835	135	142
Sei whale	Hawaii	46	121	0	0	0	167	135	138	107	121	126

Note: For the Hawaii take estimates, we compare predicted takes to abundance estimates generated from the same underlying density estimates (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule), both in and outside of the U.S. EEZ. Because the portion of the Navy's study area inside the U.S. EEZ is generally concomitant with the area used to generate the abundance estimates in the SARs, and the abundance predicted by the same underlying density estimates is the preferred abundance to use, there is no need to separately compare the take to the SARs abundance estimate.

^a Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

^b The annual mortality of 0.29 is the result of no more than two mortalities over the course of 7 years from vessel strikes as described above in the *Estimated Take of Marine Mammals* section.

TABLE 13—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR MYSTICETES IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes ^a	Abundance		Instance of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality ^b	Total takes (entire study area)	Navy abundance in action area (SOCAL)	NMFS SARs abundance	Total take as percentage of total Navy abundance in action area	Total take as percentage of total SAR abundance
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage						
Blue whale	Eastern North Pacific.	792	1,196	1	0	0.14	1,989	785	1,898	253	105
Bryde's whale	Eastern Tropical Pacific.	14	27	0	0	0	41	1.3	unknown	3,154	unknown
Fin whale	CA/OR/WA	835	1,390	1	0	0.57	2,227	363	11,065	613	20
Humpback whale	Central America/ Southern Mex- ico-CA/OR/WA.	282	594	0	0	0	876	^c 74	1,496	1,184	59
	Mainland Mexico- CA/ OR/WA.	198	920	1	0	0.14	1,119	^c 173	3,477	647	32
Minke whale	CA/OR/WA	259	666	1	0	0	926	163	915	568	101
Sei whale	Eastern North Pacific.	27	52	0	0	0.14	79	3	864	2,633	9
Gray whale	Eastern North Pacific.	1,316	3,355	7	0	0.57	4,679	193	26,960	2,424	17
Gray whale	Western North Pacific.	2	4	0	0	0	6	0	290	0	2

Note: For the SOCAL take estimates, because of the manner in which the Navy study area overlaps the ranges of many MMPA stocks (i.e., a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy study area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the study area, as well as the SARs (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule).

^a Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

^b The annual mortality of 0.14 is the result of no more than one mortality over the course of 7 years from vessel strikes as described above in the *Estimated Take of Marine Mammals* section. The annual mortality of 0.57 is the result of no more than four mortalities over the course of 7 years from vessel strikes.

^c In the 2020 HSTT final rule, NMFS reported a Navy abundance in Action Area (SOCAL) of 247 CA/OR/WA humpback whales. As explained in more detail in the *Authorized Take From Vessel Strikes and Explosives by Serious Injury or Mortality* section, NMFS estimates that approximately 30 percent of the humpback whales off the coast of California may be from the Central America DPS with the remaining 70 percent are expected to be from the Mexico DPS. Therefore, of the estimated 247 humpback whales in SOCAL, NMFS anticipates that 74 would be of the Central America/Southern Mexico-CA/OR/WA stock (Central America DPS), and 173 would be of the Mainland Mexico-CA/OR/WA stock (Mexico DPS).

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected mysticete species and stocks.

Blue Whale (Eastern North Pacific Stock)

Blue whales are listed as endangered under the ESA, and the current population trend for the Eastern North Pacific stock is unknown. We further note that this stock was originally listed under the ESA as a result of the impacts from commercial whaling, which is no longer affecting the species. NMFS authorizes one mortality over the 7 years covered by this rulemaking or 0.14 mortality annually. With the addition of this 0.14 annual mortality, residual PBR is exceeded, resulting in the total human-caused mortality exceeding PBR by 14.5. However, as described in more detail in the *Serious Injury or Mortality* section above, when total human-caused mortality exceeds PBR, we consider whether the incremental addition of a small amount of authorized mortality from the specified activity may still result in a negligible impact, in part by identifying whether it is less than 10 percent of PBR. In this case, the authorized mortality is well below 10 percent of PBR, management measures are in place to reduce mortality from other sources, and the incremental addition of a single mortality over the course of the 7-year Navy rule is not expected to, alone, lead to adverse impacts on the stock through effects on annual rates of recruitment or survival.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 253 and 105 percent, respectively (table 13). Given the range of blue whales, this information suggests that only some portion of individuals in the stock are likely impacted, but that there will likely be some repeat exposure (maybe 5 or 6 days within a year) of some subset of individuals that spend extended time within SOCAL. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Additionally, the Navy implements time/area mitigation in

SOCAL in the majority of the BIAs identified by Calambokidis *et al.* (2015). These areas overlap a portion of the blue whale feeding BIAs (parent and child; see Harrison *et al.* 2023) identified in Calambokidis *et al.* (2024) and will reduce the severity of impacts to blue whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, we have explained in the 2018 HSTT final rule that they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with blue whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For similar reasons (as described in the 2018 HSTT final rule) the single estimated Level A harassment take by PTS for this stock is unlikely to have any effect on the reproduction or survival of that one individual, even if it were to be experienced by an animal that also experiences one or more Level B harassment takes by behavioral disturbance.

Altogether, only a small portion of the stock is anticipated to be impacted and any individual blue whale is likely to be disturbed at a low-moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across 5 or 6 days but minimized in BIAs. This low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals and, therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of blue whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of blue whales.

Bryde's Whale (Eastern Tropical Pacific Stock)

Little is known about this stock or its status, and it is not listed under the ESA. No mortality or Level A harassment is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 3,154 percent; however,

the abundance upon which this percentage is based (1.3 whales from the Navy estimate, which is extrapolated from density estimates based on very few sightings) is clearly erroneous and the SAR does not include an abundance estimate because all of the survey data is outdated (table 13). However, the abundance in the early 1980s was estimated as 22,000 to 24,000, a portion of the stock was estimated at 13,000 in 1993, and the minimum number in the Gulf of California was estimated at 160 in 1990. Given this information and the fact that 41 total takes of Bryde's whales were estimated, this information suggests that only a small portion of the individuals in the stock are likely impacted, and few, if any, are likely taken over more than 1 day. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with Bryde's whale communication or other important low-frequency cues. Any associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, only a small portion of the stock is anticipated to be impacted and any individual Bryde's whale is likely to be disturbed at a low-moderate level, with few, if any, individuals exposed over more than 1 day in the year. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern Tropical Pacific stock of Bryde's whales.

Fin Whale (CA/OR/WA Stock)

The SAR identifies this stock as “increasing,” even though the larger species is listed as endangered under the ESA. NMFS authorizes four mortalities over the 7 years covered by this rulemaking, or 0.57 mortality annually. The addition of this 0.57 annual mortality still leaves the total human-caused mortality well under residual PBR.

We acknowledge the 2021 vessel strike of two fin whales by the Royal Australian Navy, and that the 2021 and 2023 vessel strikes by the U.S. Navy could have been CA/OR/WA fin whales. While the Royal Australian Navy strikes are not quantitatively included in the estimated take by vessel strike, even if they were, and if we presumed that the 2021 and 2023 U.S. Navy strikes were all fin whales, M/SI of this stock would still fall well below PBR (80).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 613 and 20 percent, respectively (table 13). This information suggests that only some portion (less than 25 percent) of individuals in the stock are likely impacted but that there is likely some repeat exposure (perhaps up to 12 days within a year) of some subset of individuals that spend extended time within the SOCAL complex. Some of these takes could occur on a few sequential days for some small number of individuals, for example, if they resulted from a multi-day exercise on a range while individuals were in the area for multiple days feeding. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Additionally, Calambokidis *et al.* (2024) identifies feeding BIAs for fin whales in SOCAL. The Navy implements time/area mitigation in SOCAL in blue whale BIAs identified by Calambokidis *et al.* (2015), and fin whales are known to sometimes feed in some of the same areas. Additionally, these mitigation areas designed for blue whales overlap a portion of the fin whale feeding BIAs (parent and child; see Harrison *et al.* 2023) identified by Calambokidis *et al.* (2024) which means fin whales could potentially accrue some benefits from the mitigation. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with fin whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For similar reasons (as described in the 2018 HSTT final rule) the single estimated Level A

harassment take by PTS for this stock is unlikely to have any effects on the reproduction or survival of that one individual.

Altogether, this population is increasing, only a small portion of the stock is anticipated to be impacted, and any individual fin whale is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 and 12 days, with a few individuals potentially taken on a few sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, and therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of fin whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stock of fin whales.

Humpback Whale (Central America/Southern Mexico-CA/OR/WA Stock)

The SAR identifies this stock as increasing, though the growth rate is uncertain. Animals in this stock are of the Central America DPS which is designated as endangered under the ESA.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 1,184 and 59 percent, respectively (table 13). Given the range of humpback whales, this information suggests that only some portion of individuals in the stock are likely impacted but that there is likely some repeat exposure (perhaps up to 23 days within a year) of some subset of individuals that spend extended time within the SOCAL complex. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Some of these takes could occur on several sequential days for some small number of individuals, for example, if they resulted from a multi-day exercise on a range while individuals were in the

area for multiple days feeding. However, these amounts are still not expected to adversely impact reproduction or survival of any individuals.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. Altogether, only a small portion of the stock is anticipated to be impacted and any individual humpback whale is likely to be disturbed at a low-moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed up to 23 days, but with no reason to think that more than a few of those days would be sequential. This low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals and, therefore, the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Central America/Southern Mexico-CA/OR/WA stock of humpback whales.

Humpback Whale (Mainland Mexico-CA/OR/WA Stock)

The status of this stock is unknown. Animals in this stock are of the Mexico DPS which is designated as threatened under the ESA. NMFS authorizes one mortality over the 7 years covered by this rulemaking, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total human-caused mortality well under residual PBR.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 647 and 32 percent, respectively (table 13). Given the range of humpback whales, this information suggests that only some portion of individuals in the stock are likely impacted but that there is likely some repeat exposure (perhaps up to 13 days within a year) of some subset of individuals that spend extended time within the SOCAL complex. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between

minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Some of these takes could occur on several sequential days for some small number of individuals, for example, if they resulted from a multi-day exercise on a range while individuals were in the area for multiple days feeding. However, these amounts are still not expected to adversely impact reproduction or survival of any individuals.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For similar reasons (as described in the 2018 HSTT final rule) the single estimated Level A harassment take by PTS for this stock is unlikely to have any effects on the reproduction or survival of that one individual.

Altogether, only a small portion of the stock is anticipated to be impacted and any individual humpback whale is likely to be disturbed at a low-moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed up to 13 days, but with no reason to think that more than a few of those days would be sequential. This low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals and, therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of humpback whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stock of humpback whales.

Minke Whale (CA/OR/WA Stock)

The status of this stock is unknown and it is not listed under the ESA. No mortality from vessel strike or tissue damage from explosive exposure is anticipated or authorized for this species. Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured

against both the Navy-estimated abundance and the SAR) is 568 and 101 percent, respectively (table 13). Based on the behaviors of minke whales, which often occur along continental shelves and sometimes establish home ranges along the West Coast, this information suggests that only a portion of individuals in the stock are likely impacted but that there is likely some repeat exposure (perhaps up to 11 days within a year) of some subset of individuals that spend extended time within the SOCAL complex. Some of these takes could occur on a few sequential days for some small number of individuals, for example, if they resulted from a multi-day exercise on a range while individuals were in the area for multiple days feeding. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with minke whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For similar reasons (as described in the 2018 HSTT final rule) the single estimated Level A harassment take by PTS for this stock is unlikely to have any effects on the reproduction or survival of that individual.

Altogether, only a portion of the stock is anticipated to be impacted and any individual minke whale is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 and 11 days, with a few individuals potentially taken on a few sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stock of minke whales.

Sei Whale (Eastern North Pacific Stock)

The status of this stock is unknown, and sei whales are listed under the ESA. NMFS authorizes one mortality over the 7 years covered by this rulemaking or

0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total human-caused mortality under residual PBR. After additionally considering several qualitative factors described above, including that the 2023 strike could have been a sei whale (or fin whale), we do not expect one authorized lethal take from Navy activities, alone, to adversely affect Eastern North Pacific sei whales through effects on annual rates of recruitment or survival. No Level A harassment is anticipated or authorized.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 2,633 and 9 percent, respectively (table 13), however, the abundance upon which the Navy percentage is based (3 from the Navy estimate, which is extrapolated from density estimates based on very few sightings) is likely an underestimate of the number of individuals in the HSTT study Area, resulting in an overestimated percentage. Given this information and the large range of sei whales, and the fact that only 79 total Level B harassment takes of sei whales were estimated, it is likely that some very small number of sei whales would be taken repeatedly, potentially up to 15 days in a year (typically 2,633 percent would lead to the estimate of 52 days/year, however, given that there are only 79 sei whale total takes, we used the conservative assumption that five individuals might be taken up to 15 times, with the few remaining takes distributed among other individuals). Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Some of these takes could occur on a few sequential days for some small number of individuals, for example, if they resulted from a multi-day exercise on a range while individuals were in the area for multiple days feeding, however, these amounts are still not expected to adversely impact reproduction or survival of any individuals. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sei whale communication or other important low-frequency cues—and that

the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, only a small portion of the stock is anticipated to be impacted and any individual sei whale is likely to be disturbed at a low-moderate level, with only a few individuals exposed over one to 15 days in a year, with no more than a few sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, and therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of sei whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of sei whales.

Gray Whale (Eastern North Pacific Stock)

The Eastern North Pacific stock of gray whale is not ESA-listed and the SAR indicates that the stock is increasing. However, recent (2021–2022) surveys conducted by NMFS' Southwest Fisheries Science Center estimated that the population has declined to 16,650 whales, though the authors note that this stock has historically shown a pattern of population growth and decline that has not impacted the population in the long term (Eguchi *et al.* 2022). NMFS is authorizing four mortalities over the 7 years covered by this rulemaking, or 0.57 mortality annually. The addition of this 0.57 annual mortality still leaves the total human-caused mortality well under the insignificance threshold of residual PBR (670). We acknowledge that the 2021 vessel strikes by the U.S. Navy could have been Eastern North Pacific gray whales. If we presumed that the 2021 U.S. Navy strikes were both gray whales, M/SI of this stock would still fall well below PBR (801).

We also consider here how the 2019–2023 West Coast Gray Whale UME informs our negligible impact determination. Because of the abundance and residual PBR of this stock, as well as the fact that the UME is closed and increased mortality stopped in late 2023 (with peak strandings ending in December 2020), this UME is not expected to have any impacts on individuals during the period of this final rule, nor is it thought to have had impacts on the population

rate when it was occurring that would influence our evaluation of the effects of the mortality authorized on the stock.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 2,424 and 17 percent, respectively (table 13). (Note that in comparison to the recent Eguchi *et al.* 2024 abundance estimate, the number of estimated total instances of take compared to the abundance would be 24 percent.) This information suggests that only some small portion of individuals in the stock are likely impacted (less than 17 percent) but that there is likely some level of repeat exposure of some subset of individuals that spend extended time within the SOCAL complex. Typically 2,424 percent would lead to the estimate of 48 days/year, however, given that a large number of gray whales are known to migrate through the SOCAL complex and the fact that there are 4,679 total takes, we believe that it is more likely that a larger number of individuals will be taken one to a few times, while a small number staying in an area to feed for several days may be taken on 5–10 days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Some of these takes could occur on a couple of sequential days for some small number of individuals; however, these amounts are still not expected to adversely impact reproduction or survival of any individuals.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with gray whale communication or other important low-frequency cues and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the seven estimated Level A harassment takes by PTS for gray whales are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with

reproductive success or survival of any individuals.

Altogether, we have considered the impacts of the recent (now closed) gray whale UME, the Eastern North Pacific stock of gray whales is not endangered or threatened under the ESA. The SAR indicates that the stock is increasing. However, recent (2023–2024) surveys conducted by NMFS' Southwest Fisheries Science Center estimated that the population has declined since the most recent Eastern North Pacific gray whale SAR was published (Eguchi *et al.* 2024). Only a small portion of the stock is anticipated to be impacted and any individual gray whale is likely to be disturbed at a low-moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across 5 to 10 days. This low magnitude and severity of harassment effects is not expected to result in impacts to reproduction or survival for any individuals and, therefore, when combined with the authorized mortality of four whales over the 7 year period (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of gray whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of gray whales.

Gray Whale (Western North Pacific Stock)

The Western North Pacific stock of gray whales is reported as increasing in the 2023 final SAR but is listed as endangered under the ESA. No mortality or Level A harassment is anticipated or authorized. This stock is expected to incur the very small number of 6 Level B harassment takes (2 behavioral disruption and 4 TTS) to a stock with a SAR-estimated abundance of 290 (table 13). These takes will likely accrue to different individuals, the behavioral disturbances will be of a low-moderate level, and the TTS instances will be at a low level and short duration. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Western North Pacific stock of gray whales.

Humpback Whale (Hawaii Stock)

The status of this stock is unknown. Animals in this stock are of the Hawaii DPS which is not listed under the ESA. No Level A harassment by tissue damage is authorized. NMFS authorizes two mortalities over the 7 years covered by this rulemaking, or 0.29 mortalities annually. The addition of this 0.29 annual mortality still leaves the total human-caused mortality well under the insignificance threshold for residual PBR.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance, both throughout the HSTT Study Area and within the U.S. EEZ, respectively, is 180 and 161 percent (table 12). This information and the complicated far-ranging nature of the stock structure suggests that some portion of the stock (but not all) are likely impacted, over 1 to several days per year, with little likelihood of take across sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Additionally, as noted above, there are two mitigation areas implemented by the Navy that span a large area of the important humpback reproductive areas (BIA, parent and child; see Harrison *et al.* (2023) identified in Kratofil *et al.* (2023) and minimize impacts by limiting the use of MF1 active sonar and explosives, thereby reducing both the number and severity of takes of humpback whales. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the 3 estimated Level A harassment takes by PTS for humpback whales are unlikely to impact behaviors,

opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, this stock's status is unknown and the DPS is not listed as endangered or threatened under the ESA. Only a small portion of the stock is anticipated to be impacted and any individual humpback whale is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 to several days per year, with little likelihood of take across sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, and therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of humpback whales), the total take is not expected to adversely affect this stock through effects on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Hawaii stock of humpback whales.

Blue Whale (Central North Pacific Stock) and the Hawaii Stocks of Bryde's Whale, Fin Whale, Minke Whale, and Sei Whale

The status of these stocks are not identified in the SARs. Blue whale (Central North Pacific stock) and the Hawaii stocks of fin whale and sei whale are listed as endangered under the ESA; the Hawaii stocks of minke whales and Bryde's whales are not listed under the ESA. No mortality or Level A harassment by tissue damage is anticipated or authorized for any of these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance, both throughout the HSTT Study Area and within the U.S. EEZ, respectively, is 92–135 and 103–142 percent (table 12). This information suggests that some portion of the stocks (but not all) are likely impacted, over 1 to several days per year, with little likelihood of take across sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178

dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with mysticete communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For similar reasons (as described in the 2018 HSTT final rule) the two estimated Level A harassment takes by PTS for the Hawaii stock of minke whales are unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, only a portion of these stocks are anticipated to be impacted and any individuals of these stocks are likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 and several days, with little chance that any are taken across sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less have impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these stocks.

*Odontocetes**Sperm Whale, Dwarf Sperm Whale, and Pygmy Sperm Whale*

In table 14 and table 15 below for sperm whale, dwarf sperm whale, and pygmy sperm whale, we indicate the total annual mortality (0 for all stocks; the 2020 HSTT final rule included 0.14 annual takes by mortality of the Hawaii stock of sperm whale), Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 14 and table 15 are unchanged from tables 20 and 21 in the 2020 HSTT final rule, except for updated information on mortality for the Hawaii stock of sperm whales, as discussed above. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 14—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR SPERM WHALES, DWARF SPERM WHALES, AND PYGMY SPERM WHALES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Takes (within NAVY EEZ)	Total Navy abundance inside and outside EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of EEZ abundance (HRC)
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							
Dwarf sperm whale.	Hawaii	5,870	14,550	64	0	0	20,484	15,310	8,218	6,379	249	240
Pygmy sperm whale.	Hawaii	2,329	5,822	29	0	0	8,180	6,098	3,349	2,600	244	235
Sperm whale.	Hawaii	2,466	30	0	0	0	2,496	1,317	1,656	1,317	151	147

Note: For the Hawaii take estimates, we compare predicted takes to abundance estimates generated from the same underlying density estimates (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule), both in and outside of the U.S. EEZ. Because the portion of the Navy's study area inside the U.S. EEZ is generally concomitant with the area used to generate the abundance estimates in the SARs, and the abundance predicted by the same underlying density estimates is the preferred abundance to use, there is no need to separately compare the take to the SARs abundance estimate. Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

TABLE 15—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR SPERM WHALES, DWARF SPERM WHALES, AND PYGMY SPERM WHALES IN THE SOCIAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance		Instances of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Navy abundance in action area	NMFS SARS abundance	Total take as percentage of total Navy abundance in action area	Total take as percentage of total SAR abundance
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage						
Kogia whales ...	CA/OR/WA	2,779	6,353	38	0	0	9,170	757	4,111	1,211	223
Sperm whale ...	CA/OR/WA	2,437	56	0	0	0	2,493	273	2,606	913	96

Note: For the SOCIAL take estimates, because of the manner in which the Navy study area overlaps the ranges of many MMPA stocks (*i.e.*, a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy study area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the study area, as well as the SARs (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species and stocks addressed in this section. Sperm Whale, Dwarf Sperm Whale, and Pygmy Sperm Whale (CA/OR/WA Stocks)

The SAR identifies the CA/OR/WA stock of sperm whales as "stable", and the species is listed as endangered under the ESA. The status of the CA/OR/WA stocks of pygmy and dwarf sperm whales is unknown and neither are listed under the ESA. Neither mortality nor Level A harassment by tissue damage from exposure to explosives is expected or authorized for any of these three stocks.

Due to their pelagic distribution, small size, and cryptic behavior, pygmy

sperm whales and dwarf sperm whales are rarely sighted during at-sea surveys and are difficult to distinguish between when visually observed in the field. Many of the relatively few observations of *Kogia* spp. off the U.S. West Coast were not identified to species. All at-sea sightings of *Kogia* spp. have been identified as pygmy sperm whales or *Kogia* spp. Stranded dwarf sperm and pygmy sperm whales have been found on the U.S. West Coast, however dwarf sperm whale strandings are rare. NMFS SARs suggest that the majority of *Kogia* sighted off the U.S. West Coast were likely pygmy sperm whales. As such, the stock estimate in the NMFS SAR for pygmy sperm whales is the estimate derived for all *Kogia* spp. in the region (Barlow, 2016), and no separate abundance estimate can be determined for dwarf sperm whales, though some low number likely reside in the U.S.

EEZ. Due to the lack of abundance estimate, it is not possible to predict the take of dwarf sperm whales and take estimates are identified as *Kogia* spp. (including both pygmy and dwarf sperm whales). We assume only a small portion of those takes are likely to be dwarf sperm whales as the density and abundance in the U.S. EEZ is thought to be low.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is, respectively, 913 and 96 for sperm whales and 1,211 and 223 for *Kogia* spp., with a large proportion of these anticipated to be pygmy sperm whales due to the low abundance and density of dwarf sperm whales in the HSTT Study Area (table 15). Given the

range of these stocks (which extends the entire length of the West Coast, as well as beyond the U.S. EEZ boundary), this information suggests that some portion of the individuals in these stocks will not be impacted but that there is likely some repeat exposure (perhaps up to 24 days within a year for *Kogia* spp. and 18 days a year for sperm whales) of some small subset of individuals that spend extended time within the SOCAL Range. Additionally, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, to occasionally moderate, level and less likely to evoke a severe response). However, some of these takes could occur on a fair number of sequential days for some number of individuals.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the estimated Level A harassment takes by PTS for the dwarf and pygmy sperm whale stocks are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals. Thus, the 38 total Level A harassment takes by PTS for these 2 stocks are unlikely to affect rates of recruitment and survival for the stocks.

Altogether, most members of the stocks will likely be taken by Level B harassment (at a low to occasionally moderate level) over several days a year, and some smaller portion of the stocks are expected to be taken on a relatively moderate to high number of days (up to 18 or 24) across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes for a subset of individuals makes it more

likely that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. As discussed in the 2020 HSTT final rule, however, foregone reproduction (especially for 1 year, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality, and a small number of instances of foregone reproduction are not expected to adversely affect these stocks through effects on annual rates of recruitment or survival. We also note that residual PBR is 19 for pygmy sperm whales and 3.5 for sperm whales. Both the abundance and PBR are unknown for dwarf sperm whales, however, we know that take of this stock is likely significantly lower in magnitude and severity (*i.e.*, lower number of total takes and repeated takes any individual) than pygmy sperm whales. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on the CA/OR/WA stocks of sperm whales and pygmy and dwarf sperm whales.

Sperm Whale (Hawaii Stock)

The SAR does not identify a trend for this stock and the species is listed as endangered under the ESA. No mortality or Level A harassment by PTS or tissue damage is expected or authorized.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance, both throughout the HSTT Study Area and within the U.S. EEZ, respectively, is 151 and 147 percent (table 14). This information and the sperm whale stock range suggest that likely only a smaller portion of the stock will be impacted, over 1 to several days per year, with little likelihood of take across sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between

minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, a relatively small portion of this stock is anticipated to be impacted and any individuals are likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 and several days, with little chance that any are taken across sequential days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Hawaii stock of sperm whales.

Pygmy and Dwarf Sperm Whales (Hawaii Stocks)

The SAR does not identify a trend for these stocks and the species are not listed under the ESA. No Level A harassment by tissue damage is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance, both throughout the HSTT Study Area and within the U.S. EEZ, respectively, is 244–249 and 235–240 percent (table 14). This information and the pygmy and dwarf sperm whale stock ranges (at least throughout the U.S. EEZ around the entire Hawaiian Islands) suggest that likely a fair portion of each stock is not impacted, but that a subset of individuals may be taken over one to perhaps 5 days per year, with little likelihood of take across sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, to occasionally moderate, level and less likely to evoke a severe response). Additionally, as discussed earlier, within the Hawaii Island Mitigation

Area, explosives are not used and the use of MF1 and MF4 active sonar is limited, greatly reducing the severity of impacts within the small and resident population BIA for dwarf sperm whales (Kratofil *et al.* 2023), which is entirely contained within this mitigation area.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale, estimated Level A harassment takes by PTS for dwarf and pygmy sperm whales are unlikely to impact

behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, even if it were to be experienced by an animal that also experiences one or more instances of Level B harassment by behavioral disturbance. Thus the 29 and 64 total Level A harassment takes by PTS for dwarf and pygmy sperm whales, respectively, are unlikely to affect rates of recruitment and survival for these stocks.

Altogether, a portion of these stocks are likely to be impacted and any individuals are likely to be disturbed at a low-moderate level, with the taken individuals likely exposed between 1 and 5 days, with little chance that any are taken across sequential days. This low magnitude and severity of Level A and Level B harassment effects is not expected to result in impacts on individual reproduction or survival, much less impacts on annual rates of recruitment or survival. For these

reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the expected and authorized take will have a negligible impact on the Hawaii stocks of pygmy and dwarf sperm whales.

Beaked Whales

In table 16 and table 17 below for beaked whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 16 and table 17 are unchanged from table 22 and table 23 in the 2020 HSTT final rule, with the exception of a correction to a rounding error as noted. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Beaked Whales* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 16—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR BEAKED WHALES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of EEZ abundance (HRC)
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							
Blainville's beaked whale.	Hawaii	5,369	16	0	0	0	5,385	4,140	989	768	^a 544	539
Goose-beaked whale.	Hawaii	1,792	4	0	0	0	1,796	1,377	345	268	521	514
Longman's beaked whale.	Hawaii	19,152	81	0	0	0	19,233	14,585	3,568	2,770	539	527

Note: For the Hawaii take estimates, we compare predicted takes to abundance estimates generated from the same underlying density estimates (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule), both in and outside of the U.S. EEZ. Because the portion of the Navy's study area inside the U.S. EEZ is generally concomitant with the area used to generate the abundance estimates in the SARs, and the abundance predicted by the same underlying density estimates is the preferred abundance to use, there is no need to separately compare the take to the SARs abundance estimate.

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

^a The 2020 final rule unintentionally presented this percentage as 545. The correct value is provided here. This error does not affect the conclusions in the 2020 HSTT final rule.

TABLE 17—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR BEAKED WHALES IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)				Total takes	Abundance		Instances of total take as percent of abundance		
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Navy abundance in action area	NMFS SARs abundance	Total take as percent of abundance	
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage					Total take as percentage of total Navy abundance in action area	Total take as percentage of total SAR abundance
Baird's beaked whale.	CA/OR/WA	2,030	14	0	0	0	2,044	74	1,363	2,762	150
Goose-beaked whale	CA/OR/WA	11,373	127	1	0	0	11,501	520	5,454	2,212	211

TABLE 17—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR BEAKED WHALES IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance		Instances of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Navy abundance in action area	NMFS SARs abundance	Total take as percent-age of total Navy abundance in action area	Total take as percent-age of total SAR abundance
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage						
Mesoplodon species.	CA/OR/WA	6,125	68	1	0	0	6,194	89	3,044	6,960	203

Note: For the SOCAL take estimates, because of the manner in which the Navy study area overlaps the ranges of many MMPA stocks (*i.e.*, a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy study area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the study area, as well as the SARs (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

Blainville's, Goose-Beaked, and Longman's Beaked Whales (Hawaii Stocks)

The SAR does not identify a trend for these stocks and the species are not listed under the ESA. No mortality or Level A harassment are expected or authorized for any of these three stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance, both throughout the HSTT Study Area and within the U.S. EEZ, respectively, is 521–544 and 514–539 percent (table 16). This information and the stock ranges (at least of the small, resident island associated stocks around Hawaii) suggest that likely a fair portion of the stocks (but not all) will be impacted, over 1 to perhaps 11 days per year, with little likelihood of much take across sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or 2 (*i.e.*, moderate level takes). However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options nearby. Additionally, as

noted earlier, within the Hawaii Island mitigation area (which overlaps a large portion of the BIAs for goose-beaked and Blainville's beaked whales identified in Kratofil *et al.* 2023), explosives are not used and the use of MF1 and MF4 active sonar is limited, greatly reducing the severity of impacts within these two small resident populations.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with beaked whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, a fair portion of these stocks are anticipated to be impacted and any individuals are likely to be disturbed at a moderate level, with the taken individuals likely exposed between 1 and 11 days, with little chance that individuals are taken across more than a few sequential days. This low, to occasionally moderate, magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less have impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Hawaii stocks of beaked whales.

Baird's Beaked Whale, Goose-Beaked Whale and *Mesoplodon* Species (All CA/OR/WA Stocks)

The species are not listed under the ESA and their populations have been identified as “increasing,” “decreasing,” and “increasing,” respectively. No

mortality is expected or authorized for any of these three stocks and only two takes by Level A harassment (PTS) are authorized.

No methods are available to distinguish between the six species of *Mesoplodon* beaked whale CA/OR/WA stocks (Blainville's beaked whale (*M. densirostris*), Perrin's beaked whale (*M. perrini*), Lesser beaked whale (*M. peruvianus*), Stejneger's beaked whale (*M. stejnegeri*), Ginkgo-toothed beaked whale (*M. ginkgodens*), and Hubbs' beaked whale (*M. carlhubbsi*)) when observed during at-sea surveys (Carretta *et al.* 2018a). Bycatch and stranding records from the region indicate that the Hubbs' beaked whale is most commonly encountered (Carretta *et al.* 2008, Moore and Barlow, 2013). As indicated in the SAR, no species-specific abundance estimates are available, the abundance estimate includes all CA/OR/WA *Mesoplodon* spp., and the six species are managed as one unit. Due to the lack of species-specific abundance estimates, it is not possible to predict the take of individual species and take estimates are identified as *Mesoplodon* spp.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance for these stocks is 2,762, 2,212, and 6,960 percent (measured against Navy-estimated abundance) and 150, 211, and 203 percent (measured against the SAR) for Baird's beaked whales, goose-beaked beaked whales, and *Mesoplodon* spp., respectively (table 17). Given the ranges of these stocks, this information suggests that some smaller portion of the individuals of these stocks will be taken, and that some subset of individuals within the stock will be taken repeatedly within the year (perhaps up to 20–25 days, and potentially more for goose-beaked)—

potentially over a fair number of sequential days, especially where individuals spend extensive time in the SOCAL Range. Note that we predict lower days of repeated exposure for these stocks than their percentages might have suggested because of the number of overall takes—*i.e.*, using the higher percentage would suggest that an unlikely portion of the takes are taken up by a small portion of the stock incurring a very large number of repeat takes, with little room for take resulting from few or moderate numbers of repeats, which is unlikely. While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or 2 (*i.e.*, of a moderate level). In addition, as noted, some of these takes could occur on a fair number of sequential days for these stocks.

The severity of TTS takes is expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not expected to impact reproduction or survival. For similar reasons (as described in the 2020 HSTT final rule) the single estimated Level A harassment take by PTS for this stock is unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, a portion of these stocks will likely be taken (at a moderate or sometimes low level) over several days

a year, and some smaller portion of the stock is expected to be taken on a relatively moderate to high number of days across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a moderate severity, the repeated takes over a potentially fair number of sequential days for some individuals makes it more likely that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. As noted previously, however, foregone reproduction (especially for 1 year, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality and a small number of instances of foregone reproduction are not expected to adversely affect these stocks through effects on annual rates of recruitment or survival, especially given the residual PBR of these three beaked whale stocks (8.7, 41.9, and 19.9, respectively).

Further, Navy activities have been conducted in SOCAL for many years at similar levels and the SAR considers *Mesoplodon* spp. and Baird's beaked whales as increasing. While NMFS' SAR indicates that goose-beaked whales on the U.S. West Coast are declining based on a Bayesian trend analysis of NMFS' survey data collected from 1991 through 2014, results from passive acoustic monitoring and other research have estimated regional goose-beaked whale densities that were higher than

indicated by NMFS' broad-scale visual surveys for the U.S. West Coast (Debach *et al.* 2015a; Debach *et al.* 2015b; Falcone and Schorr, 2012, 2014; Hildebrand *et al.* 2009; Moretti, 2016; Širović *et al.* 2016; Smultea and Jefferson, 2014). Research also indicates higher than expected residency in the Navy's instrumented Southern California Anti-Submarine Warfare Range in particular (Falcone and Schorr, 2012) and photo identification studies in the SOCAL have identified approximately 100 individual goose-beaked whale individuals with 40 percent having been seen in one or more prior years, with re-sightings up to 7 years apart (Falcone and Schorr, 2014). The documented residency by many goose-beaked whales over multiple years suggests that a stable population may exist in that small portion of the stock's overall range (Falcone *et al.* 2009; Falcone and Schorr, 2014; Schorr *et al.* 2017).

For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on the CA/OR/WA stocks of Baird's and goose-beaked whales, as well as all six species included within the *Mesoplodon* spp.

Small Whales and Dolphins

In tables 18 and 19 below for dolphins and small whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Tables 18 and 19 are updated from tables 24 and 25 in the 2020 HSTT final rule as appropriate with the 2023 final SARs. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Small Whales and Dolphins* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 18—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR DOLPHINS AND SMALL WHALES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instance of total take as percent of abundance	
		Level B harassment		Level A harassment		Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside of EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of Navy EEZ abundance (HRC)	
		Behavioral disturbance	TTS (may also include disturbance)	Mortality								
				PTS	Tissue damage							
Bottlenose dolphin	Hawaii Pe-lagic	3,196	132	0	0	0	3,328	2,481	1,528	1,442	218	172

TABLE 18—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR DOLPHINS AND SMALL WHALES IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)				Total takes		Abundance		Instance of total take as percent of abundance		
		Level B harassment		Level A harassment		Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside of EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of Navy EEZ abundance (HRC)	
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							Mortality
Bottlenose dolphin.	Kauai & Niihau.	534	31	0	0	0	565	264	184	184	307	143
Bottlenose dolphin.	Oahu	8,600	61	1	0	0	8,662	8,376	743	743	^a 1,166	^a 1,127
Bottlenose dolphin.	4-Island ...	349	10	0	0	0	359	316	189	189	190	167
Bottlenose dolphin.	Hawaii	74	6	0	0	0	80	42	131	131	61	32
False killer whale.	Hawaii Pelagic.	999	42	0	0	0	1,041	766	645	507	161	151
False killer whale.	Main Hawaiian Islands Insular.	572	17	0	0	0	589	476	147	147	^b 401	324
False killer whale.	North-western Hawaiian Islands.	365	16	0	0	0	381	280	215	169	177	166
Fraser's dolphin.	Hawaii	39,784	1,289	2	0	0	41,075	31,120	5,408	18,763	760	166
Killer whale.	Hawaii	118	6	0	0	0	124	93	69	54	180	172
Melon-headed whale.	Hawaii Islands.	3,261	231	0	0	0	3,492	2,557	1,782	1,782	196	143
Melon-headed whale.	Kohala Resident.	341	9	0	0	0	350	182	447	447	78	41
Pantropical spotted dolphin.	Hawaii Island.	3,767	227	0	0	0	3,994	2,576	2,405	2,405	166	107
Pantropical spotted dolphin.	Hawaii Pelagic.	9,973	476	0	0	0	10,449	7,600	5,462	4,637	191	164
Pantropical spotted dolphin.	Oahu	4,284	45	0	0	0	4,329	4,194	372	372	1,164	1,127
Pantropical spotted dolphin.	4-Island ...	701	17	0	0	0	718	634	657	657	109	96
Pygmy killer whale.	Hawaii	8,122	402	0	0	0	8,524	6,538	4,928	3,931	173	166
Pygmy killer whale.	Tropical ...	710	50	0	0	0	760	490	159	23	478	2,130
Risso's dolphin.	Hawaii	8,950	448	0	0	0	9,398	7,318	1,210	4,199	777	174
Rough-toothed dolphin.	Hawaii	6,112	373	0	0	0	6,485	4,859	3,054	2,808	212	173
Short-finned pilot whale.	Hawaii	12,499	433	0	0	0	12,932	9,946	6,433	5,784	201	172
Spinner dolphin.	Hawaii Island.	279	12	0	0	0	291	89	629	629	46	14
Spinner dolphin.	Hawaii Pelagic.	4,332	202	0	0	0	4,534	3,491	2,885	2,229	157	157
Spinner dolphin.	Kauai & Niihau.	1,683	63	0	0	0	1,746	812	604	604	289	134
Spinner dolphin.	Oahu & 4-Island.	1,790	34	1	0	0	1,825	1,708	354	354	516	482
Striped dolphin.	Hawaii	7,379	405	0	0	0	7,784	6,034	4,779	3,646	163	165

Note: For the Hawaii take estimates, we compare predicted takes to abundance estimates generated from the same underlying density estimates (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule), both in and outside of the U.S. EEZ. Because the portion of the Navy's study area inside the U.S. EEZ is generally concomitant with the area used to generate the abundance estimates in the SARs, and the abundance predicted by the same underlying density estimates is the preferred abundance to use, there is no need to separately compare the take to the SARs abundance estimate.

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

^a The 2020 final rule unintentionally presented these percentages as 1,169 and 1,130. The correct values are provided here. These errors do not affect the conclusions in the 2020 HSTT final rule.

^b The 2020 final rule unintentionally presented this percentage as 400. The correct value is provided here. This rounding error does not affect the conclusions in the 2020 HSTT final rule.

TABLE 19—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR DOLPHINS AND SMALL WHALES IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)				Total takes	Abundance		Instance of total take as percent of abundance		
		Level B harassment		Level A harassment			Navy abundance in action area (SOCAL)	NMFS SARs abundance	Total take as percentage of total Navy abundance in action area	Total take as percentage of total SAR abundance	
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage	Mortality					Total takes (entire study area)
Bottlenose dolphin.	California Coastal.	1,771	38	0	0	0	1,809	238	453	760	399
Bottlenose dolphin.	CA/OR/WA Offshore.	51,727	3,695	3	0	0	55,425	5,946	3,477	932	1,594
Killer whale	ENP Offshore	96	11	0	0	0	107	4	300	2,675	36
Killer whale	ENP Transient/ West Coast Transient.	179	20	0	0	0	199	30	349	663	57
Long-beaked common dolphin.	California	233,485	13,787	18	2	0	247,292	10,258	83,379	2,411	297
Northern right whale dolphin.	CA/OR/WA	90,052	8,047	10	1	0	98,110	7,705	29,285	1,273	335
Pacific white-sided dolphin.	CA/OR/WA	69,245	6,093	5	0	0	75,343	6,626	34,999	1,137	215
Risso's dolphin	CA/OR/WA	116,143	10,118	9	0	0	126,270	7,784	6,336	1,622	1,993
Short-beaked common dolphin.	CA/OR/WA	1,374,048	118,525	79	10	1.14	1,492,664	261,438	1,056,308	571	141
Short-finned pilot whale.	CA/OR/WA	1,789	124	1	0	0	1,914	208	836	920	229
Striped dolphin	CA/OR/WA	163,640	11,614	3	0	0	175,257	39,862	29,988	440	584

Note: For the SOCAL take estimates, because of the manner in which the Navy study area overlaps the ranges of many MMPA stocks (*i.e.*, a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy study area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the study area, as well as the SARs (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

For mortality takes there is an annual average of 1.14 short-beaked common dolphins (*i.e.*, where eight takes could potentially occur divided by 7 years to get the annual number of mortalities/serious injuries).

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

Long-Beaked Common Dolphin (California Stock), Northern Right Whale Dolphin (CA/OR/WA Stock), and Short-Beaked Common Dolphin (CA/OR/WA Stock)

None of these stocks are listed under the ESA and their stock statuses are considered "increasing," "unknown," and "increasing," respectively. Eight mortalities or serious injuries of short-beaked common dolphins are authorized over the 7-year rule, or 1.14 M/SI annually. The addition of this 1.14 annual mortality still leaves the total human-caused mortality well under the insignificance threshold for residual

PBR. The 3 stocks are expected to accrue 2, 1, and 10 Level A harassment takes from tissue damage resulting from exposure to explosives, respectively. As described in detail in the 2018 HSTT final rule, the impacts of a Level A harassment take by tissue damage could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's procedural mitigation, exposure closer to the source and more severe end of the spectrum is less likely and we cautiously assume some moderate impact for these takes that could lower the affected individual's fitness within the year such that a female (assuming a 50 percent chance of it being a female) might forego reproduction for 1 year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for only 1 year in 7, which is the maximum predicted because the small number anticipated in

any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low), and 1 to 10 instances would not be expected to impact annual rates of recruitment or survival for these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 2,411, 1,273, and 571 percent (relative to the stocks listed in the heading) and 297, 335, and 141 percent (relative to the stocks listed in the heading) (table 19). Given the range of these stocks, this information suggests that likely some portion (but not all or even the majority) of the individuals in the northern right whale dolphin and short-beaked common dolphin stocks are likely impacted while it is entirely possible that most or all of the range-limited long-beaked common dolphin is

taken. All three stocks likely will experience some repeat Level B harassment exposure (perhaps up to 48, 25, or 11 days within a year, respectively to the stocks listed in the heading) of some subset of individuals that spend extended time within the SOCAL range complex. While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.*, of a moderate or lower level, less likely to evoke a severe response). However, some of these takes could occur on a fair number of sequential days for long-beaked common dolphins or northern right whale dolphins, or even some number of short-beaked common dolphins, given the high number of total takes (*i.e.*, the probability that some number of individuals get taken on a higher number of sequential days is higher, because the total take number is relatively high, even though the percentage is not that high).

The severity of TTS takes is expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues, and the associated lost opportunities and capabilities are not expected to impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, as discussed in the 2020 HSTT final rule, it is unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether and as described in more detail above, 1.14 annual lethal takes of short-beaked common dolphins are authorized, all three stocks may experience a very small number of takes by tissue damage or PTS (relative to the stock abundance and PBR), and a moderate to large portion of all three stocks will likely be taken (at a low to occasionally moderate level) over several days a year, and some smaller portion of these stocks is expected to be taken on a relatively moderate to high number of days across the year, some of

which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes (in total and for certain individuals) makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. As noted previously, however, foregone reproduction (especially for only 1 year out of 7, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality and a small number of instances of foregone reproduction (including in combination with that which might result from the small number of tissue damage takes) are not expected to adversely affect the stocks through effects on annual rates of recruitment or survival, especially given the very high residual PBRs of these stocks (638.3, 156.4, and 8,858.5, respectively). For these reasons, in consideration of all of the effects of the Navy's activities combined (mortality, Level A harassment, and Level B harassment), we have determined that the authorized take will have a negligible impact on these three stocks of dolphins.

All Other SOCAL Dolphin Stocks (Except Long-Beaked Common Dolphin, Northern Right Whale Dolphin, and Short-Beaked Common Dolphin)

None of these stocks are listed under the ESA and their stock statuses are considered "unknown," except for the bottlenose dolphin (California coastal stock) and killer whale (Eastern North Pacific stock), which are considered "stable." No M/SI or Level A harassment via tissue damage from exposure to explosives is expected or authorized for these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is from 440 to 2,675 percent and

36 to 1,993 percent, respectively (table 19). Given the range of these stocks (along the entire U.S. West Coast, or even beyond, with some also extending seaward of the HSTT Study Area boundaries), this information suggests that some portion (but not all or even the majority) of the individuals of any of these stocks will be taken, with the exception that most or all of the individuals of the more range-limited California coastal stock of bottlenose dolphin may be taken. It is also likely that some subset of individuals within most of these stocks will be taken repeatedly within the year (perhaps up to 10–15 days within a year) but with no more than several potentially sequential days, although the CA/OR/WA stocks of bottlenose dolphins, Pacific white-sided dolphins, and Risso's dolphins may include individuals that are taken repeatedly within the year over a higher number of days (up to 57, 22, and 40 days, respectively) and potentially over a fair number of sequential days, especially where individuals spend extensive time in the SOCAL range complex. Note that though percentages are high for the Eastern North Pacific stock of killer whales and short-finned pilot whales, given the low overall number of takes, it is highly unlikely that any individuals would be taken across the number of days their percentages would suggest. While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, or sometimes moderate level, less likely to evoke a severe response). However, as noted, some of these takes could occur on a fair number of sequential days for the three stocks listed earlier.

The severity of TTS takes is expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, it is unlikely to impact

behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, a portion of all of these stocks will likely be taken (at a low to occasionally moderate level) over several days a year, and some smaller portion of CA/OR/WA stocks of bottlenose dolphins, Pacific white-sided dolphins, and Risso's dolphins, specifically, are expected to be taken on a relatively moderate to high number of days across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes (in total and for certain individuals) for the CA/OR/WA stocks of bottlenose dolphins, Pacific white-sided dolphins, and Risso's dolphins makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. As noted previously, however, foregone reproduction (especially for only 1 year in 7, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality and a small number of instances of foregone reproduction are not expected to adversely affect the stocks through effects on annual rates of recruitment or survival, especially given the residual PBRs of the CA/OR/WA stocks of bottlenose dolphins, Pacific white-sided dolphins, and Risso's dolphins (18.9, 272, and 42.3, respectively). For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on these stocks of dolphins.

All HRC Dolphin Stocks

With the exception of the Main Hawaiian Island stock of false killer whales (listed as endangered under the ESA, with the MMPA stock identified as "decreasing"), none of these stocks are listed under the ESA and their stock statuses are considered "unknown." No

M/SI or Level A harassment via tissue damage from exposure to explosives is expected or authorized for these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is from 46 to 1,166 percent and 14 to 2,130 percent, respectively (table 18). Given the ranges of these stocks (many of them are small, resident, island-associated stocks), this information suggests that a fairly large portion of the individuals of many of these stocks will be taken but that most individuals will only be impacted across a smaller to moderate number of days within the year (1–15), and with no more than several potentially sequential days, although two stocks (the Oahu stocks of bottlenose dolphin and pantropical spotted dolphin) have a slightly higher percentage, suggesting they could be taken up to 23 days within a year, with perhaps a few more of those days being sequential. We note that although the percentage is higher for the tropical stock of pygmy killer whale within the U.S. EEZ (2,130), given (1) the low overall number of takes (760) and (2) the fact that the small within-U.S. EEZ abundance is not a static set of individuals, but rather individuals moving in and out of the U.S. EEZ making it more appropriate to use the percentage comparison for the total takes versus total abundance—it is highly unlikely that any individuals would be taken across the number of days the within-U.S. EEZ percentage suggests (42). While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, or sometimes moderate level, less likely to evoke a severe response). However, as noted, some of these takes could occur on a fair number of sequential days for the Oahu stocks of bottlenose dolphin and pantropical spotted dolphins.

Within the Hawaii Island mitigation area (which overlaps a large portion of the BIAs for common bottlenose dolphin, dwarf sperm whale, false killer whale, melon-headed whale, pantropical spotted dolphin, pygmy killer whale, rough-toothed dolphin, short-finned pilot whale, and spinner dolphin identified in Kratofil *et al.*

2023), the Navy will not use explosives and will limit the use of MF1 and MF4 active sonar. The 4-Islands mitigation area overlaps a portion of the BIAs identified in Kratofil *et al.* (2023) for common bottlenose dolphin, false killer whale, pantropical spotted dolphin, rough-toothed dolphin, and spinner dolphin. Within the 4-Islands mitigation area (November 15–April 15), the Navy will not use MF1 surface ship hull-mounted mid-frequency active sonar or explosives that could potentially result in takes of marine mammals. The mitigation required in these two areas will reduce the severity of impacts within these small and resident populations.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, they are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, even if accrued to individuals that are also taken by behavioral harassment at the same time.

Altogether, most of these stocks (all but the Oahu stocks of bottlenose dolphin and pantropical spotted dolphins) will likely be taken (at a low to occasionally moderate level) over several days a year, with some smaller portion of the stock potentially taken on a more moderate number of days across the year (perhaps up to 15 days for Fraser's dolphin, though others notably less), some of which could be across a few sequential days, which is not expected to affect the reproductive success or survival of individuals. For the Oahu stocks of bottlenose dolphin and pantropical spotted dolphins, some subset of individuals could be taken up to 23 days in a year, with some small number being taken across several sequential days, such that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless

they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. As noted previously, however, foregone reproduction (especially for 1 year, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality and a small number of instances of foregone reproduction are

not expected to adversely affect these two stocks through effects on annual rates of recruitment or survival. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on all of the stocks of dolphins found in the vicinity of the HRC.

Dall's Porpoise

In table 20 below for porpoises, we indicate the total annual mortality, Level A harassment and Level B

harassment, and a number indicating the instances of total take as a percentage of abundance. Table 20 is updated from table 26 in the 2020 HSTT final rule with the 2023 final SARs. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Dall's Porpoise* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 20—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PORPOISES IN THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)				Total takes	Abundance		Instances of total take as percent of abundance		
		Level B harassment		Level A harassment		Total takes (entire study area)	Navy abundance in Action Area	NMFS SARs abundance	Total take as percent-age of total Navy abundance in Action Area	Total take as percent-age of total SAR abundance	
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage						Mortality
Dall's porpoise	CA/OR/WA	14,482	29,891	209	0	0	44,582	2,054	16,498	2,170	270

Note: For the SOCAL take estimates, because of the manner in which the Navy study area overlaps the ranges of many MMPA stocks (*i.e.*, a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy study area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the study area, as well as the SARs (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect Dall's porpoises through effects on annual rates of recruitment or survival.

Dall's porpoise is not listed under the ESA and the stock status is considered "unknown." No M/SI or Level A harassment via tissue damage from exposure to explosives is expected or authorized for this stock.

Most Level B harassments to Dall's porpoise from hull-mounted sonar (MF1) in the HSTT Study Area will result from received levels between 154 and 166 dB SPL (85 percent). While harbor porpoises have been observed to be especially sensitive to human activity, the same types of responses have not been observed in Dall's porpoises. Dall's porpoises are typically notably longer than and weigh more than twice as much as harbor porpoises making them generally less likely to be preyed upon and likely differentiating their behavioral repertoire somewhat from harbor porpoises. Further, they are typically seen in large groups and feeding aggregations or exhibiting bow-riding behaviors, which is very different from the group dynamics observed in the more typically solitary, cryptic harbor porpoises, which are not often

seen bow-riding. For these reasons, Dall's porpoises are not treated as especially sensitive species (as compared to harbor porpoises, which have a lower threshold for Level B harassment by behavioral disturbance and more distant cutoff) but, rather, are analyzed similarly to other odontocetes. Therefore, the majority of Level B harassment takes are expected to be in the form of milder responses compared to higher level exposures. As discussed more fully in the 2018 HSTT final rule, we anticipate more severe effects from takes when animals are exposed to higher received levels.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 2,170 and 270 percent, respectively (table 20). Given the range of this stock (up the U.S. West Coast through Washington and sometimes beyond the U.S. EEZ), this information suggests that some smaller portion of the individuals of this stock will be taken, and that some subset of individuals within the stock will be taken repeatedly within the year (perhaps up to 42 days)—potentially over a fair number of sequential days,

especially where individuals spend extensive time in the SOCAL range complex. While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB (*i.e.*, of a lower, or sometimes moderate level, less likely to evoke a severe response). However, as noted, some of these takes could occur on a fair number of sequential days for this stock.

The severity of TTS takes is expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may

mean some small loss of opportunities or detection capabilities, the estimated 209 takes by Level A harassment by PTS for Dall's porpoise are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival for most individuals. Because of the high number of PTS takes, however, we acknowledge that a few animals could potentially incur permanent hearing loss of a higher degree that could potentially interfere with their successful reproduction and growth. Given the status of the stock, even if this occurred, it would not adversely impact rates of recruitment or survival.

Altogether, a portion of this stock will likely be taken (at a low to occasionally moderate level) over several days a year, and some smaller portion of the stock is expected to be taken on a relatively moderate to high number of days across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes (in total and for certain individuals) for the Dall's porpoise makes it more likely (probabilistically) that a small number of individuals

could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal. Similarly, we acknowledge the potential for this to occur to a few individuals out of the 209 total that might incur a higher degree of PTS. As noted previously, however, foregone reproduction (especially for only 1 year in 7, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality. Further, the small number of instances of foregone reproduction that could potentially result from PTS and/or the few repeated, more severe Level B harassment takes by behavioral

disturbance are not expected to adversely affect the stock through effects on annual rates of recruitment or survival, especially given the status of the species (not endangered or threatened; minimum population of 10,286 just within the U.S. EEZ) and residual PBR of Dall's porpoise (98.3). For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on Dall's porpoise.

Pinnipeds

In tables 21 and 22 below for pinnipeds, we indicate the total annual mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Tables 21 and 22 have been updated from tables 27 and 28 in the 2020 HSTT final rule with the 2023 final SARs. For additional information and analysis supporting the negligible-impact analysis, see the *Pinnipeds* discussion in the *Group and Species-Specific Analyses* section of the 2018 HSTT final rule, all of which remains applicable to this rule unless specifically noted.

TABLE 21—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PINNIPEDS IN THE HRC PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instance of total take as percent of abundance	
	Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Takes (within Navy EEZ)	Total Navy abundance inside and outside of EEZ (HRC)	Within EEZ Navy abundance (HRC)	Total take as percentage of total Navy abundance (HRC)	EEZ take as percentage of Navy EEZ abundance (HRC)
	Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage							
Hawaiian monk seal.	143	62	1	0	0	206	195	169	169	122	115

Note: For the Hawaii take estimates, we compare predicted takes to abundance estimates generated from the same underlying density estimates (as described in the *Estimated Take of Marine Mammals* section of the 2018 HSTT final rule), both in and outside of the U.S. EEZ. Because the portion of the Navy's study area inside the U.S. EEZ is generally concomitant with the area used to generate the abundance estimates in the SARs, and the abundance predicted by the same underlying density estimates is the preferred abundance to use, there is no need to separately compare the take to the SARs abundance estimate.

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing activities.

TABLE 22—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PINNIPEDS IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total Takes	Abundance		Instance of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Navy abundance in action area (SOCAL)	NMFS SARs abundance	Total take as percentage of total Navy abundance in action area	Total take as percentage of total SAR abundance
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage						
California sea lion.	U.S.	113,419	4,789	87	9	0.71	118,305	4,085	257,606	2,896	46
Guadalupe fur seal.	Mexico	1,442	15	0	0	0	1,457	1,171	34,187	124	4

TABLE 22—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PINNIPEDS IN THE SOCAL PORTION OF THE HSTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total Takes	Abundance		Instance of total take as percent of abundance	
		Level B harassment		Level A harassment		Mortality	Total takes (entire study area)	Navy abundance in action area (SOCAL)	NMFS SARs abundance	Total take as percent- age of total Navy abundance in action area	
		Behavioral disturbance	TTS (may also include dis- turbance)	PTS	Tissue damage					Total take as percent- age of total Navy abundance in action area	Total take as percent- age of total SAR abun- dance
Northern fur seal.	California	15,167	124	1	0	0	15,292	886	14,050	1,726	109
Harbor seal	California	2,450	2,994	8	0	0	5,452	321	30,968	1,698	18
Northern ele- phant seal.	California	42,916	17,955	97	2	0	60,970	4,108	187,386	1,484	33

Note: For the SOCAL take estimates, because of the manner in which the Navy action area overlaps the ranges of many MMPA stocks (*i.e.*, a stock may range far north to Washington state and beyond and abundance may only be predicted within the U.S. EEZ, while the Navy action area is limited to Southern California and northern Mexico, but extends beyond the U.S. EEZ), we compare predicted takes to both the abundance estimates for the action area, as well as the SARs.

For mortality takes there is an annual average of 0.71 California sea lions (*i.e.*, where five takes could potentially occur divided by 7 years to get the annual number of mortalities/serious injuries).

Below we compile and summarize the information that supports our determination that the Navy's activities would not adversely affect any pinnipeds through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

Five M/SI takes of California sea lions are authorized and when this mortality is combined with the other human-caused mortality from other sources, it still falls well below the insignificance threshold for residual PBR (13,684). A small number of Level A harassment takes by tissue damage are also authorized (nine and two for California sea lions and northern elephant seals, respectively), which, as discussed in the 2020 HSTT final rule, could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, exposure at the closer to the source and more severe end of the spectrum is less likely. Nevertheless, we cautiously assume some moderate impact on the individuals that experience these small numbers of take that could lower the individual's fitness within the year such that a female (assuming a 50 percent chance of it being a female) might forego reproduction for 1 year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for only one within 7 years, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) and these low numbers of instances (especially assuming the likelihood that only 50 percent of the takes would affect females) are not

expected to impact annual rates of recruitment or survival, especially given the population sizes of these species.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disturbance), for Hawaiian monk seals and Guadalupe fur seals, the two species listed under the ESA, the estimated instances of takes as compared to the stock abundance does not exceed 124 percent, which suggests that some portion of these two stocks would be taken on 1 to a few days per year. For the remaining stocks, the number of estimated total instances of take compared to the abundance (measured against both the Navy-estimated abundance and the SAR) is 1,484 to 2,896 percent and 18 to 46 percent, respectively (table 22). Given the ranges of these stocks (*i.e.*, very large ranges, but with individuals often staying in the vicinity of haulouts), this information suggests that some very small portion of the individuals of these stocks will be taken, but that some subset of individuals within the stock will be taken repeatedly within the year (perhaps up to 58 days)—potentially over a fair number of sequential days. Regarding the severity of those individual Level B harassment takes by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.*, relatively short) and the received sound levels largely below 172 dB, which is considered a relatively low to occasionally moderate level for pinnipeds. However, as noted, some of these takes could occur on a fair number of sequential days for this stock.

As described in the 2018 HSTT final rule and 2020 HSTT final rule, the Hawaii and 4-Islands mitigation areas protect (by not using explosives and limiting MFAS within) a significant

portion of the designated critical habitat for Hawaiian monk seals in the Main Hawaiian Islands, including all of it around the islands of Hawaii and Lanai, most around Maui, and good portions around Molokai and Kaho'olawe. As discussed, this protection reduces the overall number of takes and further reduces the severity of effects by minimizing impacts near pupping beaches and in important foraging habitat.

The severity of TTS takes are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues that would affect the individual's reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the one to eight estimated Level A harassment takes by PTS for monk seals, northern fur seals, and harbor seals are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals. Because of the high number of PTS takes for California sea lions and northern elephant seals (87 and 97, respectively), we acknowledge that a few animals could potentially incur permanent hearing loss of a higher degree that could potentially interfere with their successful reproduction and growth. Given the status of the stocks, even if this occurred, it would not adversely impact rates of recruitment or

survival (residual PBR of 13,684 and 5,108, respectively).

Altogether, an individual Hawaiian monk seal and Guadalupe fur seal would be taken no more than a few days in any year with none of the expected take anticipated to affect individual reproduction or survival, let alone annual rates of recruitment and survival. With all other stocks, only a very small portion of the stock will be taken in any manner. Of those taken, some individuals will be taken by Level B harassment (at a moderate or sometimes low level) over several days a year, and some smaller portion of those taken will be on a relatively moderate to high number of days across the year (up to 58), a fair number of which will likely be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the repeated takes over a potentially fair number of sequential days for some individuals makes it more likely that some number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). As noted previously, however, foregone reproduction (especially for only 1 year within 7, which is the maximum predicted because the small number anticipated in any 1 year makes the probability that any individual would be impacted in this way twice in 7 years very low) has far less of an impact on population rates than mortality and a relatively small number of instances of foregone reproduction (as compared to the stock abundance and residual PBR) are not expected to adversely affect the stock through effects on annual rates of recruitment or survival, especially given the status of these stocks. Accordingly, we do not anticipate the relatively small number of individual northern fur seals or harbor seals that might be taken over repeated days within the year in a manner that results in 1 year of foregone reproduction to adversely affect the stocks through effects on rates of recruitment or survival, given the status of the stocks, which are respectively increasing and stable with abundances

and residual PBRs of 14,050/30,968 and 449/1,598.

For California sea lions, given the very high abundance and residual PBR (257,606 and 13,684, respectively), as well as the increasing status of the stock in the presence of similar levels of Navy activities over past years—the impacts of 0.71 annual mortalities, potential foregone reproduction for up to nine individuals in a year taken by tissue damage, and some relatively small number of individuals taken as a result of repeated behavioral harassment over a fair number of sequential days are not expected to adversely affect the stock through effects on annual rates of recruitment or survival. Similarly, for northern elephant seals, given the very high abundance and residual PBR (187,386 and 5,108, respectively), as well as the increasing status of the stock in the presence of similar levels of Navy activities over past years, the impacts of potential foregone reproduction for up to 2 individuals in a year taken by tissue damage and some relatively small number of individuals taken as a result of repeated behavioral harassment over a fair number of sequential days are not expected to adversely affect the stock through effects on annual rates of recruitment or survival. For these reasons, in consideration of all of the effects of the Navy's activities combined (M/SI, Level A harassment, and Level B harassment), we have determined that the authorized take will have a negligible impact on all pinniped species and stocks.

Determination

The 2018 HSTT final rule included a detailed discussion of all of the anticipated impacts on the affected species and stocks from serious injury or mortality, Level A harassment, and Level B harassment; impacts on habitat; and how the Navy's mitigation and monitoring measures reduce the number and/or severity of adverse effects. We have evaluated how these impacts as well as additional take of two large whales by serious injury or mortality by vessel strike, and the required mitigation measures are expected to combine, annually, to affect individuals of each species and stock. Those effects were then evaluated in the context of whether they are reasonably likely to impact reproductive success or survivorship of individuals and then, if so, further analyzed to determine whether there would be effects on annual rates of recruitment or survival that would adversely affect the species or stock.

As described above, the basis for the negligible impact determination is the

assessment of effects on annual rates of recruitment and survival. Accordingly, the analysis included in the 2018 HSTT final rule and 2020 HSTT final rule used annual activity levels, the best available science, and approved methods to predict the annual impacts to marine mammals, which were then analyzed in the context of whether each species or stock would incur more than a negligible impact based on anticipated adverse impacts to annual rates of recruitment or survival. As we have described above, none of the factors upon which the conclusions in the 2020 HSTT final rule were based have changed, with the exception of estimated take by vessel strike. Therefore, even though this final rule includes two additional takes by vessel strike, little has changed that would change our 2018 HSTT final rule and subsequent 2020 HSTT final rule analyses, and it is appropriate to rely on those analyses, as well as the new information and analysis discussed above, for this final rule.

Based on the applicable information and analysis from the 2018 HSTT final rule and 2020 HSTT final rule, as updated with the information and analysis contained herein on the potential and likely effects of the specified activities on the affected marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the incidental take from the specified activities will have a negligible impact on all affected marine mammal species and stocks.

Subsistence Harvest of Marine Mammals

There are no subsistence uses or harvest of marine mammals in the geographic area affected by the specified activities. Therefore, NMFS has determined that the total taking affecting species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Classification

Endangered Species Act

There are nine marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the HSTT Study Area: blue whale, fin whale, gray whale (Western North Pacific DPS), humpback whale (Mexico and Central America DPSs), sei whale, sperm whale, false killer whale (Main Hawaiian Islands Insular DPS), Hawaiian monk seal, and

Guadalupe fur seal. There is also ESA-designated critical habitat for Hawaiian monk seals and Main Hawaiian Islands Insular false killer whales. The Navy consulted with NMFS pursuant to section 7 of the ESA for HSTT activities. NMFS also consulted internally on the issuance of the 2018 HSTT regulations and LOAs under section 101(a)(5)(A) of the MMPA.

NMFS issued a Biological Opinion on December 10, 2018 concluding that the issuance of the 2018 HSTT final rule and subsequent LOAs are not likely to jeopardize the continued existence of the threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the HSTT Study Area. The 2018 Biological Opinion included specified conditions under which NMFS would be required to reinstate section 7 consultation. NMFS reviewed these specified conditions for the 2020 HSTT rulemaking and determined that reinstatement of consultation was not warranted. The incidental take statement that accompanied the 2018 Biological Opinion was amended to cover the 7-year period of the 2020 HSTT rule. The 2018 Biological Opinion for this action is available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>.

The 2018 Biological Opinion reinstatement clause (2), states that formal consultation should be reinstated if "new information reveals effects of the agency action that may affect ESA-listed species or critical habitat in a manner or to an extent not previously considered." Given the new information regarding the recent occurrence of large whale strikes by naval vessels in the southern California portion of the HSTT Study Area, as described herein, the Navy reinstated consultation with NMFS pursuant to section 7 of the ESA for HSTT Study Area activities, and NMFS also reinstated consultation internally on the issuance of these revised regulations and LOAs under section 101(a)(5)(A) of the MMPA.

NMFS issued a reinstated Biological and Conference Opinion on June 3, 2024 concluding that the issuance of the 2024 HSTT final rule and subsequent LOAs are not likely to jeopardize the continued existence of the threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the HSTT Study Area. The opinion is available at <https://doi.org/10.25923/7y9x-vw84>.

National Marine Sanctuaries Act

Federal agency actions that are likely to injure national marine sanctuary resources are subject to consultation with the Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA). There are two national marine sanctuaries in the HSTT Study Area, the Hawaiian Islands Humpback Whale National Marine Sanctuary and the Channel Islands National Marine Sanctuary. NMFS has fulfilled its responsibilities and completed all requirements under the NMSA.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must evaluate our proposed actions and alternatives with respect to potential impacts on the human environment. NMFS participated as a cooperating agency on the 2018 HSTT FEIS/OEIS (published on October 26, 2018, <http://www.hstteis.com>) which evaluated impacts from Navy training and testing activities in the HSTT Study Area for the reasonably foreseeable future (including through 2025). In accordance with 40 CFR 1506.3, NMFS independently reviewed and evaluated the 2018 HSTT FEIS/OEIS and determined that it was adequate and sufficient to meet our responsibilities under NEPA for the issuance of the 2018 HSTT final rule and associated LOAs. NMFS therefore adopted the 2018 HSTT FEIS/OEIS.

In accordance with 40 CFR 1502.9 and the information and analysis contained in this final rule, NMFS has determined that this final rule and any subsequent LOAs will not result in impacts that were not fully considered in the 2018 HSTT FEIS/OEIS. As indicated in this final rule, the Navy has made no substantial changes to the activities that are relevant to environmental concerns nor are there substantial new circumstances or information about the significance of adverse effects that bear on the analysis. Therefore, NMFS has determined that the 2018 HSTT FEIS/OEIS remains valid, and there is no need to supplement the document for this rulemaking. NOAA therefore, has adopted the 2018 HSTT FEIS/OEIS. NMFS has prepared a separate Record of Decision. NMFS' Record of Decision for adoption of the 2018 HSTT FEIS/OEIS and issuance of this final rule and subsequent LOAs can be found at

<https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>.

Regulatory Flexibility Act

The Office of Management and Budget has determined that this rule is not significant for purposes of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

Waiver of Delay in Effective Date Under the Administrative Procedure Act

NMFS has determined that there is good cause under the Administrative Procedure Act (5 U.S.C. 553(d)) to waive the 30-day delay of the effective date for this rule. This rule relieves the Navy from the restrictions of the take prohibitions under the MMPA by granting the Navy's request for incidental take authorization under MMPA section 101(a)(5)(A). In addition, there is good cause to waive the 30-day effective date period because a delay would be contrary to the public interest and unnecessary. A delay in effectiveness is contrary to public interest because this rule allows the Navy to continue training and testing activities that are necessary for national security in compliance with the MMPA. Further, a delay is unnecessary because this rule is not generally applicable to the public. The Navy is the only entity affected by the regulations, the Navy specifically requested the modification to the regulations, and the Navy has fully agreed to the requirements included herein. The Navy is anticipating finalization of the rule and, as such, is ready to comply immediately upon publication. As such, there is good cause to waive the 30-day delay in effective date.

List of Subjects in 50 CFR Part 218

Administrative practice and procedure, Endangered and threatened species, Fish, Fisheries, Marine mammals, Penalties, Reporting and recordkeeping requirements, Transportation, Wildlife.

Dated: December 23, 2024.

Samuel D. Rauch III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

For reasons set forth in the preamble,
50 CFR part 218 is amended as follows:

**PART 218—REGULATIONS
GOVERNING THE TAKING AND
IMPORTING OF MARINE MAMMALS**

■ 1. The authority citation for part 218
continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Revise subpart H to read as follows:

**Subpart H—Taking and Importing Marine
Mammals; U.S. Navy’s Hawaii-Southern
California Training and Testing (HSTT)**

Sec.

218.70 Specified activity and geographical
region.

218.71 Effective dates.

218.72 Permissible methods of taking.

218.73 Prohibitions.

218.74 Mitigation requirements.

218.75 Requirements for monitoring and
reporting.

218.76 Letters of Authorization (LOA).

218.77 Renewals and modifications of
Letters of Authorization.

218.78–218.79 [Reserved]

**Subpart H—Taking and Importing
Marine Mammals; U.S. Navy’s Hawaii-
Southern California Training and
Testing (HSTT)**

**§ 218.70 Specified activity and
geographical region.**

(a) Regulations in this subpart apply
only to the U.S. Navy (Navy) for the

taking of marine mammals that occurs
in the area described in paragraph (b) of
this section and that occurs incidental
to the activities listed in paragraph (c)
of this section.

(b) The taking of marine mammals by
the Navy under this subpart may be
authorized in Letters of Authorization
(LOAs) only if it occurs within the
Hawaii-Southern California Training
and Testing (HSTT) Study Area, which
includes established operating and
warning areas across the north-central
Pacific Ocean, from the mean high tide
line in Southern California west to
Hawaii and the International Date Line.
The HSTT Study Area includes the at-
sea areas of three existing range
complexes, the Hawaii Range Complex
(HRC), the Southern California Range
Complex (SOCAL), and the Silver
Strand Training Complex, and overlaps
a portion of the Point Mugu Sea Range
(PMSR). Also included in the HSTT
Study Area are Navy pierside locations
in Hawaii and Southern California,
Pearl Harbor, San Diego Bay, and the
transit corridor on the high seas where
sonar training and testing may occur.

(c) The taking of marine mammals by
the Navy is only authorized if it occurs
incidental to the Navy conducting
training and testing activities:

- (1) *Training.* (i) Amphibious warfare;
- (ii) Anti-submarine warfare;
- (iii) Electronic warfare;
- (iv) Expeditionary warfare;
- (v) Mine warfare;
- (vi) Surface warfare; and
- (vii) Pile driving.

(2) *Testing.* (i) Naval Air Systems
Command Testing Activities;

(ii) Naval Sea System Command
Testing Activities;

(iii) Office of Naval Research Testing
Activities; and

(iv) Naval Information Warfare
Systems Command.

§ 218.71 Effective dates.

This subpart is effective from January
16, 2025, through December 20, 2025.

§ 218.72 Permissible methods of taking.

(a) Under LOAs issued pursuant to
§§ 216.106 of this chapter and 218.76,
the Holder of the LOAs (hereinafter
“Navy”) may incidentally, but not
intentionally, take marine mammals
within the area described in § 218.70(b)
by Level A harassment and Level B
harassment associated with the use of
active sonar and other acoustic sources
and explosives as well as serious injury
or mortality associated with vessel
strikes and explosives, provided the
activity is in compliance with all terms,
conditions, and requirements of these
regulations in this subpart and the
applicable LOAs.

(b) The incidental take of marine
mammals by the activities listed in
§ 218.70(c) is limited to the following
species:

TABLE 1 TO PARAGRAPH (b)

Species	Stock
Blue whale	Central North Pacific
Blue whale	Eastern North Pacific
Bryde’s whale	Eastern Tropical Pacific
Bryde’s whale	Hawaii
Fin whale	CA/OR/WA
Fin whale	Hawaii
Humpback whale	Central America/Southern Mexico-CA/OR/WA
Humpback whale	Mainland Mexico-CA/OR/WA
Humpback whale	Hawaii
Minke whale	CA/OR/WA
Minke whale	Hawaii
Sei whale	Eastern North Pacific
Sei whale	Hawaii
Gray whale	Eastern North Pacific
Gray whale	Western North Pacific
Sperm whale	CA/OR/WA
Sperm whale	Hawaii
Dwarf sperm whale	Hawaii
Pygmy sperm whale	Hawaii
Kogia whales	CA/OR/WA
Baird’s beaked whale	CA/OR/WA
Blainville’s beaked whale	Hawaii
Goose-beaked whale	CA/OR/WA
Goose-beaked whale	Hawaii
Longman’s beaked whale	Hawaii
Mesoplodon spp.	CA/OR/WA

TABLE 1 TO PARAGRAPH (b)—Continued

<i>Species</i>	<i>Stock</i>
Bottlenose dolphin	California Coastal
Bottlenose dolphin	CA/OR/WA Offshore
Bottlenose dolphin	Hawaii Pelagic
Bottlenose dolphin	Kauai & Niihau
Bottlenose dolphin	Oahu
Bottlenose dolphin	4-Island
Bottlenose dolphin	Hawaii
False killer whale	Hawaii Pelagic
False killer whale	Main Hawaiian Islands Insular
False killer whale	Northwestern Hawaiian Islands
Fraser's dolphin	Hawaii
Killer whale	Eastern North Pacific (ENP) Offshore
Killer whale	ENP Transient/West Coast Transient
Killer whale	Hawaii
Long-beaked common dolphin	California
Melon-headed whale	Hawaiian Islands
Melon-headed whale	Kohala Resident
Northern right whale dolphin	CA/OR/WA
Pacific white-sided dolphin	CA/OR/WA
Pantropical spotted dolphin	Hawaii Island
Pantropical spotted dolphin	Hawaii Pelagic
Pantropical spotted dolphin	Oahu
Pantropical spotted dolphin	4-Island
Pygmy killer whale	Hawaii
Pygmy killer whale	Tropical
Risso's dolphin	CA/OR/WA
Risso's dolphin	Hawaii
Rough-toothed dolphin	Hawaii
Short-beaked common dolphin	CA/OR/WA
Short-finned pilot whale	CA/OR/WA
Short-finned pilot whale	Hawaii
Spinner dolphin	Hawaii Island
Spinner dolphin	Hawaii Pelagic
Spinner dolphin	Kauai & Niihau
Spinner dolphin	Oahu & 4-Island
Striped dolphin	CA/OR/WA
Striped dolphin	Hawaii
Dall's porpoise	CA/OR/WA
California sea lion	U.S.
Guadalupe fur seal	Mexico
Northern fur seal	California
Harbor seal	California
Hawaiian monk seal	Hawaii
Northern elephant seal	California

Note to Table 1: CA/OR/WA = California/Oregon/Washington.

§ 218.73 Prohibitions.

Except for incidental takings contemplated in § 218.72(a) and authorized by LOAs issued under §§ 216.106 of this chapter and 218.76, it is unlawful for any person to do any of the following in connection with the activities listed in § 218.70(c):

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or an LOA issued under §§ 216.106 of this chapter and 218.76;

(b) Take any marine mammal not specified in § 218.72(b);

(c) Take any marine mammal specified in § 218.72(b) in any manner other than as specified in the LOAs; or

(d) Take a marine mammal specified in § 218.72(b) after NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal.

§ 218.74 Mitigation requirements.

When conducting the activities identified in § 218.70(c), the mitigation measures contained in any LOAs issued under §§ 216.106 of this chapter and 218.76 must be implemented. These mitigation measures include, but are not limited to:

(a) *Procedural mitigation.* Procedural mitigation is mitigation that the Navy must implement whenever and wherever an applicable training or testing activity takes place within the HSTT Study Area for each applicable activity category or stressor category and includes acoustic stressors (*i.e.*, active sonar, air guns, pile driving, weapons firing noise), explosive stressors (*i.e.*, sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles and rockets, bombs, sinking exercises,

mines, anti-swimmer grenades, and mat weave and obstacle loading), and physical disturbance and strike stressors (*i.e.*, vessel movement; towed in-water devices; small-, medium-, and large-caliber non-explosive practice munitions; non-explosive missiles and rockets; and non-explosive bombs and mine shapes).

(1) *Environmental awareness and education.* Navy personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities will complete one or more modules identified in their career path training plan, as specified in the LOAs.

(2) *Active sonar.* Active sonar includes low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar. For vessel-based

activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (e.g., sonar sources towed from manned surface platforms). For aircraft-based activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (e.g., rotary-wing aircraft). Mitigation does not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (e.g., maritime patrol aircraft). For active sonar subject mitigation requirements:

(i) *Number of Lookouts and observation platform*—(A) *Hull-mounted sources*. One Lookout is required for hull-mounted sources for platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and for platforms using active sonar while moored or at anchor (including pierside). Two Lookouts are required for hull mounted-sources for platforms without space or manning restrictions while underway (at the forward part of the ship).

(B) *Sources that are not hull-mounted sources*. One Lookout is required on the ship or aircraft conducting the activity for sources that are not hull-mounted.

(ii) *Mitigation zone and requirements*. During active sonar use, the following requirements apply:

(A) *Powerdown for marine mammals at 1,000 yards*. At 1,000 yards (yd) (914.4 m) from a marine mammal, Navy personnel must power down by 6 decibels (dB).

(B) *Powerdown for marine mammals at 500 yards*. At 500 yd (457.2 m) from a marine mammal, Navy personnel must power down by an additional 4 dB (for a total of 10 dB).

(C) *Shutdowns for marine mammals at 200 yards*. At 200 yd (182.9 m) from a marine mammal, Navy personnel must shut down low-frequency active sonar ≥ 200 dB and hull-mounted mid-frequency active sonar; or Navy personnel must shut down low-frequency active sonar < 200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar.

(D) *Prior to activity*. Prior to the start of the active sonar activity (e.g., when maneuvering on station), Navy personnel must observe the 1,000 yd (914.4 m) mitigation zone for floating vegetation; if floating vegetation is observed in the mitigation zone, Navy personnel must relocate or delay the start of active sonar transmission until the mitigation zone is clear. Navy personnel must also observe the mitigation zone for marine mammals; if

marine mammals are observed, Navy personnel must relocate or delay the start of active sonar transmission.

(E) *During the activity for low-frequency active sonar at or above 200 dB and hull-mounted mid-frequency active sonar*. When using low-frequency active sonar at or above 200 dB and hull-mounted mid-frequency active sonar, Navy personnel must observe the 1,000 yd (914.4 m) mitigation zone for marine mammals and power down active sonar transmission by 6 dB if marine mammals are observed within 1,000 yd (914.4 m) of the sonar source; power down by an additional 4 dB (for a total of 10 dB total) if marine mammals are observed within 500 yd (457.2 m) of the sonar source; and cease transmission if marine mammals are observed within 200 yd (182.9 m) of the sonar source.

(F) *During the activity for low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull mounted, and high-frequency active sonar*. During the activity for low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull mounted, and high-frequency active sonar, Navy personnel must observe the 1,000 yd (914.4 m) mitigation zone for marine mammals and cease active sonar transmission if marine mammals are observed within 200 yd (182.9 m) of the sonar source.

(G) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity*. Navy personnel must allow a sighted marine mammal to leave the mitigation zone indicated in § 218.74(a)(2)(ii) prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met:

(1) *Observed exiting*. The animal is observed exiting the mitigation zone;

(2) *Thought to have exited*. The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source;

(3) *Clear from additional sightings*. The mitigation zone has been clear from any additional sightings for 10 minutes (min) for aircraft-deployed sonar sources or 30 min for vessel-deployed sonar sources;

(4) *Sonar source transit*. For mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or

(5) *Bow-riding dolphins*. For activities using hull-mounted sonar where a dolphin(s) is observed in the mitigation

zone, the Lookout concludes that the dolphin(s) are deliberately closing in on the ship to ride the ship's bow wave, and are therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

(3) *Air guns*. For activities using air guns:

(i) *Number of Lookouts and observation platform*. One Lookout must be positioned on a ship or pierside.

(ii) *Mitigation zone and requirements*. The mitigation zone is 150 yd (137.2 m) around the air gun.

(A) *Prior to activity*. Prior to the initial start of the activity (e.g., when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel must also observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of air gun use.

(B) *During activity*. During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease air gun use.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity*. Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing air gun use) until one of the following conditions has been met:

(1) *Observed exiting*. The animal is observed exiting the mitigation zone;

(2) *Thought to have exited*. The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the air gun;

(3) *Clear from additional sightings*. The mitigation zone has been clear from any additional sightings for 30 min; or

(4) *Air gun transit*. For mobile activities, the air gun has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(4) *Pile driving*. For pile driving and pile extraction sound during Elevated Causeway System training:

(i) *Number of Lookouts and observation platform*. One Lookout must be positioned on the shore, the elevated causeway, or a small boat.

(ii) *Mitigation zone and requirements*. The mitigation zone is 100 yd (91.4 m) around the pile driver.

(A) *Prior to activity.* Prior to the initial start of the activity (for 30 min), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay the start of pile driving or vibratory pile extraction.

(B) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease impact pile driving or vibratory pile extraction.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.*

Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing pile driving or pile extraction) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the pile driving location; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 30 minutes.

(5) *Weapons firing noise.* For weapons firing noise associated with large-caliber gunnery activities:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the ship conducting the firing. Depending on the activity, the Lookout could be the same as the one provided for under “Explosive medium-caliber and large-caliber projectiles” or under “Small-, medium-, and large-caliber non-explosive practice munitions” in paragraphs (a)(8)(i) and (a)(18)(i) of this section.

(ii) *Mitigation zone and requirements.* The mitigation zone is 30 degrees on either side of the firing line out to 70 yd (64 m) from the muzzle of the weapon being fired.

(A) *Prior to activity.* Prior to the start of the activity, Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of weapons firing until the mitigation zone is clear. Navy personnel must also observe the mitigation zone for marine mammals; if marine mammals are observed, Navy

personnel must relocate or delay the start of weapons firing.

(B) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease weapons firing.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.*

Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship;

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 30 min; or

(4) *Firing ship transit.* For mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(6) *Explosive sonobuoys.* For explosive sonobuoys:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft or on a small boat. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* The mitigation zone is 600 yd (548.6 m) around an explosive sonobuoy.

(A) *Prior to activity.* Prior to the initial start of the activity (e.g., during deployment of a sonobuoy field, which typically lasts 20–30 min), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations until the mitigation zone is clear. Navy personnel must conduct passive acoustic monitoring for marine mammals and use information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations.

(B) *During activity.* During the activity, Navy personnel must observe

the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease sonobuoy or source/receiver pair detonations.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.*

Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints (e.g., helicopter), or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(7) *Explosive torpedoes.* For explosive torpedoes:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* The mitigation zone is 2,100 yd (1,920.2 m) around the intended impact location.

(A) *Prior to activity.* Prior to the initial start of the activity (e.g., during deployment of the target), Navy personnel must observe the mitigation zone for floating vegetation and jellyfish aggregations; if floating vegetation or jellyfish aggregations are observed, Navy personnel must relocate or delay the start of firing until the mitigation zone

is clear. Navy personnel must conduct passive acoustic monitoring for marine mammals and use the information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(B) *During activity.* During the activity, Navy personnel must observe for marine mammals and jellyfish aggregations; if marine mammals or jellyfish aggregations are observed, Navy personnel must cease firing.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), Navy personnel must when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(8) *Explosive medium-caliber and large-caliber projectiles.* For gunnery activities using explosive medium-caliber and large-caliber projectiles, the following mitigation applies to activities using a surface target:

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel or aircraft conducting the activity. For activities using explosive large-caliber projectiles, depending on the activity, the Lookout

could be the same as the one described in “Weapons firing noise” in paragraph (a)(5)(i) of this section. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements—(A) Air-to-surface activities.* The mitigation zone is 200 yd (182.9 m) around the intended impact location for air-to-surface activities using explosive medium-caliber projectiles.

(B) *Surface-to-surface activities, medium-caliber.* The mitigation zone is 600 yd (548.6 m) around the intended impact location for surface-to-surface activities using explosive medium-caliber projectiles.

(C) *Surface-to-surface activities, large-caliber.* The mitigation zone is 1,000 yd (914.4 m) around the intended impact location for surface-to-surface activities using explosive large-caliber projectiles.

(D) *Prior to activity.* Prior to the start of the activity (e.g., when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(E) *During activity.* During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(F) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location;

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or for activities using mobile targets, the intended impact location has transited a distance equal

to double that of the mitigation zone size beyond the location of the last sighting.

(G) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), Navy personnel must, when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(9) *Explosive missiles and rockets.* For aircraft-deployed explosive missiles and rockets. Mitigation applies to activities using a surface target:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements—(A) Missiles or rockets with 0.6–20 lb net explosive weight.* The mitigation zone is 900 yd (823 m) around the intended impact location for missiles or rockets with 0.6–20 lb net explosive weight.

(B) *Missiles with 21–500 lb net explosive weight.* The mitigation zone is 2,000 yd (1,828.8 m) around the intended impact location for missiles with 21–500 lb net explosive weight.

(C) *Prior to activity.* Prior to the initial start of the activity (e.g., during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(D) *During activity.* During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the

activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), Navy personnel must, when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(10) *Explosive bombs.* For explosive bombs:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* The mitigation zone is 2,500 yd (2,286 m) around the intended target.

(A) *Prior to activity.* Prior to the initial start of the activity (e.g., when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of bomb deployment until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of bomb deployment.

(B) *During activity.* During the activity (e.g., during target approach), Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease bomb deployment.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.*

Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target;

(3) *Clear from additional sightings.*

The mitigation zone has been clear from any additional sightings for 10 min; or for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), Navy personnel must, when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(11) *Sinking exercises.* For sinking exercises:

(i) *Number of Lookouts and observation platform.* Two Lookouts (one must be positioned in an aircraft and one must be positioned on a vessel). If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* The mitigation zone is 2.5 nautical miles (4.6 km) around the target ship hulk.

(A) *Prior to activity.* Prior to the initial start of the activity (90 min prior to the first firing), Navy personnel must conduct aerial observations of the mitigation zone for floating vegetation and jellyfish aggregations; if floating vegetation or jellyfish aggregations are observed, Navy personnel must delay the start of firing until the mitigation zone is clear. Navy personnel also must

conduct aerial observations of the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay the start of firing.

(B) *During activity.* During the activity, Navy personnel must conduct passive acoustic monitoring for marine mammals and use the information from detections to assist visual observations. Navy personnel must visually observe the mitigation zone for marine mammals from the vessel; if marine mammals are observed, Navy personnel must cease firing. Immediately after any planned or unplanned breaks in weapons firing of longer than 2 hours, Navy personnel must observe the mitigation zone for marine mammals from the aircraft and vessel; if marine mammals are observed, Navy personnel must delay recommencement of firing.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.*

Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the target ship hulk; or

(3) *Clear from additional sightings.*

The mitigation zone has been clear from any additional sightings for 30 minutes.

(D) *After activity.* After completion of the activity (for 2 hours after sinking the vessel or until sunset, whichever comes first), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(12) *Explosive mine countermeasure and neutralization activities.* For explosive mine countermeasure and neutralization activities:

(i) *Number of Lookouts and observation platform—(A) Smaller mitigation zone.* One Lookout must be positioned on a vessel or in an aircraft when implementing the smaller mitigation zone.

(B) *Larger mitigation zone.* Two Lookouts (one must be positioned in an aircraft and one must be on a small boat)

when implementing the larger mitigation zone.

(C) *Additional platforms.* If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements—(A) Activities using 0.1–5 lb net explosive weight.* The mitigation zone is 600 yd (548.6 m) around the detonation site for activities using 0.1–5 lb net explosive weight.

(B) *Activities using 6–650 lb net explosive weight.* The mitigation zone is 2,100 yd (1,920.2 m) around the detonation site for activities using 6–650 lb net explosive weight (including high explosive target mines).

(C) *Prior to activity.* Prior to the initial start of the activity (e.g., when maneuvering on station; typically, 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonations.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds; if marine mammals, concentrations of seabirds, or individual foraging seabirds are observed, Navy personnel must cease detonations.

(E) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity or a sighting of seabird concentrations or individual foraging seabirds during the activity.* Navy personnel must allow a sighted animal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to detonation site; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min

when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (typically 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(13) *Explosive mine neutralization activities involving Navy divers.* For explosive mine neutralization activities involving Navy divers:

(i) *Number of Lookouts and observation platform—(A) Smaller mitigation zone.* Two Lookouts (two small boats with one Lookout each, or one Lookout must be on a small boat and one must be in a rotary-wing aircraft) when implementing the smaller mitigation zone.

(B) *Larger mitigation zone.* Four Lookouts (two small boats with two Lookouts each), and a pilot or member of an aircrew must serve as an additional Lookout if aircraft are used during the activity, when implementing the larger mitigation zone.

(C) *Divers.* All divers placing the charges on mines will support the Lookouts while performing their regular duties and will report applicable sightings to their supporting small boat or Range Safety Officer.

(D) *Additional platforms.* If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements—(A) Activities under positive control using 0.1–20 lb net explosive weight.* The mitigation zone is 500 yd (457.2 m) around the detonation site during activities under positive control using 0.1–20 lb net explosive weight.

(B) *Activities under positive control using 21–60 lb net explosive weight charges.* The mitigation zone is 1,000 yd (914.4 m) around the detonation site during all activities using time-delay fuses (0.1–29 lb net explosive weight) and during activities under positive control using 21–60 lb net explosive weight charges.

(C) *Prior to activity.* Prior to the initial start of the activity (e.g., when maneuvering on station for activities under positive control; 30 min for activities using time-delay firing devices), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of detonations or fuse initiation until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonations or fuse initiation.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals, concentrations of seabirds, and individual foraging seabirds (in the water and not on shore); if marine mammals, concentrations of seabirds, or individual foraging seabirds are observed, Navy personnel must cease detonations or fuse initiation. To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, Navy personnel must position boats near the mid-point of the mitigation zone radius (but outside of the detonation plume and human safety zone), must position themselves on opposite sides of the detonation location (when two boats are used), and must travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone. If used, Navy aircraft must travel in a circular pattern around the detonation location to the maximum extent practicable. Navy personnel must not set time-delay firing devices (0.1–29 lb net explosive weight) to exceed 10 minutes.

(E) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity or a sighting of seabird concentrations or individual foraging seabirds during the activity.* Navy personnel must allow a sighted animal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min during activities under positive control with aircraft that have fuel constraints, or 30 min during activities under positive control with aircraft that are not typically fuel constrained and during activities using time-delay firing devices.

(F) *After activity.* After completion of an activity (for 30 min), the Navy must observe for marine mammals for 30 minutes. Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(14) *Maritime security operations—anti-swimmer grenades—(i) Number of Lookouts and observation platform.* One Lookout must be positioned on the small boat conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* 200 yd (182.9 m) around the intended detonation location.

(A) *Prior to activity.* Prior to the initial start of the activity (e.g., when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonations.

(B) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease detonations.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location;

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 30 min; or

(4) *Detonation location transit.* The intended detonation location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) *After activity.* After completion of the activity (e.g., prior to maneuvering off station), Navy personnel must, when practical (e.g., when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(15) *Underwater demolition multiple charge—mat weave and obstacle loading exercises.* For underwater demolition multiple charge—mat weave and obstacle loading exercises:

(i) *Number of Lookouts and observation platform.* Two Lookouts (one must be positioned on a small boat and one must be positioned on shore from an elevated platform). If additional platforms are participating in the activity, Navy personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone while performing their regular duties.

(ii) *Mitigation zone and requirements.* The mitigation zone is 700 yd (640.1 m) around the intended detonation location.

(A) *Prior to activity.* Prior to the initial start of the activity, or 30 min prior to the first detonation, the Lookout positioned on a small boat must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or marine mammals are observed, Navy personnel must delay the start of detonations until the mitigation zone is clear. For 10 min prior to the first detonation, the Lookout positioned on shore must use binoculars to observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay the start of detonations.

(B) *During activity.* During the activity, Navy personnel must observe

the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease detonations.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation location; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min (as determined by the Navy shore observer).

(D) *After activity.* After completion of the activity (for 30 min), the Lookout positioned on a small boat must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (e.g., providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(16) *Vessel movement.* The following requirements apply to vessel movement, except mitigation will not be applied if: the vessel's safety is threatened; the vessel is restricted in its ability to maneuver (e.g., during launching and recovery of aircraft or landing craft, during towing activities, when mooring); the vessel is operated autonomously; or when impracticable based on mission requirements (e.g., during Amphibious Assault—Battalion Landing exercise).

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel that is underway.

(ii) *Mitigation zone and requirements—(A) Whales.* The mitigation zone is 500 yd (457.2 m) around whales.

(B) *Marine mammals other than whales.* The mitigation zone is 200 yd (182.9 m) around all other marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).

(iii) *During the activity.* When underway, Navy personnel must observe the mitigation zone for marine

mammals; if marine mammals are observed, Navy personnel must maneuver (which may include reducing speed as the mission or circumstances allow) to maintain distance.

(iv) *Incident reporting procedures.* If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures.

(v) *Post-strike alerts.* Navy personnel must send alerts to Navy vessels of increased risk of strike following any reported Navy vessel strike in the HSTT Study Area.

(vi) *Large whale aggregation alerts.* Navy personnel must issue real-time notifications to Navy vessels of large whale aggregations (four or more whales) within 1 nmi (1.9 km) of a Navy vessel in the area between 32–33 degrees North and 117.2–119.5 degrees West.

(17) *Towed in-water devices.* The following mitigation applies to devices that are towed from a manned surface platform or manned aircraft, except the mitigation will not be applied if the safety of the towing platform or in-water device is threatened:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a manned towing platform.

(ii) *Mitigation zone and requirements.* The mitigation zone is 250 yd (228.6 m) around marine mammals.

(iii) *During the activity.* During the activity (*i.e.*, when towing an in-water device), Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance.

(18) *Small-, medium-, and large-caliber non-explosive practice munitions.* For small-, medium-, and large-caliber non-explosive practice munitions, the following mitigation applies to activities using a surface target:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the platform conducting the activity. Depending on the activity, the Lookout could be the same as the one described for “Weapons firing noise” in paragraph (a)(5)(i) of this section.

(ii) *Mitigation zone and requirements.* The mitigation zone is 200 yd (182.9 m) around the intended impact location.

(A) *Prior to activity.* Prior to the start of the activity (*e.g.*, when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of firing until the

mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(B) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(C) *Commencement/recommencement conditions after a marine mammal sighting before or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location;

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or

(4) *Impact location transit.* For activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(19) *Non-explosive missiles and rockets.* For aircraft-deployed non-explosive missiles and rockets, the following mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* The mitigation zone is 900 yd (823 m) around the intended impact location.

(A) *Prior to activity.* Prior to the initial start of the activity (*e.g.*, during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(B) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are

observed, Navy personnel must cease firing.

(C) *Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(20) *Non-explosive bombs and mine shapes.* For non-explosive bombs and non-explosive mine shapes during mine laying activities:

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* The mitigation zone is 1,000 yd (914.4 m) around the intended target.

(A) *Prior to activity.* Prior to the initial start of the activity (*e.g.*, when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying.

(B) *During activity.* During the activity (*e.g.*, during approach of the target or intended minefield location), Navy personnel must observe the mitigation zone for marine mammals and, if marine mammals are observed, Navy personnel must cease bomb deployment or mine laying.

(C) *Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met:

(1) *Observed exiting.* The animal is observed exiting the mitigation zone;

(2) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location;

(3) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min; or

(4) *Target transit.* For activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(b) *Mitigation areas.* In addition to procedural mitigation, Navy personnel must implement mitigation measures within mitigation areas to avoid or reduce potential impacts on marine mammals.

(1) *Mitigation areas for marine mammals in the Hawaii Range Complex for sonar, explosives, and vessel strikes—(i) Mitigation area requirements—(A) Hawaii Island Mitigation Area (year-round)—(1) MF1 surface ship hull-mounted mid-frequency active sonar, MF4 dipping sonar, or explosives.* Except as provided in paragraph (b)(1)(i)(A)(2) of this section, within the Hawaii Island Mitigation Area, Navy personnel must not conduct more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of MF4 dipping sonar annually, or use explosives that could potentially result in takes of marine mammals during training and testing.

(2) *National security exception.* Should national security require conduct of more than 300 hours of MF1 surface ship hull-mounted mid-frequency active sonar or 20 hours of MF4 dipping sonar, or use of explosives that could potentially result in the take of marine mammals during training or testing, Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., sonar hours or explosives usage) in its annual activity reports submitted to NMFS.

(B) *4-Islands Region Mitigation Area (November 15–April 15 for active sonar; year-round for explosives)—(1) MF1 surface ship hull-mounted mid-frequency active sonar or explosives.* Except as provided in paragraph (b)(1)(i)(B)(2) of this section, within the 4-Islands Region Mitigation Area, Navy personnel must not use MF1 surface ship hull-mounted mid-frequency active sonar from November 15–April 15 or

explosives that could potentially result in takes of marine mammals at any time during training and testing.

(2) *National security exception.* Should national security require use of MF1 surface ship hull-mounted mid-frequency active sonar or explosives that could potentially result in the take of marine mammals during training or testing, Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., sonar hours or explosives usage) in its annual activity reports submitted to NMFS.

(C) *Humpback Whale Special Reporting Areas (December 15–April 15).* Navy personnel must report the total hours of surface ship hull-mounted mid-frequency active sonar used in the Humpback Whale Special Reporting Areas established from December 15–April 15 in its annual training and testing activity reports submitted to NMFS.

(D) *Humpback Whale Awareness Notification Message Area (November–April).* The following requirements apply in the Humpback Whale Awareness Notification Message Area established from November–April.

(1) *Seasonal awareness notification message.* Navy personnel must issue a seasonal awareness notification message to alert ships and aircraft operating in the area to the possible presence of concentrations of large whales, including humpback whales.

(2) *Vessel instruction.* To maintain safety of navigation and to avoid interactions with large whales during transits, Navy personnel must instruct vessels to remain vigilant to the presence of large whale species (including humpback whales).

(3) *Awareness notification message use.* Platforms must use the information from the awareness notification message to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

(ii) [Reserved]

(2) *Mitigation areas for marine mammals in the southern California portion of the study area for sonar, explosives, and vessel strikes—(i) Mitigation area requirements—(A) San Diego Arc, San Nicolas Island, and Santa Monica/Long Beach Mitigation Areas (June 1–October 31)—(1) MF1 surface ship hull-mounted mid-frequency active sonar.* Except as provided in paragraph (b)(2)(i)(A)(2) of this section, within the San Diego Arc,

San Nicolas Island, and Santa Monica/Long Beach Mitigation Areas from June 1–October 31, Navy personnel must not conduct more than a total of 200 hours of MF1 surface ship hull-mounted mid-frequency active sonar in the combined areas, excluding normal maintenance and systems checks, during training and testing.

(2) *National security exception.* Should national security require conduct of more than 200 hours of MF1 surface ship hull-mounted mid-frequency active sonar in the combined areas during training and testing (excluding normal maintenance and systems checks), Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., sonar hours) in its annual activity reports submitted to NMFS.

(3) *Explosives in San Diego Arc Mitigation Area.* Except as provided in paragraph (b)(2)(i)(A)(4) of this section, within the San Diego Arc Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training and testing.

(4) *National security exception.* Should national security require use of explosives that could potentially result in the take of marine mammals during large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training or testing within the San Diego Arc Mitigation Area, Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., explosives usage) in its annual activity reports submitted to NMFS.

(5) *Explosives in San Nicolas Island Mitigation Area.* Except as provided in paragraph (b)(2)(i)(A)(6) of this section, within the San Nicolas Island Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training.

(6) *National security exception.* Should national security require use of explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery,

torpedo, bombing, and missile (including 2.75-inch rockets) activities during training in the San Nicolas Island Mitigation Area, Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., explosives usage) in its annual activity reports submitted to NMFS.

(7) *Explosives in the Santa Monica/Long Beach Mitigation Area.* Except as provided in paragraph (b)(2)(i)(A)(8) of this section, within the Santa Monica/Long Beach Mitigation Area, Navy personnel must not use explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training and testing.

(8) *National security exception.* Should national security require use of explosives that could potentially result in the take of marine mammals during mine warfare, large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training or testing in the Santa Monica/Long Beach Mitigation Area, Naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., explosives usage) in its annual activity reports submitted to NMFS.

(B) *Santa Barbara Island Mitigation Area (year-round)*—(1) *MF1 surface ship hull-mounted mid-frequency active sonar or explosives.* Except as provided in paragraph (b)(2)(i)(B)(2) of this section, within the Santa Barbara Island Mitigation Area, Navy personnel must not use MF1 surface ship hull-mounted mid-frequency active sonar during training or testing, or explosives that could potentially result in the take of marine mammals during medium-caliber or large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training.

(2) *National security exception.* Should national security require use of MF1 surface ship hull-mounted mid-frequency active sonar during training or testing, or explosives that could potentially result in the take of marine mammals during medium-caliber or large-caliber gunnery, torpedo, bombing, and missile (including 2.75-inch rockets) activities during training, Naval units must obtain permission from the

appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include the information (e.g., sonar hours or explosives usage) in its annual activity reports submitted to NMFS.

(C) *Spring Large Whale Awareness Notification Message*—(1) *Awareness notification message.* Navy personnel must issue an awareness notification message during the spring to alert ships and aircraft within the eastern Pacific to the possible presence of concentrations of large whales, including blue whales, fin whales, and humpback whales.

(2) *Applicable period.* This message must apply to a period that is based on predicted oceanographic conditions for a given year.

(3) *Marine mammals and vessel transit.* To maintain safety of navigation and to avoid interactions with large whales during transits, Navy personnel must instruct personnel on vessels that when a marine mammal is spotted, this may be an indicator that additional marine mammals are present nearby, and increased vigilance and awareness of Navy personnel is warranted.

(4) *Platform use of message.* Platforms must use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

(D) *Gray Whale (November–March) and Fin Whale (November–May) Awareness Notification Message Areas.* The following requirements apply in the Gray Whale Awareness Notification Areas from November–March and Fin Whale Awareness Notification Message Areas from November–May.

(1) *Seasonal awareness message.* Navy personnel must issue a seasonal awareness notification message to alert ships and aircraft operating in the area to the possible presence of concentrations of large whales, including gray whales, and fin whales.

(2) *Marine mammals and vessel transit.* To maintain safety of navigation and to avoid interactions with large whales during transits, Navy personnel must instruct personnel on vessels to remain vigilant to the presence of large whale species.

(3) *Platform use of message.* Platforms must use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

(ii) [Reserved]

§ 218.75 Requirements for monitoring and reporting.

(a) *Unauthorized take.* Navy personnel must notify NMFS immediately (or as soon as operational security considerations allow) if the specified activity identified in § 218.70 is thought to have resulted in the mortality or serious injury of any marine mammals, or in any Level A harassment or Level B harassment of marine mammals not identified in § 218.72(b).

(b) *Monitoring and reporting under the LOAs.* The Navy must conduct all monitoring and reporting required under the LOAs. Details on program goals, objectives, project selection process, and current projects are available at www.navy.mil/speciesmonitoring.us.

(c) *Notification of injured, live stranded, or dead marine mammals.* The Navy must comply with all notification and reporting requirements under the LOAs. The Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or live stranded marine mammals are detected. The Notification and Reporting Plan is available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities>.

(d) *Changes in Lookout policies.* The Navy must report changes in its Lookout policies to NMFS as soon as practicable after a change is made.

(e) *Annual HSTT Study Area marine species monitoring report.* The Navy must submit an annual report of the HSTT Study Area monitoring describing the implementation and results from the previous calendar year. Data collection methods must be standardized across range complexes and study areas to allow for comparison in different geographic locations. The report must be submitted to the Director, Office of Protected Resources, NMFS, either within 3 months after the end of the calendar year, or within 3 months after the conclusion of the monitoring year, to be determined by the Adaptive Management process. This report will describe progress of knowledge made with respect to intermediate scientific objectives within the HSTT Study Area associated with the Integrated Comprehensive Monitoring Program (ICMP). Similar study questions must be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions. As an alternative,

the Navy may submit a multi-Range Complex annual Monitoring Plan report to fulfill this requirement. Such a report will describe progress of knowledge made with respect to monitoring study questions across multiple Navy ranges associated with the ICMP. Similar study questions must be treated together so that progress on each topic can be summarized across multiple Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring study question. This will continue to allow the Navy to provide a cohesive monitoring report covering multiple ranges (as per ICMP goals), rather than entirely separate reports for the HSTT, Gulf of Alaska, Mariana Islands, and Northwest Study Areas.

(f) *Annual HSTT Study Area training exercise report and testing activity report.* Each year, the Navy must submit two preliminary reports (Quick Look Report) detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. Each year, the Navy must submit detailed reports to the Director, Office of Protected Resources, NMFS, within 3 months after the 1-year anniversary of the date of issuance of the LOA. The HSTT annual Training Exercise Report and Testing Activity Report can be consolidated with other exercise reports from other range complexes in the Pacific Ocean for a single Pacific Exercise Report, if desired. The annual reports must contain information on major training exercises (MTEs), Sinking Exercise (SINKEX) events, and a summary of all sound sources used, including within specific mitigation reporting areas, as described in paragraphs (f)(3) through (5) of this section. The analysis in the detailed reports must be based on the accumulation of data from the current year's report and data collected from previous reports. The detailed reports must contain information identified in paragraphs (f)(1) through (9) of this section.

(1) *MTEs.* This section of the report must contain the following information for MTEs conducted in the HSTT Study Area.

(i) Exercise information (for each MTE).

(A) Exercise designator.

(B) Date that exercise began and ended.

(C) Location.

(D) Number and types of active sonar sources used in the exercise.

(E) Number and types of passive acoustic sources used in exercise.

(F) Number and types of vessels, aircraft, and other platforms participating in each exercise.

(G) Total hours of all active sonar source operation.

(H) Total hours of each active sonar source bin.

(I) Wave height (high, low, and average) during exercise.

(ii) Individual marine mammal sighting information for each sighting in each exercise where mitigation was implemented:

(A) Date, time, and location of sighting.

(B) Species (if not possible, indication of whale/dolphin/pinniped).

(C) Number of individuals.

(D) Initial Detection Sensor (*e.g.*, sonar, Lookout).

(E) Indication of specific type of platform observation was made from (including, for example, what type of surface vessel or testing platform).

(F) Length of time observers maintained visual contact with marine mammal.

(G) Sea state.

(H) Visibility.

(I) Sound source in use at the time of sighting.

(J) Indication of whether animal was less than 200 yd (182.9 m), 200 to 500 yd (182.9 to 457.2 m), 500 to 1,000 yd (457.2 m to 914.4 m), 1,000 to 2,000 yd (914.4 m to 1,828.8 m), or greater than 2,000 yd (1,828.8 m) from sonar source.

(K) Whether operation of sonar sensor was delayed, or sonar was powered or shut down, and the length of the delay.

(L) If source in use was hull-mounted, true bearing of animal from the vessel, true direction of vessel's travel, and estimation of animal's motion relative to vessel (opening, closing, parallel).

(M) Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming, *etc.*) and if any calves were present.

(iii) An evaluation (based on data gathered during all of the MTEs) of the effectiveness of mitigation measures designed to minimize the received level to which marine mammals may be exposed. This evaluation must identify the specific observations that support any conclusions the Navy reaches about the effectiveness of the mitigation.

(2) *SINKEXs.* This section of the report must include the following information for each SINKEX completed that year.

(i) Exercise information (gathered for each SINKEX).

(A) Location.

(B) Date and time exercise began and ended.

(C) Total hours of observation by Lookouts before, during, and after exercise.

(D) Total number and types of explosive source bins detonated.

(E) Number and types of passive acoustic sources used in exercise.

(F) Total hours of passive acoustic search time.

(G) Number and types of vessels, aircraft, and other platforms participating in exercise.

(H) Wave height in feet (high, low, and average) during exercise.

(I) Narrative description of sensors and platforms utilized for marine mammal detection and timeline illustrating how marine mammal detection was conducted.

(ii) Individual marine mammal observation (by Navy Lookouts) information for each sighting where mitigation was implemented.

(A) Date/Time/Location of sighting.

(B) Species (if not possible, indicate whale, dolphin, or pinniped).

(C) Number of individuals.

(D) Initial detection sensor (*e.g.*, sonar or Lookout).

(E) Length of time observers maintained visual contact with marine mammal.

(F) Sea state.

(G) Visibility.

(H) Whether sighting was before, during, or after detonations/exercise, and how many minutes before or after.

(I) Distance of marine mammal from actual detonations (or target spot if not yet detonated): Less than 200 yd (182.9 m), 200 to 500 yd (182.9 to 457.2 m), 500 to 1,000 yd (457.2 m to 914.4 m), 1,000 to 2,000 yd (914.4 m to 1,828.8 m), or greater than 2,000 yd (1,828.8 m).

(J) Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming *etc.*), including speed and direction and if any calves were present.

(K) The report must indicate whether explosive detonations were delayed, ceased, modified, or not modified due to marine mammal presence and for how long.

(L) If observation occurred while explosives were detonating in the water, indicate munition type in use at time of marine mammal detection.

(3) *Summary of sources used.* This section of the report must include the following information summarized from the authorized sound sources used in all training and testing events:

(i) Total annual hours or quantity (per the LOA) of each bin of sonar or other acoustic sources (*e.g.*, pile driving and air gun activities); and

(ii) Total annual expended/detonated ordinance (missiles, bombs, sonobuoys, *etc.*) for each explosive bin.

(4) *Humpback Whale Special Reporting Area (December 15–April 15)*. The Navy must report the total hours of operation of surface ship hull-mounted mid-frequency active sonar used in the Humpback Whale Special Reporting Area.

(5) *Mitigation areas*. The Navy must report any use of restricted acoustic and explosive sources identified in § 218.74(b). Information included in the classified annual reports may be used to inform future adaptive management of activities within the HSTT Study Area.

(6) *Geographic information presentation*. The reports must present an annual (and seasonal, where practical) depiction of training and testing bin usage (as well as pile driving activities) geographically across the HSTT Study Area.

(7) *Sonar exercise notification*. The Navy must submit to NMFS (contact as specified in the LOA) an electronic report within 15 calendar days after the completion of any MTE indicating:

- (i) Location of the exercise;
- (ii) Beginning and end dates of the exercise; and
- (iii) Type of exercise.

(8) *Large whale aggregations*. For each instance that an aggregation of large whales (4 or more whales within 1 nmi (1.9 km)) is reported in the area between 32–33 degrees North and 117.2–119.5 degrees West, Navy personnel must report the following information and to the extent practicable, this information should be provided in the Navy's unclassified version of these reports:

- (i) Date, time, and general location (*e.g.*, approximately 10–12 nmi (18.5 to 22.2 km) Southeast of San Clemente Island) of the whales when the aggregation was first sighted
- (ii) Total number of whales observed within 1 nmi (1.9 km) of a Navy vessel that make up the aggregation
- (iii) Approximate distance (or distances if more than 1 group of whales is sighted) of the vessel from the whales in the aggregation when the whales were first sighted.

(9) *Foreign military sonar and explosives*. Navy personnel must confirm that foreign military use of sonar and explosives, when such militaries are participating in a U.S. Navy-led exercise or event, combined with the U.S. Navy's use of sonar and explosives, would not cause exceedance of the analyzed levels within each

NAEMO modeled sonar and explosive bin used for estimating predicted impacts.

(g) *7-year close-out comprehensive training and testing activity report*. This report must be included as part of the 2025 annual training and testing report. This report must provide the annual totals for each sound source bin with a comparison to the annual allowance and the 7-year total for each sound source bin with a comparison to the 7-year allowance. Additionally, if there were any changes to the sound source allowance, this report must include a discussion of why the change was made and include the analysis to support how the change did or did not result in a change in the 2018 HSTT FEIS/OEIS and final rule determinations. The draft report must be submitted within 3 months after the expiration of this subpart to the Director, Office of Protected Resources, NMFS. NMFS must submit comments on the draft close-out report, if any, within 3 months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or 3 months after the submittal of the draft if NMFS does not provide comments.

§ 218.76 Letters of Authorization (LOA).

(a) To incidentally take marine mammals pursuant to the regulations in this subpart, the Navy must apply for and obtain LOAs in accordance with § 216.106 of this chapter.

(b) LOAs, unless suspended or revoked, may be effective for a period of time not to exceed December 20, 2025.

(c) If an LOA expires prior to December 20, 2025, the Navy may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision of § 218.77(c)(1)) required by an LOA issued under this subpart, the Navy must apply for and obtain a modification of the LOA as described in § 218.77.

(e) Each LOA must set forth:

- (1) Permissible methods of incidental taking;
- (2) Geographic areas for incidental taking;
- (3) Means of effecting the least practicable adverse impact (*i.e.*, mitigation) on the species or stocks of marine mammals and their habitat; and
- (4) Requirements for monitoring and reporting.

(f) Issuance of the LOA(s) must be based on a determination that the level of taking is consistent with the findings made for the total taking allowable under the regulations in this subpart.

(g) Notice of issuance or denial of the LOA(s) must be published in the **Federal Register** within 30 days of a determination.

§ 218.77 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 218.76 for the activity identified in § 218.70(c) may be renewed or modified upon request by the applicant, provided that:

(1) The planned specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for the regulations in this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA(s) were implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or to the mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or stock or years), NMFS may publish a notice of planned LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 of this chapter and 218.76 may be modified by NMFS under the following circumstances:

(1) After consulting with the Navy regarding the practicability of the modifications, NMFS may modify (including adding or removing measures) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include:

- (A) Results from the Navy's monitoring from the previous year(s);
- (B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by the regulations in this subpart or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of planned LOA in the **Federal Register** and solicit public comment.

(2) If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 218.76, an LOA may be modified without prior notice or

opportunity for public comment. Notice would be published in the **Federal Register** within 30 days of the action.

§§ 218.78–218.79 [Reserved]

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1160

Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain
Other Combusted Tobacco Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1160

[Docket No. FDA-2024-N-5471]

RIN 0910-A176

Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products

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

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing a tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products. FDA is proposing this action to reduce the addictiveness of these products, thus giving people who are addicted and wish to quit the ability to do so more easily. The proposed product standard is anticipated to benefit the population as a whole. For example, it would help to prevent people who experiment with cigarettes and cigars from developing addiction and using combusted tobacco products regularly.

DATES: Either electronic or written comments on the proposed rule must be submitted by September 15, 2025. Submit comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by September 15, 2025.

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 15, 2025. 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-2024-N-5471 for "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products." 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.

Go to the Federal eRulemaking Portal at <https://www.regulations.gov> for access to the rulemaking docket, including any background documents and the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

Submit comments on the information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The title of this proposed collection is "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products."

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Nate Mease or Dhanya John, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

With regard to the information collection: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

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I. Executive Summary**A. Purpose of the Proposed Rule**

Each year, 480,000 people die prematurely from a smoking-attributable disease, making tobacco use the leading cause of preventable disease and death in the United States (Ref. 1). Nearly all these adverse health effects are ultimately the result of addiction to the nicotine in combusted tobacco products, leading to repeated exposure to toxicants from those products. Nicotine, the primary addictive constituent in tobacco products, can be delivered through a variety of products along a continuum of risk. To protect youth and reduce tobacco-related disease and death, the Agency utilizes a comprehensive approach to tobacco and nicotine regulation (<https://www.fda.gov/media/174911/download>). As part of this comprehensive approach, FDA is proposing a tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes¹ and certain

¹ Throughout this document, FDA generally uses the term “cigarettes” to refer to combusted cigarettes, unless specifically stated or context indicates that noncombusted cigarettes are referenced. In general, the term is not meant to include any noncombusted tobacco products that meet the definition of cigarette in section 900(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387(3)).

other combusted tobacco products (proposed product standard).

As the U.S. District Court for the District of Columbia recognized in *United States v. Philip Morris USA, Inc. et al.*, 449 F.Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), the tobacco industry has long known that nicotine creates and sustains addiction, and the industry is dependent on maintaining this addiction. *Id.* at 307. The court noted how cigarette companies have engaged in extensive research to understand how nicotine operates within the human body and then designed their cigarettes to precisely control nicotine delivery and provide nicotine doses to create and sustain addiction. *Id.* at 307–309. Moreover, the court confirmed that industry documents supported the conclusion that these companies “knew early on in their research that if a cigarette did not deliver a certain amount of nicotine, new smokers would not become addicted, and ‘confirmed’ smokers would be able to quit.” *Id.* at 219. In fact, the tobacco industry has had programs in place since the 1960s to obtain “any level of nicotine desired” (Ref. 2). These companies sought to identify the “optimum” dose needed to “satisfy” people who smoke cigarettes and, thereby, assure their continued smoking. *Philip Morris*, 449 F.Supp.2d at 309–10. This proposed product standard would seek to set a maximum nicotine level such that cigarettes and certain other combusted tobacco products could no longer create and sustain this addiction among people who smoke cigarettes and certain other combusted tobacco products.

The proposed product standard would limit the addictiveness of the most toxic and widely used tobacco products, which would have significant public health benefits for all age groups. The proposal would have cessation benefits for adults who use cigarettes and certain other combusted tobacco products, most of whom want to quit but are repeatedly unsuccessful because of the highly addictive nature of these products (see section IV.A of this document). Because these products would not create and sustain addiction, users would be able to quit when they would like, something many who use these products currently do not have the ability to do. Additionally, combusted tobacco products at minimally addictive or nonaddictive levels of nicotine would remain on the market for those who currently smoke and would like to continue to do so.

It would also help prevent people who experiment with cigarettes or certain other combusted tobacco

products (mainly youth) from moving beyond experimentation, developing an addiction to nicotine, and progressing to regular use of combusted tobacco products as a result of that addiction (see section VIII.B of this document). Reducing the number of people who experiment with cigarettes or certain other combusted tobacco products who then transition to regular use of these products would prevent severe adverse health consequences of long-term smoking at the individual level and result in public health benefits at the population level. Based on FDA's population health model, by the year 2100, in the United States, approximately 48 million youth and young adults who would have otherwise initiated habitual cigarette smoking would not as a result of the proposed product standard. The model also projects that more than 12.9 million additional people who smoke cigarettes would quit smoking cigarettes² 1 year after implementation of the proposed product standard; this estimate increases to 19.5 million additional people within 5 years of implementation (this includes people who exclusively smoke cigarettes quitting all tobacco products or completely switching to noncombusted tobacco product use, as well as people who engage in dual use of cigarettes and noncombusted tobacco products quitting cigarette use). In addition, the model estimates that, by the year 2060, in the United States, this proposed product standard would result in 1.8 million tobacco-related deaths averted, rising to 4.3 million deaths averted by the end of the century. The reduction in premature deaths attributable to the proposed product standard would result in 19.6 million life years gained by 2060 and 76.4 million life years gained by 2100. For the reasons discussed in the preamble, FDA finds that the proposed product standard would be appropriate for the protection of the public health.

As explained in section VIII.A., the population health model uses inputs derived from available empirical evidence and expert opinion to estimate the impact of this proposed rule. To obtain expert opinion for the model inputs, FDA conducted a formal expert elicitation process in 2015 and repeated it in 2018. FDA is conducting another expert elicitation process and intends to publish the results of this update for public review and additional comment

on this proposed standard in light of that update.

B. Summary of the Major Provisions of the Proposed Rule

There are currently no tobacco product standards regulating nicotine in tobacco products. The proposed rule would establish a maximum level of nicotine in cigarettes and certain other combusted tobacco products. FDA issued an Advance Notice of Proposed Rulemaking regarding a potential nicotine tobacco product standard (Nicotine ANPRM), and the Agency reviewed and analyzed the comments to that ANPRM (83 FR 11818 (March 16, 2018)). FDA also conducted an extensive and robust review of the relevant scientific literature, as discussed throughout this document. FDA is proposing the following provisions based on the comments received and the Agency's analysis of relevant scientific literature.

Proposed scope—Given that approximately 28 million adults and 380,000 youth in the United States currently smoke cigarettes and the toxicity and addictiveness of these products, cigarettes are the tobacco product category that causes the largest amount of harm to public health in the United States (Refs. 3 and 4). However, if a product standard were to cover only cigarettes, it is likely that a significant number of addicted people who smoke cigarettes would migrate to other similar combusted tobacco products after the standard went into effect to maintain their nicotine exposure, thereby undermining the public health benefits of the standard (Ref. 5) (see also section VI.B of this document). Therefore, to increase the public health benefits, we are proposing to cover the following products under this proposed product standard: Cigarettes (other than noncombusted cigarettes, such as heated tobacco products (HTPs)³ that meet the definition of a cigarette), cigarette tobacco, roll-your-own (RYO) tobacco, cigars (including little cigars, cigarillos, and large cigars but excluding premium cigars⁴), and pipe tobacco (other than waterpipe tobacco⁵). FDA requests

³ Tobacco products that meet the statutory or regulatory definition of a cigarette but are not combusted (do not exceed 350 °C) are categorized as "heated tobacco products" (HTPs) for purposes of FDA's premarket review. HTPs that meet the definition of a cigarette must be in compliance with the applicable statutory and regulatory requirements for cigarettes, unless otherwise noted in a marketing authorization order (Ref. 6).

⁴ See section III.B.3 of this document.

⁵ Waterpipe tobacco (also known as hookah tobacco) is a type of tobacco product that produces smoke that people inhale when a hookah device is heated. Hookah tobacco (also known as waterpipe

comments, data, and research regarding this proposed scope.

FDA is proposing to exclude noncombusted cigarettes, such as HTPs that meet the definition of a cigarette in section 900(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387(3)) from the scope of this proposed product standard (proposed § 1160.3 includes a definition of cigarette). Therefore, "cigarettes" in this proposed rule refers to combusted cigarettes, not HTPs. Based on FDA's experience with application review, certain noncombusted cigarettes produce fewer or lower levels of some toxicants than combusted cigarettes. FDA recognizes that tobacco products exist on a continuum of risk, with combusted cigarettes being the deadliest, and that certain noncombusted cigarettes pose less risk to individuals who use cigarettes or certain other combusted tobacco products or to population health than other products meeting the definition of a cigarette. Accordingly, FDA requests comments, data, and research regarding the proposal to exclude noncombusted cigarettes from the scope of this proposed rule, including any data that could justify otherwise.

FDA also proposes to exclude waterpipe tobacco from the proposed product standard because, unlike cigarette tobacco, pipe tobacco, RYO tobacco, and cigars (other than premium cigars), FDA believes there is little risk of switching under the proposed product standard. Waterpipes as currently marketed and used generally require substantial time for preparation and use (*i.e.*, an approximately 1-hour session with waterpipes compared to 5–7 minutes with cigarettes). In addition, they are generally large and unwieldy and thus ill-suited for mobile usage, such as while driving or walking. FDA requests comments, data, and research regarding the proposal to exclude waterpipe tobacco from the scope of this proposed rule, including any data that could justify otherwise.

FDA is also not including noncombusted non-cigarette tobacco products, such as electronic nicotine delivery systems (ENDS) (which include e-cigarettes) and smokeless tobacco products, in the scope of this proposed product standard. As discussed throughout this document, nicotine is the primary addictive constituent in

tobacco, maassel, shisha, narghile, or argileh) typically contains a mixture of tobacco, sweeteners, and flavoring. The hookah device (or waterpipe) used to smoke the hookah tobacco works by passing charcoal or electric heated air through the tobacco mixture and ultimately through a water-filled chamber (Ref. 7).

² For the purposes of this proposed rule, where describing expected transition behaviors, we also use the shorter phrase "quit smoking" to refer to stopping use of combusted cigarettes.

tobacco products, and it is the nicotine in such products that both creates and sustains addiction and ultimately leads to the significant adverse health effects caused by these products. While these effects raise concerns in the context of any tobacco product—none of which is without risk—at this time, FDA is focusing this proposed rule on nicotine levels in cigarettes and certain other combusted tobacco products because combusted tobacco products are responsible for the majority of death and disease due to tobacco use. FDA expects that, if this proposed rule is finalized as proposed, many people who smoke cigarettes will quit smoking, either by quitting all tobacco use or by completely switching to a noncombusted tobacco product. Those who switch completely to use of a noncombusted tobacco product may sustain their nicotine dependence but may significantly reduce their risk of tobacco-related death and disease because switching completely to a noncombusted tobacco product would reduce exposure to the chemical constituents created through combustion, which are currently the primary contributors of tobacco-related harm (Ref. 8). Importantly, this action would also help to prevent people who experiment with cigarettes and cigars (mainly youth) from moving beyond experimentation, developing an addiction to nicotine, and progressing to regular use of combusted tobacco products as a result of that addiction. We request comments, data, and research regarding the proposed scope of this rule.

For further discussion regarding considerations and request for comments on the proposed scope of this rule, see section IX.C of this document.

Proposed product standard for nicotine—FDA is proposing to make cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive⁶ by limiting the nicotine yield of these products. We propose to limit nicotine yield by setting a maximum nicotine content level of 0.70 milligrams (mg) of nicotine per gram of total tobacco in these tobacco products. For comparison, the average nicotine content in the top 100 cigarette brands for 2017 is 17.2 mg/g of total tobacco (Ref. 9). Nicotine yield is the amount of

nicotine in smoke, in other words, the amount of nicotine to which a smoker potentially is exposed. While nicotine yield can be measured through machine-generated smoking methods (e.g., International Organization for Standardization (ISO) machine smoking method, Canadian Intense (CI) smoking method, Federal Trade Commission (FTC) smoking method), it can vary due to a user's compensatory behaviors—e.g., inhaling more deeply, taking larger puffs, and blocking cigarette features designed to reduce nicotine yield—such that users can increase the amount of nicotine yield compared to the machine-generated yield. In contrast, nicotine “content,” which refers to the amount of nicotine present in tobacco filler, is not affected by smoking behavior or cigarette design features. Reducing the nicotine content to the proposed 0.70 mg of nicotine per gram of total tobacco limit in the finished tobacco products subject to this proposed product standard places an absolute maximum limit on the amount of nicotine present in tobacco smoke available for intake by users of these products. There are many different tobacco product characteristics that can be manipulated to affect nicotine yield, one of which is nicotine content. Setting a limit on nicotine content and measuring that content is more effective in reducing yield (i.e., the amount of nicotine the user is exposed to) than setting a limit based on a direct measurement of yield under standardized smoking-machine protocols because nicotine content cannot be affected by the compensatory behavior described above. Therefore, limiting nicotine yield through a maximum nicotine content level would better achieve the public health benefits that come from reducing the amount of the nicotine to which a user is exposed than would setting a limit based on a measurement of the maximum machine-measured yield of tobacco products. For further discussion, see section VII.A.

The proposed limit of 0.70 mg of nicotine per gram of total tobacco is based on FDA's analysis of studies regarding the likely effects of reducing nicotine, which shows that extended exposure to very low nicotine content (VLNC) combusted cigarettes is associated with reduced addiction potential, dependence levels, number of cigarettes smoked per day and increased quit attempts among people who currently smoke cigarettes, without increasing toxicant exposure, craving, withdrawal, or compensatory smoking. Throughout this preamble, “VLNC cigarettes” refers to combusted cigarettes that have been reported to

contain ≤ 1.0 mg nicotine per gram of total tobacco, “low nicotine content (LNC) cigarettes” refers to cigarettes with > 1.0 mg and < 11.4 mg nicotine per gram of total tobacco, and “normal nicotine content (NNC) cigarettes” refers to cigarettes with ≥ 11.4 mg nicotine per gram of total tobacco.⁷ FDA uses these acronyms in places where we have confirmed that the nicotine content of the cigarettes referenced meets these definitions. In documents that reference nicotine content in tobacco, but do not specify the levels of nicotine and therefore cannot be confirmed to meet these definitions, we have maintained the full description that best reflects what was used in the original document (e.g., low nicotine content tobacco).

FDA is not seeking to require the reduction of nicotine yields in any tobacco product to zero, which would violate section 907(d)(3) of the FD&C Act (21 U.S.C. 387g(d)(3)). FDA requests comments, data, and research regarding this proposed maximum nicotine level.

Immediate nicotine reduction approach—FDA is proposing an immediate nicotine reduction (i.e., single target) approach to reach the proposed maximum nicotine level (rather than a gradual reduction, or stepped-down, approach) to limit additional toxicant exposure. Based on studies involving VLNC cigarettes and other reduced nicotine content (RNC) cigarettes, we expect that there would be very little or no compensatory smoking (and, consequently, additional limited toxicant exposure) with an immediate reduction approach, as opposed to a gradual reduction approach which showed evidence of increased compensatory smoking. As such, an immediate reduction approach would increase the benefits of the proposed product standard. FDA also notes that this immediate nicotine reduction approach would reduce manufacturing costs for those products covered by the proposed standard because manufacturers would not have reason to formulate multiple products and then prepare and submit premarket review applications at each phase of a gradual reduction approach. We request comments, data, and information regarding the selection of an immediate reduction approach.

Analytical test method—To assist FDA in determining compliance with this rule, the proposed product standard would require manufacturers to analyze

⁶ FDA is using the term “nonaddictive” throughout this preamble specifically in the context of the available data on very low nicotine content cigarettes. We acknowledge the highly addictive potential of nicotine itself depending upon the route of delivery. As discussed elsewhere in this preamble, questions remain with respect to the precise level of nicotine in cigarettes that might render them either minimally addictive or nonaddictive for specific individual members or segments of the population.

⁷ The term VLNC should not be confused with the cigarette brand name “VLN;” “VLN” refers to cigarette products authorized for marketing by FDA in 2019. See <https://www.fda.gov/media/133633/download?attachment> and <https://www.fda.gov/media/133635/download?attachment>.

the nicotine levels of cigarettes and certain other combusted tobacco products covered by the rule using an analytical test method that has been validated in an analytical test laboratory. In addition, FDA is proposing to require product testing prior to commercial distribution in the United States to prevent nonconforming tobacco products from entering the stream of commerce and reaching consumers.

Sampling plan—The proposed product standard would require tobacco product manufacturers to design and implement a sampling plan that covers each batch of finished tobacco product⁸ that they manufacture. This sampling plan would be based on a valid scientific rationale (such as representative sampling) to ensure that each product complies with the proposed product standard. This sampling plan would provide procedures for the manufacturer to select samples to demonstrate conformance to the proposed product standard requirement. The required procedures would help ensure that products that do not conform to the product standard are not sold or distributed to consumers.

Nonconforming tobacco product—The proposed product standard would require tobacco product manufacturers to establish procedures for the control and disposition of tobacco products that do not conform to the requirements of this rule. These procedures are necessary to help prevent the distribution of nonconforming tobacco products by ensuring that all potential nonconforming products are identified, investigated, and segregated and that appropriate disposition and followup are taken for products determined to be nonconforming. This proposed requirement would ensure that any reports of nonconforming products, whether as a result of manufacturer testing or otherwise, are examined and investigated and that appropriate measures are taken to ensure that nonconforming products are not distributed to consumers and to prevent future nonconformity.

Manufacturing code—Currently, there is no requirement for the use of a

manufacturing code for tobacco products. However, the proposed regulation Requirements for Tobacco Product Manufacturing Practice (TPMP) (see <https://www.federalregister.gov/documents/2023/03/10/2023-04591/requirements-for-tobacco-product-manufacturing-practice>) includes a requirement for a manufacturing code, and this rulemaking's provision is modeled on the proposed TPMP provision. The proposed product standard would require the use of a manufacturing code to serve as a common identifier for production and distribution records. The purpose of the manufacturing code is to allow manufacturers and FDA to identify the production batch of a particular finished 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 tobacco product investigation and any corrective actions to be taken by a manufacturer as a result of the investigation.

Recordkeeping requirements—To assist FDA in determining compliance with the rule and aid in nonconforming product investigations, the proposed product standard would require that manufacturers establish and maintain records regarding the results of testing conducted on each batch to determine conformance with the proposed standard. In addition, this proposed product standard would require that manufacturers maintain records of sampling plans and sampling procedures, records related to manufacturing controls, and all records related to its analytical test method validation. FDA also is proposing to require that it be possible to identify the production batch of a particular finished product that has been released for distribution.

Proposed effective date—FDA proposes that any final rule that may issue based on this proposed rule become effective 2 years after the date of publication of the final rule. Therefore, after the effective date no person could distribute, sell, or offer for sale or distribution within the United States finished tobacco products that are not in compliance with part 1160 (21 CFR part 1160). Prior to the effective date of any final rule that may issue based on this proposed rule, wholesalers, retailers, and related entities would be able to sell available stock of finished tobacco products were not in compliance with part 1160 while transitioning inventory in anticipation of the effective date of the final rule;

however, they would not be permitted to sell off such stock after the effective date. FDA believes this approach would allow adequate time for developing any necessary changes in technology or inputs to comply with a finalized product standard. It also would provide sufficient time for tobacco product manufacturers to submit, and FDA to review, applications for new tobacco products that comply with the finalized product standard. Additionally, FDA believes that this approach would allow adequate time for making any changes to tobacco purchasing choices and curing methods, and for preparation or changes needed in facilities and processes. FDA requests comments and data on this proposed effective date. For further discussion regarding considerations and request for comments on the proposed effective date of this rule, see section XI of this document.

Given that any new tobacco products that comply with this product standard would be required to undergo premarket review, FDA is considering options for addressing any influx of applications.

C. Legal Authority

Section 907 of the FD&C Act authorizes FDA to adopt tobacco product standards, including product standards that include provisions for nicotine yields; for the reduction or elimination of other constituents (including smoke constituents) or harmful components; respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of tobacco products; for the testing of tobacco products; and for restricting the sale of tobacco products to the extent consistent with section 906 (21 U.S.C. 387f) (section 907(a)(3), (a)(4)(A)(i) to (iii), and (a)(4)(B)(i) to (ii) and (iv) to (v)). The FD&C Act also establishes FDA's authority to require tobacco product manufacturers to establish and maintain records in section 909 (21 U.S.C. 387i); authority related to adulterated and misbranded tobacco products in sections 902 and 903 (21 U.S.C. 387b and 387c); authority regarding premarket review of new tobacco products in section 910 (21 U.S.C. 387j); authority related to prohibited acts in section 301 (21 U.S.C. 331); and FDA's rulemaking and inspection authorities in sections 701 and 704 (21 U.S.C. 371 and 374).

D. Costs and Benefits

The main quantified benefits come from averted mortality and morbidity as a result of reduced prevalence for people who currently use combusted

⁸ For the purpose of this document, the term "finished tobacco product" refers to those products subject to this proposed rule. FDA proposes to define a "finished tobacco product" to mean a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers. For a discussion of products FDA proposes to include within the scope of this product standard, see sections IX.C and X.A.1 of this document.

tobacco products, and reduced mortality from reduced exposure to secondhand smoke among people. Unquantified benefits include medical cost savings, productivity loss savings, reduced exposure to thirdhand smoke, and environmental impacts. We expect this proposed rule, if finalized, to impose costs on industry to follow the product standard, on the broader economy to repurpose land, labor, and capital, on consumers impacted by the product

standard, and on FDA to enforce this product standard. In addition to benefits and costs, this rule would cause transfers from the Federal Government and State governments in the form of tax revenue, from firms in the form of reduced revenue, and transfers between or within firms to cover shifts in user fee obligations.

The annualized monetized benefits over a 40-year time horizon far exceed the annualized monetized costs over the same time. We estimate that the

annualized benefits over a 40-year time horizon would be \$1.1 trillion at a 2 percent discount rate, with a low estimate of \$0.27 trillion and a high estimate of \$1.2 trillion. Over a 40-year time horizon, we estimate that the annualized costs would be \$2.07 billion at a 2 percent discount rate, with a low estimate of \$0.7 billion and a high estimate of \$2.73 billion.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
3-HPMA	3-hydroxypropyl mercapturic acid.
AI/AN	American Indians/Alaska Native.
ANPRM	Advance Notice of Proposed Rulemaking.
BAP	Benzo[a]pyrene.
CDC	Centers for Disease Control and Prevention.
CFR	Code of Federal Regulations.
CISNET	Cancer Intervention and Surveillance Modeling Network.
CO	Carbon monoxide.
COHb	Carboxyhemoglobin.
COPD	Chronic obstructive pulmonary disease.
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco.
CPD	Cigarettes per day.
CPS-I	Cancer Prevention Study I.
CPS-II	Cancer Prevention Study II.
CRM	CORESTA Recommended Method.
DSM	Diagnostic and Statistical Manual of Mental Disorders.
ENDS	Electronic nicotine delivery systems.
E.O.	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
FTCD	Fagerström Test for Cigarette Dependence.
FTND	Fagerström Test for Nicotine Dependence.
GC-MS	Gas chromatography-mass spectrometry.
HHS	U.S. Department of Health and Human Services.
HPHCs	Harmful and potentially harmful constituents.
HTP	Heated tobacco product.
IOM	Institute of Medicine.
LGBTQI+	Lesbian, gay, bisexual, transgender, queer, and intersex.
LNC	Low nicotine content.
mg	milligram.
MINWS	Minnesota Nicotine Withdrawal Scale.
MRI	Magnetic resonance imaging.
nAChR	Nicotinic acetylcholine receptor.
NATS	National Adult Tobacco Survey.
NCI	National Cancer Institute.
NDSS	Nicotine Dependence Syndrome Scale.
NHANES	National Health and Nutrition Examination Survey.
NHIS	National Health Interview Survey.
NHIS-LMF	National Health Interview Survey-Linked Mortality Files.
NIDA	National Institute on Drug Abuse.
NIH	National Institutes of Health.
NJATS	New Jersey Adult Tobacco Survey.
NLMS	National Longitudinal Mortality Study.
NNAL	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol.
NNC	Normal nicotine content.
NNN	N-Nitrosornicotine.
NPRM	Notice of proposed rulemaking.
NRC	National Research Council.
NRT	Nicotine replacement therapy.
NSDUH	National Survey on Drug Use and Health.
NYTS	National Youth Tobacco Survey.
OOS	Out-of-specification.
PAH	Polycyclic aromatic hydrocarbon.
PATH	Population Assessment of Tobacco and Health.
PET	Position emission tomography.
PD	Product static ID number.
QALYs	Quality-adjusted life years.

Abbreviation/ acronym	What it means
QSU	Questionnaire of Smoking Urges.
RCT	Randomized clinical trial.
RNC	Reduced nicotine content.
RR	Relative risk.
RYO	Roll-your-own.
S-PMA	S-phenylmercapturic acid.
SE	Substantial Equivalence.
SES	Socioeconomic status.
STN	Submission tracking number.
TNE	Total nicotine equivalents.
TPSAC	Tobacco Products Scientific Advisory Committee.
TUS-CPS	Tobacco Use Supplement to the Current Population Survey.
U.S.	United States.
VLNC	Very low nicotine content.
WISDM	Wisconsin Inventory of Smoking Dependence Motives.
YRBS	Youth Risk Behavior Survey.

III. Background

A. Need for the Regulation

Cigarettes are responsible for the majority of tobacco-related death and disease in the United States. Each year, 480,000 people die prematurely from a smoking-attributable disease, putting a substantial burden on the U.S. healthcare system and causing massive economic losses to society (Ref. 1). In terms of a monetary measure of the impact of cigarette smoking on the public health, in 2018, cigarette smoking cost the United States more than \$600 billion, including more than \$240 billion in healthcare spending (Ref. 10), nearly \$185 billion in lost productivity from smoking-related illnesses and health conditions (Ref. 10), nearly \$180 billion in lost productivity from smoking-related premature death (Refs. 1 and 10), and \$7 billion in lost productivity from premature death from secondhand smoke exposure (Refs. 1 and 11). The mortality rate among people who currently smoke cigarettes is 2 to 3 times as high as that among individuals who never smoked (Ref. 12). Nicotine, the primary addictive constituent in tobacco products, can be delivered through a variety of products along a continuum of risk, with combusted tobacco products at the most harmful end of this continuum. To protect youth and reduce tobacco-related disease and death, FDA utilizes a comprehensive approach to tobacco and nicotine regulation. Shortly after FDA announced its comprehensive approach in 2017 (<https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>), the Agency began a public dialogue about lowering nicotine levels in combusted cigarettes to minimally addictive or nonaddictive levels through achievable product

standards. On March 16, 2018, FDA issued a Nicotine ANPRM to seek input on the potential public health benefits and any possible adverse effects of regulating nicotine yield by lowering nicotine levels in cigarettes and invited comments on many issues associated with the development of a product standard to establish a maximum nicotine level (83 FR 11818). The Nicotine ANPRM also acknowledged that if FDA were to establish a nicotine tobacco product standard that covered only cigarettes, some number of people who smoke cigarettes could migrate to other similar combusted tobacco products to maintain their nicotine dependence (or engage in dual use with other combusted tobacco products), potentially reducing the positive public health impact of such a rule. FDA sought comments on whether the standard therefore should cover other combusted tobacco products. Based on FDA's scientific knowledge, extensive research regarding VLNC cigarettes, and comments submitted in response to this Nicotine ANPRM, FDA is proposing a tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products.

As the U.S. District Court for the District of Columbia recognized in *United States v. Philip Morris USA, Inc. et al.*, 449 F.Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), the tobacco industry has long known that nicotine creates and sustains addiction, and the industry is dependent on maintaining this addiction. *Id.* at 307. The court noted how cigarette companies have engaged in extensive research to understand how nicotine operates within the human body and then designed their cigarettes to precisely control nicotine delivery and provide nicotine doses to create and

sustain addiction. *Id.* at 307–309. Moreover, the court confirmed that industry documents supported the conclusion that these companies “knew early on in their research that if a cigarette did not deliver a certain amount of nicotine, new smokers would not become addicted, and ‘confirmed’ smokers would be able to quit.” *Id.* at 219. In fact, the tobacco industry has had programs in place since the 1960s to obtain “any level of nicotine desired” (Ref. 2). These companies sought to identify the “optimum” dose needed to “satisfy” people who smoke cigarettes and, thereby, assure their continued smoking. *Philip Morris* 449 F.Supp.2d at 309–11. This proposed product standard would seek to set a maximum nicotine level requirement such that cigarettes and certain other combusted tobacco products would no longer be able to create and sustain this addiction among people who smoke cigarettes.

The proposed product standard would limit the addictiveness of the most toxic and widely used products, which would have significant benefits for all age groups. Adults who use tobacco products, most of whom want to quit, are often unsuccessful because of the highly addictive nature of these products (Ref. 13). Researchers estimate that each year, only between 5.4 and 5.6 percent of adults who use cigarettes successfully quit for good (Ref. 14). Similar analysis of 2022 NHIS data indicates that only 8.8 percent of adults who formerly smoked cigarettes had quit smoking cigarettes in the past year (Ref. 4). Lowering nicotine to minimally addictive or nonaddictive levels would improve their ability to successfully quit using the products within the proposed scope of this rule. It also would prevent people who experiment with cigarettes and non-premium cigars, including youth, from moving beyond experimentation, developing an

addiction to nicotine, and progressing to regular use as a result of that addiction. Furthermore, it is well-established that secondhand tobacco smoke causes premature death and disease in children and in adults who do not smoke (Ref. 15 at p.11). It is estimated that exposure to secondhand smoke caused 41,280 deaths per year in the United States from 2005 to 2009 (Ref. 1 at Table 12.4). This increased cessation and reduced initiation, in turn, would result in a significant decrease in harms from the products to people who currently or would otherwise use cigarettes and certain other combusted tobacco products, as well as harms to people who do not use the products, including harms caused by secondhand smoke to both adults and children, harmful perinatal effects due to parental tobacco use, and fires.

Preventing people who do not smoke cigarettes, particularly youth, from regularly smoking cigarettes due to nicotine addiction would allow them to avoid the severe adverse health consequences of smoking and would result in significant public health benefits. Without changes like those proposed here, an estimated 3.66 million youth under the age of 18 who were alive in 2018—and 2.54 million youth who are alive in 2024, accounting for the projected continued decline in smoking prevalence—will die prematurely later in life from a smoking-related disease (Ref. 16). As a result of the proposed product standard, many youth and young adults would not be subjected to the impacts of nicotine addiction from cigarette smoking and certain other combusted tobacco products (which have a significantly stronger effect on youth due, in part, to their developing brains, as described in sections IV.B and IV.C of this document), nor would they suffer from the adverse health effects and mortality that these products cause.

Nicotine is powerfully addictive, and youth and young adults⁹ are particularly susceptible to developing a nicotine addiction. Multiple Surgeon General's Reports on smoking and health have noted that almost 90 percent of adults who regularly smoke cigarettes initiated smoking by age 18, and 98 percent initiated smoking by age 26, which is notable given that 25 is the approximate age at which the brain has

completed development (Refs. 1, 17 to 19). The developing brain is more vulnerable to nicotine dependence than the adult brain is, and the earlier an individual begins smoking the less likely they are to quit (Ref. 20). Generally, those who begin smoking before the age of 18 are not aware of the degree of addictiveness and the full extent of the consequences of smoking (Ref. 21). It is clear that many youth who smoke cigarettes want to quit but have difficulty doing so. An analysis of data from the 2015 Youth Risk Behavior Survey (YRBS) looking at youth cigarette quit attempts found that 45.4 percent of high school students currently smoking cigarettes had sought to quit in the previous year (Ref. 22); 2020 National Youth Tobacco Survey (NYTS) data were congruent, indicating that 68.1 percent of middle and high school students who smoke cigarettes had sought to quit in the previous year (Ref. 23).

More than half (52.2 percent) of U.S. middle and high school students who use cigarettes, cigars, smokeless tobacco—including those with low levels of use—report experiencing at least one symptom of nicotine dependence (Ref. 24). Notably, 12.7 percent of youth using tobacco products 1 to 2 days per month and 21.2 percent of youth using tobacco products 3 to 5 days per month reported sometimes/often/always feeling irritable or restless when not using tobacco products for a while, and 15.6 percent of youth using tobacco products 1 to 2 days per month and 32.0 percent of youth using tobacco products 3 to 5 days per month reported having strong cravings for a tobacco product during the past 30 days (Ref. 24). Additionally, other researchers analyzing data from the 2021 NYTS found that a sizeable proportion of high school students using tobacco products in the past 30 days report symptoms of nicotine dependence, including 27.2 percent reporting a strong craving for tobacco use and 19.5 percent reporting wanting to first use tobacco products within 30 minutes of waking (Refs. 25 and 26). While prevalence rates of youth use of noncombusted tobacco products (e.g., ENDS) in recent years have exceeded those of cigarettes and other combusted tobacco products (Refs. 25 and 26), FDA expects that this proposed product standard would have significant benefits for youth by reducing the risk that youth who experiment with cigarettes and certain other combusted tobacco products, or who may consider using these products as an alternative to noncombusted tobacco products, would

progress to regular use of these products as a result of nicotine dependence.

The adolescent and young adult brain is more vulnerable to developing nicotine dependence than the adult brain is; data indicate that nicotine has stronger rewarding effects in adolescents than in adults (Ref. 17). Adolescents who use tobacco and initiated use at earlier ages were more likely than those initiating at older ages to report symptoms of tobacco dependence, putting them at greater risk for maintaining tobacco product use into adulthood (Ref. 24). Additionally, the earlier that individuals begin smoking—and therefore the greater amount of time that individuals experience nicotine dependence—the less likely they are to successfully quit (Ref. 27). Evidence indicates that exposure to substances such as nicotine can disrupt brain development and have long-term consequences for executive cognitive functioning (such as decreased attention and working memory and increased impulsivity) and for the risk of developing a substance use disorder and various mental health problems (particularly affective disorders such as anxiety and depression) as an adult (Ref. 27). Furthermore, the 2010 Surgeon General's report noted that adolescents report symptoms of dependence even at low levels of cigarette smoking, and thus may be particularly vulnerable to addiction (Ref. 28). FDA expects that this proposed product standard, therefore, would have significant benefits for youth and young adults by reducing the risk that those who experiment with cigarettes and certain other combusted tobacco products would progress to regular use as a result of nicotine dependence.

Research studies involving VLNC cigarettes—defined previously in this document as cigarettes containing up to 1.0 mg of nicotine per gram of total tobacco—demonstrate that setting the maximum nicotine level we are proposing here, would lead to a reduction in nicotine dependence, which would help people who smoke cigarettes quit smoking. In studies that immediately reduced the nicotine content of cigarettes by switching participants from usual brand cigarettes to LNC or VLNC cigarettes, dependence decreased in people who smoked cigarettes who were not interested in quitting compared to those who smoked normal nicotine content (NNC) or usual brand cigarettes for 6 weeks (Ref. 29), 10 weeks (Ref. 30), or 12 weeks (Ref. 31). In smoking cessation studies in which participants endorsed wanting to quit, VLNC cigarettes were also associated

⁹ Though age ranges for youth and young adults vary across studies, in general, "youth" or "adolescent" encompasses those ages 11–17, while those who are ages 18–25 are considered "young adults" (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those ages 26 and older are considered "adults" (Ref. 17).

with reductions in nicotine dependence over time (Refs. 32 to 35).

FDA is issuing this proposal because the tobacco products subject to this proposed product standard remain addictive due to the nicotine yield they offer users and because combusted tobacco products are responsible for the majority of tobacco-related death and disease (see section IV.D of this document for a discussion regarding the serious negative health effects of smoking cigarettes and other combusted tobacco products). Cigarettes have been precisely designed to create and maintain addiction among people who smoke. *United States v. Philip Morris USA, Inc. et al.*, 449 F.Supp.2d 1, 307 (D.D.C. 2006). To protect the public health, particularly youth, FDA is proposing this standard, in part, to ensure that people who smoke these products would be less likely to: (1) initiate regular use; (2) become addicted to these products; and (3) suffer from the many diseases and debilitating effects, including death, caused by combusted tobacco product use.

Similarly, FDA expects that the proposed product standard would have significant benefits for adults who use combusted tobacco products, most of whom want to quit but are often unsuccessful because of the highly addictive nature of these products (Ref. 13). Data from the 2022 National Health Interview Survey (NHIS) and 2018–2019 Tobacco Use Supplement to the Current Population Survey (TUS–CPS) indicate that 67.7 and 76.6 percent, respectively, of adults who smoke cigarettes wanted to quit (Ref. 36), while 2022 NHIS data (Ref. 4) and 2018–2019 TUS–CPS data (Ref. 36) show that 53.3 and 51.3 percent, respectively, of adults who smoke cigarettes in the United States actually made a quit attempt within the past year. However, analyses of NHIS and TUS–CPS data for these years indicate that only 8.8 and 7.5 percent of adults had successfully quit smoking cigarettes, respectively (Refs. 4 and 36). Adults who smoke cigarettes may make 30 or more quit attempts before succeeding (Ref. 37). FDA expects that decreasing the nicotine yield of cigarettes and certain other combusted tobacco products covered by this rule, by reducing nicotine content, so that they are minimally addictive or nonaddictive would likely help people who smoke reduce their dependence on combusted tobacco products, thereby making it easier for them to quit smoking. As discussed throughout this document, FDA also expects that decreasing the nicotine content in these products, and thus the nicotine yield offered to users, would prevent people

who experiment with cigarettes and cigars (mainly youth) from moving beyond experimentation, developing an addiction to nicotine, and progressing to regular use as a result of that addiction.

Although many factors contribute to an individual's initial experimentation with tobacco products, the addictive nature of tobacco is the key reason people progress to regular use, and scientists agree that it is the presence of nicotine that causes addiction and sustains a person's tobacco use (Refs. 1 HHS at p. 113 and 28). While nicotine is the primary addictive chemical in tobacco, sensorimotor stimuli (e.g., smell/taste of smoke; airway sensations; holding the cigarette) repeatedly occur during smoking (Ref. 38). These stimuli often act as secondary or conditioned reinforcers that contribute to the cycle of nicotine dependence by motivating and maintaining smoking behavior (Ref. 38). Once people who use tobacco become addicted to nicotine, they require nicotine to avoid withdrawal symptoms. In the process of obtaining their nicotine, people who use combusted tobacco products are exposed to an array of toxicants in tobacco and tobacco smoke that lead to a substantially increased risk of morbidity and mortality (Ref. 28). Because of their nicotine addiction, many people who smoke cigarettes struggle to stop using these toxic tobacco products despite their stated desire to quit (Ref. 28).

An advisory report from the World Health Organization notes that the ultimate health benefits of a nicotine reduction strategy, like the one FDA is proposing here, would require that the standard cover other combusted tobacco products—not just cigarettes (Ref. 39). In alignment with this recommendation from the World Health Organization, this proposed rule would cover combusted cigarettes and certain other combusted tobacco products (i.e., cigarette tobacco, RYO tobacco, cigars other than premium cigars, pipe tobacco). The World Health Organization report also noted that such a strategy should be accompanied by the provision of cessation treatments to help people quit, including behavioral support and nicotine replacement therapy (NRT) or other medications (Ref. 39). FDA remains committed to facilitating the development and use of therapeutic nicotine products for tobacco product cessation and increased availability of services alongside enhanced outreach efforts to support tobacco use cessation. For example, FDA's Nicotine Steering Committee, which helps to develop and implement nicotine policy and regulation for the

Agency, held a 21 CFR part 15 hearing in early 2018 on the Agency's approach to evaluating the safety and efficacy of NRT products, including how they should be used and labeled (82 FR 56759 (November 30, 2017)). Also, in May 2023, FDA's Center for Drug Evaluation and Research announced the availability of a final guidance for industry entitled "Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products," which provides guidance to assist sponsors in the clinical development of NRT drug products, including but not limited to those intended for smoking cessation and related chronic conditions (88 FR 26559, May 1, 2023; see <https://www.fda.gov/media/167599/download>). Additionally, as described further below, the Agency is contributing to a comprehensive effort coordinated by the U.S. Department of Health and Human Services (HHS or the Department) to support tobacco use cessation.

Rendering cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive through a nicotine product standard would address the principal reason that people who smoke cigarettes have difficulty quitting smoking. If this proposed product standard is finalized, people who use cigarettes and other combusted tobacco products covered by this rule would be unable to obtain enough nicotine from those products to sustain addiction no matter how they smoked the products (e.g., more frequent smoking, intensive puffing) (Refs. 32, 40, and 41), facilitating people who currently smoke cigarettes to make more successful quit attempts.¹⁰ At the same time, combusted tobacco products at minimally addictive or nonaddictive levels of nicotine would remain on the market for those who currently smoke and would like to continue to do so.

FDA expects that, if this proposed rule is finalized and a nicotine product standard for cigarettes and certain other combusted tobacco products is in place, many people who smoke cigarettes will either quit all tobacco-product use or switch to a noncombusted tobacco product. Those who switch completely to use of a noncombusted tobacco product may sustain their nicotine dependence but may significantly

¹⁰ As stated throughout this preamble, in the event that a nicotine product standard addresses only cigarettes, FDA expects that, to maintain their nicotine dependence, some number of people who are addicted to cigarettes would likely migrate to other similar combusted tobacco products (or engage in dual use with such products) after the product standard goes into effect, reducing the benefits of the standard.

reduce their risk of tobacco-related death and disease because switching completely to a noncombusted tobacco product would reduce exposure to the chemical constituents created through combustion, which are the primary contributors of tobacco-related harm (Ref. 8).

The benefits of this rule have been determined without taking into consideration the impact of any smoking cessation services that may be coordinated by HHS, and are expected to be significant. Also, FDA expects that unassisted cessation attempts, *i.e.*, those made by people who smoke without help, may be more successful in an environment in which the product being quit is no longer addictive as compared to historic quitting success rates where it has been easy to relapse to the same highly addictive product. Nevertheless, FDA recognizes that increasing and improving cessation resources, particularly in communities where access to cessation resources have been historically lacking, may provide an opportunity to further increase the expected benefits of this proposed product standard and to enhance the degree to which such benefits are experienced by people in populations that are disproportionately impacted by combusted tobacco use. Accordingly, FDA is contributing to a comprehensive effort being coordinated by HHS to support and accelerate cessation of combusted tobacco products.¹¹ With input from subject matter experts from across HHS Operating Divisions, the Department has finalized the “HHS Framework To Support and Accelerate Smoking Cessation” (Framework). The Framework aims to accelerate smoking cessation and reduce smoking-related disparities by building on current activities and collaborations across the Department. The Framework vision is to ensure that every person in America has access to comprehensive, evidence-based cessation treatment and can benefit from HHS cessation supports, programs, and policies. Specific Framework goals are to: (1) reduce smoking and cessation-related disparities; (2) increase awareness and knowledge related to smoking and cessation; (3) strengthen, expand, and sustain cessation services and supports; (4) increase access to and coverage of comprehensive, evidence-based cessation treatment; (5) advance, expand, and sustain surveillance and

strengthen performance measurement and evaluation; and (6) promote ongoing and innovative research to support and accelerate smoking cessation (<https://www.hhs.gov/about/news/2024/03/08/hhs-announces-new-smoking-cessation-framework-support-quitting.html>). With increased availability and accessibility of services, more people who smoke may be motivated to take advantage of cessation resources, whether they smoke cigarettes or other combusted tobacco products. Additionally, FDA has numerous processes and tools at its disposal to communicate directly with consumers, including communities that are underserved by cessation services and/or are disproportionately impacted by tobacco use, and will continue to evaluate the need for additional public outreach, including targeted education initiatives, in support of this proposed rule. However, the Agency does not have evidence to suggest that such an effort is necessary at this time in order to experience the public health benefits of this proposed product standard.

For the reasons stated here and throughout this document, FDA is proposing this tobacco product standard to: (1) reduce the risk of progression to regular use and nicotine dependence for those who experiment with such tobacco products, especially youth and (2) make it easier for people who are addicted to cigarettes and certain other combusted tobacco products and who are interested in quitting to quit by reducing the nicotine in these products to minimally addictive or nonaddictive levels. FDA expects that this proposed product standard would significantly reduce the morbidity and mortality caused by smoking. Based on FDA’s population health model, by the year 2100, in the United States, approximately 48 million youth and young adults who would have otherwise initiated smoking would not start as a result of the proposed product standard. The model also projects that more than 12.9 million additional people who smoke cigarettes would quit smoking (including those who switch to noncombusted tobacco products) 1 year after implementation of the proposed product standard, increasing to 19.5 million additional people who formerly smoked cigarettes within 5 years of implementation. Section XII discusses that the main quantified benefits come from averted mortality and morbidity, as a result of tobacco use transitions, including switching. In terms of mortality benefits, the model considers a higher risk for people who switch to noncombusted products compared to those who quit tobacco product use

entirely. Specifically, the model assumes that the risk for people who switch to noncombusted product use is 8 percent higher than the risk for those who quit tobacco use entirely. Details of this approach can be found in the FDA’s modeling document (Ref. 42). In addition, the model estimates that, by the year 2060, in the United States, this proposed product standard would result in 1.8 million tobacco-related deaths averted, rising to 4.3 million deaths averted by the end of the century (Ref. 42). The reduction in premature deaths attributable to the proposed product standard would result in 19.6 million life years gained by 2060 and 76.4 million life years gained by 2100 (see section VIII.A of this document for further discussion of the model) (Ref. 42).

B. Relevant Regulatory History

In its implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) since its passage in 2009, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to nicotine in cigarettes and other combusted tobacco products. FDA issued an ANPRM to solicit data and information for consideration in developing a tobacco product standard to regulate nicotine yield by setting the maximum nicotine level for cigarettes, conducted a robust scientific assessment related to a nicotine product standard for combusted tobacco products, developed a population health model to assess the potential public health impacts of such a product standard, and sponsored research on a variety of nicotine-related topics through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH).¹² FDA has considered the comments and information received in response to the ANPRM, scientific assessment, and population health model in developing this proposed rule. Please see the remainder of this section for further discussion.

1. ANPRM

In July 2017, FDA announced a comprehensive approach to tobacco and nicotine regulation to protect youth and reduce tobacco-related disease and death (Ref. 43). As part of the public dialogue on the comprehensive approach, in March 2018, FDA issued three ANPRMs related to the regulation

¹¹ See, for *e.g.*, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-and-nih-joint-public-meeting-advancing-smoking-cessation-priorities-registration-open?utm_campaign=ctp-research&utm_content=landingpage&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

¹² Information on specific projects supported by FDA is available at <https://www.fda.gov/tobacco-products/tobacco-science-research/research>.

of nicotine in combusted cigarettes (83 FR 11818), flavors (including menthol) in tobacco products (83 FR 12294, March 21, 2018) (Flavors ANPRM), and premium cigars (83 FR 12901, March 26, 2018). In addition, FDA announced the availability of a draft concept paper entitled “Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard,” and sought public comment (83 FR 11754, March 16, 2018). This paper analyzes the potential for illicit trade markets to develop in response to a tobacco product standard (Ref. 44).

The Nicotine ANPRM requested data and information for consideration in developing a tobacco product standard to set a maximum nicotine level for cigarettes to make them minimally addictive or nonaddictive. Specifically, FDA sought comments, evidence, and other information regarding whether a potential tobacco product standard should cover tobacco products other than cigarettes (*e.g.*, cigarette tobacco, RYO tobacco, some or all cigars, pipe tobacco, waterpipe tobacco); what maximum level of nicotine would be appropriate for the protection of the public health, in light of scientific evidence about the addictive properties of nicotine in cigarettes; whether such a standard should propose either a single target (*i.e.*, an immediate reduction, where the nicotine is reduced all at once) or a stepped-down approach (*i.e.*, a gradual reduction, where the nicotine is reduced gradually over time) to reach the desired maximum nicotine level; whether such a product standard should specify a method for manufacturers to use to detect the level of nicotine in their products; the technical feasibility of current as well as more recent, novel nicotine reduction techniques; and the proper timeframe for implementation of a possible nicotine tobacco product standard to allow adequate time for industry to comply. The Nicotine ANPRM also requested comment on possible negative effects that could diminish the population health benefits expected as a result of a nicotine product standard, such as continued combusted tobacco product use, where people who currently use tobacco products subject to a nicotine tobacco product standard could turn to other combusted tobacco products to maintain their nicotine dependence, both in combination with cigarettes (*i.e.*, dual use) or in place of cigarettes (*i.e.*, switching); the potential for increased harm due to continued VLNC cigarette smoking with altered smoking behaviors (*e.g.*, increase in number of cigarettes smoked, increased depth of inhalation);

people seeking to add nicotine in liquid or other form to their combusted tobacco product; and whether illicit trade could occur as a result of a nicotine product standard and how that could impact public health. Finally, FDA also sought comments, data, research results, and other information regarding economic impacts of a potential nicotine tobacco product standard.

FDA received over 7,700 comments on the Nicotine ANPRM, with approximately 6,700 of those comments submitted as part of 20 different organized campaigns. The key ANPRM areas of comments are covered in the relevant sections in this document and include the possible scope of products covered by the rule (section IX.C), technical achievability (section VII.E), illicit trade (section IX.D), and implementation/effective date (section XI). Some of the issues raised in the comments to the ANPRM are highlighted below.

Comments generally in support of setting a maximum nicotine level in cigarettes stated that a nicotine product standard would be appropriate for the protection of the public health. In particular, many comments argued that reducing the nicotine content in cigarettes to minimally addictive or nonaddictive levels would be appropriate for the following reasons: (1) reduced nicotine content in cigarettes will contribute to smoking cessation, as well as decreased initiation and addiction by people newly using cigarettes and certain other combusted tobacco products and youth and (2) such increased cessation and decreased initiation will reduce the instances of preventable deaths and other negative health effects caused by smoking. Some comments also urged FDA to issue a nicotine product standard as part of a comprehensive package of tobacco regulatory measures, including increasing consumer access to reduced risk products, regulating flavors in tobacco products, taking action as soon as possible, fully reviewing premarket applications for new tobacco products, and making effective smoking cessation treatments and ongoing cessation support accessible and affordable to people who smoke cigarettes.

FDA received many comments expressing concern about the effect of nicotine on the adolescent brain and its role in addicting those who experiment with tobacco products, particularly youth and young adults, leading them to progress to regular use. Some comments recommended extending the scope of a nicotine product standard to noncombusted tobacco products (*e.g.*,

smokeless, ENDS) to prevent migration to such products, particularly among youth; a significant number of comments urged FDA to extend the scope of a nicotine product standard to combusted tobacco products other than cigarettes. Citing national survey data trends and various recent studies, numerous comments—including those from public health associations, government agencies, and advocacy groups—asserted that including all combusted tobacco products, not only cigarettes, would prevent potential youth initiation of, migration to, and dual use with other combusted products with higher nicotine content that may be harmful to health, thus aligning with the public health goals of a nicotine product standard. Additionally, citing studies relating to tobacco use patterns by young people, a joint submission from several nicotine and tobacco researchers stated that adolescents who use tobacco are particularly prone to dual and multiple tobacco product use; therefore, the potential for adolescents to shift to other nicotine-containing tobacco products underscores the need for a nicotine reduction policy to cover all combusted tobacco products. The joint submission comment further stated that if the scope of a nicotine product standard only covered combusted cigarettes, there is evidence from adult studies that cigars—and in particular little cigars—would be an attractive substitute for full nicotine content combusted cigarettes. These researchers noted, if the scope of a proposed nicotine product standard included combusted cigarettes and other combusted products, it would increase the likelihood that people who use combusted cigarettes, including youth and young adults, who migrate to other nicotine-containing products (rather than quit), would transition to noncombusted products, thereby increasing the health benefits of the policy.

FDA also received comments from individuals, advocacy groups, and members of the tobacco industry generally opposing efforts to reduce nicotine levels in cigarettes to minimally addictive or nonaddictive levels. These comments generally stated that such a regulation would stifle free enterprise or would negatively limit consumer freedom of choice and that the regulation would result in a *de facto* ban on cigarettes that would have a devastating impact on tobacco farming, as well as the manufacturing, distribution, and retail sectors. Some comments discussed the technical feasibility of achieving lower nicotine

levels. Some comments opposed to a nicotine product standard stated that there is not enough scientific research to support reducing nicotine in cigarettes. Other comments argued that FDA should instead focus on giving adults who smoke cigarettes access to a wider choice of less harmful tobacco products and truthful information about the benefits of switching to those products, as well as focus resources on a plan to reduce harm through proven strategies to prevent initiation and encourage cessation.

FDA has reviewed and closely considered the comments to the Nicotine ANPRM, as well as additional evidence and information not available at the time of the Nicotine ANPRM, in developing this proposed rule.

2. Scientific Review

As the body of evidence has continued to grow, FDA undertook a robust systematic review of the scientific evidence regarding the likely effects of reducing nicotine in combusted tobacco products. This review, entitled “The Science of a Nicotine Standard for Combusted Tobacco Products” (Ref. 45), covers peer-reviewed, publicly available literature and focuses on the likely effects of reducing nicotine in combusted tobacco products. This scientific assessment has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 46), FDA revised the scientific assessment, and the final peer-reviewed document is available in the docket for this proposed rule (Ref. 45). Additionally, this final peer-reviewed document and other related documents such as FDA’s response to the peer review comments can be found at <https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews>.

FDA’s peer reviewed scientific assessment examined the effects of reducing the level of nicotine in combusted tobacco products on use behavior, dependence, and toxicant exposure, as well as the knowledge, beliefs, and perceptions around nicotine and VLNC cigarettes. This scientific review found that the totality of the evidence supports that extended exposure to combusted cigarettes containing VLNC tobacco filler is associated with reduced addiction potential, dependence levels, and number of cigarettes smoked per day, and increased quit attempts among people who currently smoke cigarettes, without evidence of increased toxicant exposure, craving, withdrawal, or

compensatory smoking. The review also determined that if FDA were to establish a nicotine product standard that covered only cigarettes, a portion of people who are currently addicted to cigarettes would likely migrate to other, similar combusted tobacco products to maintain their nicotine dependence (or engage in dual use without substantially reducing their combusted tobacco product use), thereby reducing the positive public health impact of such a rule. Based on FDA’s review of the literature on combusted tobacco products, including cigarettes, cigarette tobacco, RYO tobacco, cigars, and pipe tobacco, the final scientific assessment concluded that use of any of these combusted products is sufficient to create or sustain nicotine dependence and would therefore continue to expose people who use these products to toxicants. Further, FDA’s scientific assessment concluded that the establishment of a maximum nicotine level in combusted tobacco products that would render them minimally addictive or nonaddictive could increase the likelihood of successful quit attempts and help prevent people who experiment with cigarettes and cigars (mainly youth) from progressing to regular use, thereby significantly reducing the morbidity and mortality caused by smoking. FDA has considered the scientific assessment conclusions in the development of this proposed product standard.

In addition, to assess the potential public health impacts of a nicotine product standard, FDA developed a population health model using inputs derived from available empirical evidence and expert opinion to estimate the impact of changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States. Details of this modeling approach have been previously published in two peer-reviewed publications (Refs. 47 and 48), which describe the overall model in terms of the inputs, transition behaviors, and outputs that it contains, along with results from simulation studies. In preparation for this proposed product standard, FDA updated a previously-published model (Ref. 47), which describes the impact of a potential product standard that limits the level of nicotine in cigarettes, RYO tobacco, non-premium cigars, and pipe tobacco so that they are minimally addictive or nonaddictive. In this updated modeling document, entitled “Methodological Approach to Modeling the Potential Impact of a Nicotine Product Standard

on Tobacco Use, Morbidity, and Mortality in the U.S.” (Ref. 42), we estimated the potential impacts of a nicotine product standard by modeling a baseline scenario of use of cigarettes and noncombusted tobacco products including smokeless tobacco, e-cigarettes, and HTPs. These product classes (cigarettes and noncombusted products) were selected because of the magnitude of population health effects from cigarette smoking and the likelihood of product switching to noncombusted products, especially e-cigarettes. Estimates of changes in mortality from other exposures including non-premium cigar and pipe tobacco use are not produced directly by the model but are derived from model outputs instead. We then compared the baseline scenario to a product standard scenario characterized by the introduction of a potential nicotine product standard that would apply to cigarettes, cigarette tobacco, RYO tobacco, non-premium cigars, and pipe tobacco. FDA’s modeling framework and methodological approach and the associated data inputs and assumptions have been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 49), FDA revised the modeling document, and the final modeling document is available in the docket for this proposed product standard (Ref. 42). FDA’s modeling work informed the development of this proposed product standard. Additionally, the modeling document, model code, and inputs are publicly available at <https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews>. Further discussion of FDA’s estimates of the public health impact of this proposed product standard can be found in section VIII of this document.

3. Premium Cigars

On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA’s rule deeming tobacco products to be subject to FDA’s tobacco product authorities “insofar as it applies to premium cigars.”¹³ *Cigar*

¹³ For purposes of its ruling, the court specified that a premium cigar is a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.*, whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (*i.e.*, no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco,

Continued

Ass'n of Am. v. FDA, No. 16–cv–01460, 2023 WL 5094869 (D.D.C. Aug. 9, 2023), *appeal docketed*, No. 23–5220 (D.C. Cir. argued Sept. 13, 2024). The government has appealed this decision. When the deemed status of premium cigars is resolved, FDA will consider any impacts with respect to this proposed rule and take additional steps as warranted, including for example, by reopening the comment period and/or issuing a supplemental notice of proposed rulemaking. References to premium cigars in this document serve merely to clarify the current proposed scope of products covered, evaluate the scientific evidence related to non-premium cigars, and describe FDA's approach to modeling the projected public health impacts of this proposed standard.

C. Legal Authority

1. Product Standard Authority

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 901 of the FD&C Act (21 U.S.C. 387a) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco to protect the public health and to reduce tobacco use by youth. The Tobacco Control Act also gave the Agency authority to conduct rulemaking to “deem” any other tobacco products subject to chapter IX of the FD&C Act (21 U.S.C. 387 to 387t). In 2016, FDA issued a final rule deeming products meeting the statutory definition of “tobacco product” (including cigars and pipe tobacco), except accessories of the newly deemed products, to be subject to chapter IX of the FD&C Act, as amended by the Tobacco Control Act (81 FR 28974) (deeming final rule).

Among the tobacco product authorities provided to FDA is the authority to adopt tobacco product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(3)(A) of the FD&C Act). To establish a tobacco product standard, section 907(a)(3)(A) and (B) of the FD&C Act requires that FDA find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits to the population as a whole, including users

water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.

and nonusers of tobacco products, of the proposed standard;

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

2. Authority To Establish a Maximum Nicotine Level and Related Provisions

Section 907 of the FD&C Act authorizes FDA to adopt tobacco product standards that are appropriate for the protection of the public health, including expressly authorizing FDA to adopt product standards with provisions for nicotine yields; for the reduction or elimination of other constituents (including smoke constituents) or harmful components; and respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of tobacco products (section 907(a)(3), (a)(4)(A)(i) to (iii), and (a)(4)(B)(i)). This includes the authority to issue a new product standard to establish a maximum level of nicotine in tobacco products.

FDA is proposing to limit nicotine yield by setting a maximum nicotine content level for finished cigarettes and certain other finished combusted tobacco products not to exceed 0.70 mg of nicotine per gram of total tobacco. FDA is not seeking to require the reduction of nicotine yields in any tobacco product to zero, which is prohibited under section 907(d)(3) of the FD&C Act. To ensure that tobacco products subject to the product standard comply with the proposed maximum nicotine level, FDA also is including provisions that would require manufacturers to test their products using an analytical test method for conformance with the maximum nicotine level pursuant to section 907(a)(4)(B)(ii) and (iv) of the FD&C Act.

3. Sale and Distribution Restrictions

Section 907(a)(4)(B)(v) of the FD&C Act states that product standards shall, where appropriate for the protection of the public health, include provisions requiring that the sale and distribution of tobacco products be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under section 906(d) of the FD&C Act. Similar to section 907, section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would

be appropriate for the protection of the public health. The finding as to whether a regulation is appropriate for the protection of the public health must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco products, and must take into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products (see section 906(d)(1) of the FD&C Act).

Under these authorities and section 701 of the FD&C Act, which provides FDA with the authority to promulgate regulations for the efficient enforcement of the FD&C Act, FDA is proposing provisions that would restrict the manufacture, sale, and distribution of cigarettes and certain other combusted tobacco products that are not in compliance with this standard. These provisions are not intended to restrict the manufacture of cigarettes intended for export. Consistent with section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)), a tobacco product intended for export shall not be deemed to be in violation of section 907 of the FD&C Act or this product standard, if it meets the criteria enumerated in section 801(e)(1) of the FD&C Act, including not being sold or offered for sale in domestic commerce. These provisions are critical to maintain the purpose of the standard by helping to ensure that the tobacco products conform to the proposed maximum nicotine level when used by consumers.

FDA is also proposing, under these authorities and others described herein regarding testing and recordkeeping, a requirement that the labels of tobacco products covered under this proposed product standard contain a manufacturing code to identify, among other things, the date of manufacture of a production batch, so that FDA can determine whether a product on store shelves is in conformance with the proposed product standard. The proposed manufacturing code would allow manufacturers and FDA to identify the production batch of a particular finished 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 tobacco product investigation and any corrective actions to be taken by a manufacturer as a result

of the investigation. The manufacturing code must also contain an “-NS” designation. The “-NS” designation will enable retailers to readily identify that a finished tobacco product conforms with this standard. Finished tobacco products that do not have this designation do not conform to this standard. The manufacturing code information also would aid FDA in ensuring compliance with this proposed product standard by clearly identifying those products that conform to the standard and linking those products to records that substantiate their conformance.

4. Testing Requirements

This proposal contains provisions regarding testing requirements pursuant to sections 907(a)(4)(A)(iii) and 907(a)(4)(B) of the FD&C Act to help ensure that finished cigarettes and certain other finished combusted tobacco products conform to the requirements of the proposed product standard before they are distributed to consumers.

Section 907(a)(4)(A)(iii) states that product standards shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate, relating to any requirement under section 907(a)(4)(B) of the FD&C Act. Section 907(a)(4)(B)(ii) of the FD&C Act, in turn, provides that a product standard shall, where appropriate for the protection of the public health, include provisions for testing the tobacco product. In addition, section 907(a)(4)(B)(iv) of the FD&C Act provides that, where appropriate for the protection of the public health, a product standard shall include provisions requiring that the results of test(s) required under section 907(a)(4)(B)(ii) show that the product is in conformity with the portions of the standard for which the test(s) were required. FDA is proposing testing requirements because it finds that such requirements are appropriate for the protection of the public health.

Consistent with these statutory provisions, proposed §§ 1160.12, 1160.14, and 1160.16 would establish product testing and sampling plan requirements. Proposed § 1160.12 would require that a manufacturer conduct testing on each batch of finished cigarettes and certain other finished combusted tobacco products to determine whether the products conform to the proposed maximum nicotine level requirement and would also require the manufacturer to document all testing. Proposed § 1160.14 would require manufacturers

to use an analytical test method and to demonstrate that the test method was validated in an analytical test laboratory. Proposed § 1160.16 would require that manufacturers design and implement a sampling plan for finished cigarettes and certain other finished combusted tobacco products to ensure the batch consistently conforms to the proposed maximum nicotine level.

To support these proposed requirements, proposed § 1160.18(b) would require each tobacco product manufacturer to investigate all potential nonconforming tobacco products to determine if the product is nonconforming. For example, if any representative samples from a batch of finished cigarettes or certain other finished combusted tobacco products are determined to be out of conformance or if FDA notifies a tobacco product manufacturer that a finished tobacco product in commercial distribution does not conform to the requirements of this part, the manufacturer must conduct an investigation to determine the extent of the nonconformity and locations to which nonconforming tobacco products have been distributed. This proposed requirement would ensure that any reports of nonconforming products, whether as a result of manufacturer testing or otherwise, are examined and investigated and that appropriate measures are taken to ensure that nonconforming products are not distributed to consumers and to prevent future nonconformity.

5. Recordkeeping

Section 909 of the FD&C Act authorizes FDA to require tobacco product manufacturers to establish and maintain records, make reports, and provide such information as the Agency may by regulation reasonably require to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.

FDA is proposing a requirement that manufacturers maintain certain records, including the results of batch testing and analyses conducted to determine conformance with the proposed product standard, records of sampling plans and sampling procedures, records related to manufacturing controls, and all records related to the analytical test method used to assess finished cigarettes and certain other finished combusted tobacco products for conformance with the proposed maximum nicotine level requirement. FDA is also proposing to require that manufacturers use a manufacturing code, from which the Agency must be able to identify the production batch of finished cigarettes and certain other finished combusted

tobacco products that have been released for distribution. The maintenance of these records for the time period specified in this proposed product standard is necessary to help ensure that such tobacco products are in conformance with the proposed product standard and are not adulterated or misbranded, consistent with the authority provided in section 909 of the FD&C Act. FDA has authority to inspect manufacturers, including access to these records, under, among other authorities, section 704 of the FD&C Act. In addition, the recordkeeping and record access requirements would help FDA with the efficient enforcement of the Act, consistent with the rulemaking authority provided by section 701(a) of the FD&C Act.

IV. Nicotine in Cigarettes and Other Combusted Tobacco Products: Addiction, Initiation, Dependence, Cessation, Relapse, Health Effects, and Consumer Perceptions

Tobacco products are addictive, primarily due to the presence of nicotine, and the magnitude of public health harm caused by tobacco products is inextricably linked to their addictive nature (Ref. 50 at p. xi). Some evidence suggests that nicotine is more addictive than many other addictive substances. For example, one study showed the probability of transitioning from first use to dependence was 68 percent for nicotine, but less than 23 percent for alcohol, cocaine, and cannabis (Ref. 51). While cigarettes are the most widely used tobacco products among adults, other combusted tobacco products that are possible targets of product migration (*i.e.*, alternatives that allow people who smoke cigarettes to maintain their nicotine addiction) or dual use have similar adverse health effects, and also cause nicotine dependence (Refs. 52 and 53). For example, persons who use cigars and pipe tobacco are still subject to the addictive effects of nicotine through nicotine absorption (and to the health impacts of long-term use that may follow from regular use due to addiction) even if they report that they do not inhale (Refs. 54 to 56).

A. Nicotine Is Addictive

The scientific evidence is clear that nicotine is the primary chemical in tobacco products that causes addiction through its psychoactive and reinforcing effects (Ref. 57). Since 1988, the U.S. Surgeon General has determined that there is a causal relationship between smoking and addiction to nicotine (Refs. 1 and 57), and the earlier that individuals begin smoking, the less likely they are to successfully quit (Ref.

27). Upon inhaling smoke from a burning cigarette, nicotine is absorbed into the lungs and rapidly travels to the brain. Once in the brain, nicotine produces its initial effects by binding to nicotinic receptors—the primary targets for nicotine in the brain—and inducing release of the chemical dopamine (Refs. 58 and 59). Dopamine plays a major role in the pleasurable and reinforcing effects of smoking that promote continued use (Refs. 58 and 59). Nicotine addiction occurs as the result of repeated exposure to nicotine, which induces changes in the brain (Refs. 58 to 60). Addiction to nicotine can lead to symptoms of nicotine dependence, which may include tolerance to the effects of nicotine, withdrawal symptoms upon cessation of use, and craving cigarettes (Refs. 1 and 58).

The addiction potential of a nicotine delivery system varies as a function of its total nicotine dosing capability, the speed at which it can deliver nicotine, the rate of absorption, its palatability and sensory characteristics, how easy it is for the person using the product to extract nicotine, and its cost (Ref. 61). The amount of nicotine delivered and the means through which it is delivered can either reduce or enhance a product's potential for abuse and physiological effects (Ref. 28 at p.113). Quicker delivery, higher rate of absorption, and higher resulting concentration of nicotine increase the potential for addiction (Ref. 28 at p.113). A cigarette is an inexpensive and extremely effective nicotine delivery system that maximizes the cigarette's addicting and toxic effects (Ref. 61).

Tobacco use disorder is a psychiatric disorder, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) as being characterized by tolerance to the effects of tobacco products, withdrawal symptoms that are mitigated by the self-administration of nicotine-containing products, and unsuccessful attempts at reducing or quitting the use of nicotine-containing products (Ref. 62). Researchers consider several behaviors indicative of a substance with addictive properties. These behaviors include reinforcement, tolerance, withdrawal, and craving—all of which support the fact that nicotine is the primary addictive constituent in tobacco products. The scientific evidence is clear that nicotine is the primary chemical in tobacco products that causes and maintains addiction.

1. Reinforcement

The reinforcement threshold for nicotine can be defined as the lowest nicotine level that would maintain or increase nicotine self-administration

behavior. Currently, most marketed cigarettes are above that threshold; people who smoke cigarettes develop and maintain their addiction through continued smoking (Refs. 17 and 63). Evidence supports that VLNC cigarettes (see table 1 of this document) are below that threshold, as studies show a reduction in the level of addiction based on dependence scales (Ref. 32) and cigarettes per day (CPD) (Refs. 32, 64, and 65). The maximum nicotine level included in this proposed product standard is based on FDA's analysis of studies regarding the likely effects of reducing nicotine, which demonstrates that extended exposure to VLNC cigarettes, which result in very low nicotine yield that cannot be overcome by use behaviors, is associated with reduced addiction potential, dependence levels, number of cigarettes smoked per day, and increased quit attempts among people who currently smoke cigarettes, without evidence of increased toxicant exposure, craving, withdrawal, or compensatory smoking (Ref. 45).

2. Tolerance

Tolerance is defined as a state in which, after repeated exposure, a substance produces less of an effect than previously (Ref. 66) and increasing amounts are required to achieve the effect observed with the first exposure. Both clinical and preclinical research has shown that nicotine has euphoric effects, produces a "pleasurable buzz," and directly enhances positive affect or indirectly increases the reward value of pleasurable situations (Refs. 67 to 70). With repeated exposure to nicotine, neuroadaptation occurs to some of these positive effects, and symptoms of craving and withdrawal begin during periods of abstinence (Ref. 58). Nicotine addiction results from a combination of positive reinforcement from smoking and avoidance of these withdrawal symptoms (Ref. 58). Evidence of tolerance in people who smoke cigarettes is demonstrated as they tend to progressively increase the number of cigarettes they smoke over a period of several years before plateauing to a relatively constant level of use (Ref. 71).

3. Withdrawal and Craving

Nicotine produces a characteristic withdrawal syndrome manifested by irritability/anger/frustration, anxiety, depressed mood, difficulty concentrating, increased appetite, insomnia, and restlessness (Ref. 72). Symptoms typically emerge within the first 1–2 days following abstinence, peak within the first week, and last 2–4 weeks (Ref. 73). The symptoms and

time course are consistent with most prototypical addictive substances (*e.g.*, alcohol, benzodiazepines, opioids, amphetamines, cocaine, caffeine) (Ref. 74). While some have asserted that people smoke cigarettes as a "tool" or "resource" that provides them with needed "psychological benefits," such as increased mental alertness and anxiety reduction (Ref. 75), this view is not borne out by the scientific evidence. In fact, the claimed "psychological benefits" (*i.e.*, increased mental alertness, anxiety reduction, coping with stress) that have been ascribed to a smoking "habit" are actually symptoms of withdrawal suppression (Ref. 76). Craving or urge is described as a motivation for substance use, which is seen in people who use nicotine (Refs. 77 to 79). Although craving is often characterized as a symptom of nicotine and tobacco withdrawal, it is also a prominent symptom of nicotine dependence (Ref. 72), and it can occur in the absence of other withdrawal symptoms.

4. Nicotine Use Is an Addiction, Not a Habit

A few individual reports have challenged the conclusion that nicotine is the constituent in tobacco products that causes addiction, stating that nicotine only causes habitual behavior (Refs. 67 and 75), and that the craving associated with nicotine is determined by nonpharmacological factors that are disassociated from smoking withdrawal (Ref. 80). However, nicotine has been extensively studied and the evidence overwhelmingly demonstrates that nicotine is an addictive drug and the fundamental reason that individuals continue using tobacco products (Refs. 57 and 28). Since 1988, the U.S. Surgeon General has concluded that nicotine is the substance in tobacco products that causes addiction through its psychoactive effects, reinforcing effects, tolerance, and physical dependence/withdrawal, and that nicotine use is not habitual (Ref. 57). The tobacco industry also has acknowledged that nicotine is addictive (Refs. 81 and 82).

For these reasons, FDA concludes that the addictiveness of nicotine in tobacco products leads to regular use (even when people wish to quit), which is at the root of tobacco-related disease and death from cigarettes and certain other combusted tobacco products.

B. The Developing Brain's Vulnerability to the Effects of Nicotine Leads to Progression to Regular Cigarette Use Among Youth and Young Adults Who Experiment

Youth and young adults are particularly susceptible to developing an addiction to nicotine. Due to the brain's ongoing development during adolescence and young adulthood—until about age 25—it is more vulnerable to nicotine's effects than the adult brain is (Refs. 83 to 85). The 1994, 2012, 2014, and 2020 Surgeon General's Reports on smoking and health note that almost 90 percent of adults who currently and regularly smoke initiated smoking by age 18, and 98 percent initiated smoking by age 26, which is notable given that 25 is the approximate age at which the brain has completed development (Refs. 1, 17 to 19). The developing brain is more vulnerable to developing nicotine dependence than the adult brain is, and the earlier an individual begins smoking the less likely they are to quit (Ref. 20). The maximum nicotine level requirement included in this proposed product standard to regulate nicotine yield would make cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive, limiting the number of youth and young adults who progress from experimentation to regular use and reducing their risk for smoking-related diseases.

There are three primary stages that occur as an individual transitions from never smoking to smoking cigarettes regularly: initiation, experimentation, and regular use. An individual initiates smoking once he or she first tries a cigarette, even one or two puffs (Ref. 17). The vast majority of smoking initiation occurs during adolescence (Ref. 17). Initiation can progress to experimentation, where individuals continue to occasionally try cigarettes, but do not smoke every day, and then to smoking regularly (*i.e.*, smoking daily or on most days) (Ref. 17).

Adolescence is a period of development when individuals who experiment with tobacco products are more susceptible to transitioning to regular use and developing addiction to nicotine. Data from the 2024 NYTS found that 10.1 percent of high school students and 5.4 percent of middle school students reported current use of any tobacco product (Ref. 3). Each day, approximately 1,200 youth (ages 18 and below) try their first cigarette (Ref. 86 at Table A.13A). The transition to regular cigarette use (*i.e.*, smoking on ≥ 20 of the past 30 days) can occur relatively quickly and can be achieved by smoking

as few as 100 cigarettes (Ref. 17). Longitudinal and nationally representative cross-sectional data indicate that an established pattern of cigarette use—including those who “rapidly escalate” to regular use—typically occurs by early adulthood (ages 20–22) (Refs. 87 and 88). The Centers for Disease Control and Prevention (CDC) and other researchers have estimated that 30 percent or more of people who experiment with cigarettes transition to regular cigarette use (Refs. 89 to 92). Researchers applied the 30 percent estimate to the number of adolescents who were at the early experimentation stage in 2000, translating to approximately 2.9 million of these adolescents who have or will become people who regularly smoke cigarettes (Ref. 91). Based on the number of persons under the age of 18 in 2012 in the United States, the U.S. Surgeon General estimated that 17,371,000 of that group would begin smoking cigarettes regularly and 5,557,000 will die from a smoking-related disease (Ref. 1 at Table 12.2.1). These concerning high numbers speak to the extreme vulnerability of youth and young adults to the health harms of tobacco use resulting from addiction to nicotine.

Nicotine addiction is a critical factor in the transition of people who smoke cigarettes from experimentation to regular smoking and in the continuation of smoking for those who want to quit (Ref. 28 at p.113, Ref. 1). Although the majority of adolescents who smoke daily meet the criteria for nicotine dependence, one study found that the most susceptible youth lose autonomy (*i.e.*, independence in their actions) regarding tobacco within 1 or 2 days of first inhaling from a cigarette (Refs. 93 and 94). Another study found that 19.4 percent of adolescents (initially ages 12–13 and followed over 6 years) who smoked weekly were dependent on nicotine (Ref. 95). In a study regarding nicotine dependence among adolescents who recently initiated smoking (9th and 10th grade students), adolescents who smoked cigarettes at the lowest levels (*i.e.*, smoking on only 1 to 3 days of the past 30 days) experienced nicotine dependence symptoms such as loss of control over smoking (42 percent) and irritability after not smoking for a while (23 percent) (Ref. 96). Researchers in a 4-year study of 6th grade students also found that “[e]ach of the nicotine withdrawal symptoms appeared in some subjects *prior* to daily smoking” (Ref. 93) (emphasis added). Ten percent of the study participants showed signs of tobacco dependence within 1 or 2 days

of first inhaling from a cigarette, and half had done so by the time they were smoking seven cigarettes per month (Ref. 93).

Similarly, researchers have found that among the 3.9 million middle and high school students who reported current use of tobacco products (including cigarettes and cigars) in 2012, 2 million of those students—including those who used intermittently (*e.g.*, smoking cigarettes on a monthly basis)—reported at least one symptom of dependence (Ref. 24). Other researchers analyzing data from the 2021 NYTS found that a sizeable proportion of high school students using tobacco products in the past 30 days report symptoms of nicotine dependence, including 27.2 percent reporting a strong craving for tobacco use and 19.5 percent reporting wanting to first use tobacco products within 30 minutes of waking (Ref. 25). Overall, these findings demonstrate that youth and young adults who experiment with cigarettes (and other tobacco products) are particularly vulnerable to the effects of nicotine on progression to regular use and dependence, leading to maintained tobacco product use into adulthood.

C. Youth and Adult Cigarette Smoking Cessation and Relapse

Like adults, many youths who smoke cigarettes want to quit but have difficulty doing so. An analysis of data from the 2015 YRBS looking at youth cigarette quit attempts found that 45.4 percent of high school students currently smoking cigarettes had sought to quit in the previous year (Ref. 22); 2012 NYTS data were congruent, indicating that 51.5 percent of middle and high school students who smoke cigarettes had sought to quit all tobacco use in the previous year (Ref. 22).

For adults who smoke who report quit attempts, few are successful. As of 2019, researchers estimate that only between 5.4 and 5.6 percent of people who smoked cigarettes successfully quit for good, according to data from the NHIS and National Survey on Drug Use and Health (NSDUH), respectively (Ref. 14). According to recent data regarding adult quit attempts, analyses of 2022 NHIS and 2018–2019 TUS–CPS data indicate that 67.7 and 76.6 percent of adults, respectively, who smoke cigarettes were interested in quitting (Refs. 4 and 36), while the 2022 NHIS data and 2018–2019 TUS–CPS data show that only 53.3 and 51.3 percent, respectively, of U.S. adults who smoke actually made a quit attempt within the past year (Refs. 4 and 36). Analyses of 2022 NHIS and 2018–2019 TUS–CPS data indicates that only 8.8 and 7.5 percent of adults who

formerly smoked cigarettes had successfully quit smoking cigarettes, respectively (Ref. 4 and 36). Adults who smoke may make 30 or more quit attempts before succeeding (Ref. 37). Some population groups are less successful than others: for example, adults with education levels at or below the equivalent of a high school diploma have the highest smoking prevalence levels but the lowest quit ratios (*i.e.*, the ratio of persons who have smoked at least 100 cigarettes during their lifetime but do not currently smoke to persons who report smoking at least 100 cigarettes during their lifetime) (Ref. 97). Nicotine addiction and associated withdrawal symptoms make it difficult for people who smoke cigarettes to quit, and quit rates rarely exceed 25 percent (Ref. 98).

Relapse is the principal limiting factor in the transition from smoking to nonsmoking status (Ref. 28). Relapse refers to the point after an attempt to stop smoking when a person's tobacco use again becomes ongoing and persistent (Ref. 28 citing Brandon et al., 1986). Most people who relapse do so soon after their quit attempt (Ref. 28). One study found that 80 to 90 percent of individuals who were smoking at 6 months following a quit attempt had resumed smoking within 2 weeks following their quit attempt (Ref. 99). However, even those who quit smoking for longer periods of time frequently relapse. Long-term studies of individuals trying to quit smoking reveal that 30 to 40 percent of those who quit smoking for 1 year eventually relapsed (Ref. 99). In addition, one study following 840 participants for more than 8 years found that approximately one-half of people who smoke who stopped smoking for 1 year relapsed to regular smoking within the subsequent 7 years (Ref. 100). Researchers have found that a higher frequency of smoking is associated with earlier lapses after cessation (*e.g.*, smoking on the first day of cessation or within the first 2 weeks), which in turn is strongly associated with an increased risk of relapse, and is also associated with more severe withdrawal symptoms and earlier relapse after an attempt to quit smoking (Ref. 28 at p.119). These findings confirm the powerful addictive properties of nicotine in tobacco products, a principal factor limiting the ability to quit for a person who uses combusted tobacco products, and further underscore the public health importance of decreasing the addictiveness of these products by decreasing nicotine yield, particularly for youth and young adults who

experiment with smoking and for people currently smoking and who hope to quit.

D. Smoking Cigarettes and Other Combusted Tobacco Products Causes Serious Negative Health Effects

Nicotine is a powerfully addictive chemical. The effects of nicotine on the central nervous system occur rapidly after absorption (Ref. 57 at p.12). People who use cigarettes and other combusted tobacco products absorb nicotine readily from tobacco smoke through the lungs (Ref. 57 at p. iii), and, from the lungs, nicotine is then rapidly transmitted to the brain (Ref. 57 at p.13). In the case of cigars, nicotine is also absorbed through the mouth. With regular use, nicotine levels accumulate in the body during the day from tobacco product use and the nicotine persists overnight, allowing for continuous exposure throughout the entire 24-hour period (Ref. 57 at p.38). While mild nicotine intoxication can occur among people who are smoking for the first time (Ref. 57 at p. 15–16), tolerance to the effects of nicotine develops rapidly.

Cigarette smoking is responsible for 480,000 premature deaths every year from many diseases, puts a substantial burden on the U.S. healthcare system, and causes massive economic losses to society (Ref. 1 at p. 659–666). In terms of a monetary measure of the impact of cigarette smoking on the public health, in 2018 smoking cost the United States more than \$600 billion, including more than \$240 billion in healthcare spending (Ref. 10), nearly \$185 billion in lost productivity from smoking-related illnesses and health conditions (Ref. 10), nearly \$180 billion in lost productivity from smoking-related premature death (Refs. 1 and 10), and \$7 billion in lost productivity from premature death from secondhand smoke exposure (Refs. 1 and 11). Current evidence shows that, while nicotine itself is not the direct cause of most smoking-related diseases, addiction to the nicotine in tobacco products is the proximate driver of tobacco-related death and disease because it sustains tobacco use even when people who smoke want to quit (which most people who smoke report wanting to do) (Refs. 1, 13, 28, 58, and 61). Inhalation of smoke from cigarettes and other combusted tobacco products exposes people who use the products to over 7,000 chemicals, many known to be hazardous to health and lead to disease (Ref. 28). According to the 2014 Surgeon General's Report, which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of disease and death

in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (Ref. 1). Every year, cigarette smoking is the primary causal factor for 163,700 deaths from cancer, 160,600 deaths from cardiovascular and metabolic diseases, and 131,100 deaths from pulmonary diseases (Ref. 1 at p.659). In the United States, about 87 percent of all lung cancer deaths, 32 percent of coronary heart disease deaths, and 79 percent of all cases of chronic obstructive pulmonary disease (COPD) are attributable to cigarette smoking (Ref. 1). Smoking during pregnancy can result in negative outcomes for a newborn baby, such as low birth weight, lungs that fail to develop properly, birth defects such as cleft lip and/or cleft palate, and Sudden Infant Death Syndrome (Ref. 101). As stated in the 2014 Surgeon General's Report, "[c]igarette smoking has been causally linked to diseases of nearly all organs of the body, to diminished health status, and to harm to the fetus . . . [and] the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products" (Ref. 1 at p.7).

Tobacco and cigarette smoking-related morbidity and mortality also have been experienced differentially across different sociodemographic characteristics, such as race, ethnicity, socioeconomic status, educational attainment, mental health status, and homelessness. Black¹⁴ adults, and in particular Black men, experience the highest rates of incidence and mortality from many tobacco-related cancers, such as lung and bronchus cancer and head and neck cancer, compared to those from other racial and ethnic groups (Refs. 102 to 104). Deaths from other tobacco-related conditions such as heart disease, stroke, and hypertension are higher among Black individuals compared to other racial and ethnic groups regardless of tobacco use status (Refs. 105 to 110). Compared to persons identifying as non-Hispanic White, Hispanic and Black persons smoke fewer cigarettes (Refs. 111 to 113) and are more likely to be people who do not smoke daily (Refs. 111 and 114), yet

¹⁴ Throughout this document, FDA uses both the terms "Black" and "African American." The term "African American" is used to describe or refer to a person of African ancestral origins or who identifies as African American. "Black" is used to broadly describe or refer to a person who identifies with that term. Though these terms may overlap, they are distinct concepts (*e.g.*, a Black person may not identify as African American). As a result, FDA relies on the specific term used by researchers when citing to specific studies. FDA uses the term "Black" when not citing to a specific study.

have greater risk of lung cancer morbidity and mortality (Refs. 1, 115 to 118). Additionally, American Indian/Alaska Native (AI/AN) populations have the highest cigarette use prevalence (Refs. 119 to 121) and are more likely to suffer disproportionate rates of tobacco-related death (Ref. 119). An analysis of 2001–2009 mortality data for people living in the Indian Health Service Contract Health Service Delivery Area counties in the United States indicated that age-adjusted death rates, smoking-attributable fractions, and smoking-attributable mortality for all-cause mortality were statistically significantly higher among AI/AN populations than among White populations for adult men and women aged 35 years and older (Ref. 122). Cigarette smoking caused 21 percent of ischemic heart disease, 15 percent of other heart disease, and 17 percent of stroke deaths in AI/AN men, compared with 15 percent, 10 percent, and 9 percent, respectively, for White men (Ref. 122). Among AI/AN women, smoking caused 18 percent of ischemic heart disease deaths, 13 percent of other heart disease deaths, and 20 percent of stroke deaths, compared with 9 percent, 7 percent, and 10 percent, respectively, among White women (Ref. 122). Some Asian populations, Native Hawaiians, and other Pacific Islander populations also suffer from disproportionate rates of tobacco-related mortality as compared to non-Hispanic White persons (Refs. 115, 117, 123, and 124).

Disparities in tobacco-related morbidity and mortality have also been observed for additional population groups that have higher levels of tobacco use. Those with low household income and/or educational attainment bear a disproportionate burden of myocardial infarction prevalence and coronary heart disease-related mortality (Ref. 125). National Health and Nutrition Examination Survey (NHANES) data from 2007 to 2010 indicate that prevalence of co-occurring obesity and smoking was linearly associated with educational attainment as women with the lowest levels of education had greater likelihood of being obese and smoking than women with the highest levels of education (Ref. 126). Some research also indicates that race/ethnicity status interacts with the effects of higher educational attainment on the likelihood of current smoking. The protective effect of higher education against current smoking was shown to be a stronger effect for White as compared to Black respondents (Ref. 127). Research has also demonstrated that individuals with behavioral health conditions and other medical

comorbidities have higher prevalence of combusted tobacco use compared to those without these conditions (Refs. 128 and 129) and have increased risk of tobacco-related morbidity and mortality (Refs. 120, 130, and 131). Inpatient hospital admission data from 1990 to 2005 from California indicate that approximately half of the deaths in those who had been hospitalized for schizophrenia, bipolar disorder, or major depressive disorder were due to diseases causally linked to tobacco use (Ref. 130) and that the majority of deaths for those hospitalized for opioid-related conditions were related to tobacco and alcohol, not to opioids (Ref. 132). Tobacco-related cancers are a leading cause of death among adults experiencing homelessness (Ref. 133). While cigarette smoking and exposure to cigarette smoke are responsible for significant mortality—480,000 premature deaths annually, as previously stated—this estimate does not include deaths caused by other tobacco products, such as cigars and pipes (Ref. 1 at p. 665).¹⁵ Additionally, for every person who dies from a smoking-related disease in the United States, approximately 30 more people will suffer from at least one smoking-related disease (Ref. 1).

Inhalation of the chemicals produced by combustion results in numerous adverse health outcomes through mechanisms that include DNA damage, inflammation, and oxidative stress (Ref. 28). The three leading causes of smoking-attributable death for people who currently and formerly smoke cigarettes are lung cancer, heart disease, and COPD (Ref. 1 at p. 660). Cigarette smoking results in a chronic inflammatory state in the cardiovascular system that is known to be a powerful predictor of cardiovascular events including heart disease (Ref. 28). For COPD, although studies have shown that the disease can be almost completely prevented with the elimination of smoking (Ref. 63), for those who have already developed the disease, evidence indicates that the related morbidity persists long after cessation of smoking (Ref. 28). In addition, it has been established that more than 85 percent of lung cancers are due to smoking, and lung cancer is the

country's leading cause of cancer death (Refs. 1, 28, 63, and 136).

Cigarettes and other combusted tobacco products also have deadly effects on people who do not smoke because they produce secondhand smoke. It is well-established that secondhand tobacco smoke causes premature death and disease in children and in adults who do not smoke (Ref. 15 at p.11). Secondhand smoke exposure is currently estimated to be responsible for over 41,000 deaths annually in the United States (Ref. 1). For example, an estimated 7,300 lung cancer deaths and nearly 34,000 coronary heart disease deaths annually can be attributed to secondhand smoke (Ref. 1). Additionally, productivity losses due to secondhand smoke-attributable deaths are estimated to cost the United States \$5.6 billion each year (Ref. 1).

Secondhand smoke is particularly harmful to children. For instance, the 2014 Surgeon General's Report estimated that each year, secondhand smoke is associated with 150,000 to 300,000 lower respiratory tract infections in infants and children under 18 months of age, 790,000 doctor's office visits related to ear infections, and 202,000 asthma cases (Refs. 1 and 137). In addition, thirdhand smoke—the chemical residue from combusted tobacco smoke that can become embedded in the environment (*e.g.*, carpet, dust)—results in exposure to harmful constituents such as tobacco specific nitrosamines (Ref. 138). Exposure to thirdhand smoke is especially concerning for young children given their size and behaviors, like crawling on the ground and frequently putting their hands in their mouths.

Additionally, the burden of secondhand smoke exposure is experienced disproportionately among members of some racial and ethnic groups and people with lower household income and educational attainment. Among people who do not smoke, ages 3 and older, findings from 2011 to 2018 NHANES data indicate that non-Hispanic Black respondents and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 (Ref. 139). From 1999 to 2012, the percentage of persons who do not smoke (ages 3 and older) with detectable serum

¹⁵ Regular cigar smoking was responsible for approximately 9,000 premature deaths and more than 140,000 years of potential life lost among adults aged 35 years or older in 2010 (Ref. 134). The 2014 Surgeon General's Report states that the methodology for estimating the current population burden for use of combusted tobacco products other than cigarettes remains under discussion, but the number of added deaths is expected to be in the thousands per year (Refs. 1 and 135).

cotinine¹⁶ levels (defined in the study as levels ≥ 0.05 nanogram per milliliter to indicate secondhand smoke exposure) declined across all racial and ethnic groups (Ref. 141). However, a higher proportion of non-Hispanic Black individuals who do not smoke continued to have detectable serum cotinine levels, compared to Hispanic and non-Hispanic White individuals who do not smoke. For example, in 2017–2018, nearly 50 percent of non-Hispanic Black people who do not smoke had detectable serum cotinine levels, compared with 22 percent of non-Hispanic White and 17 percent of Mexican American people who do not smoke (Ref. 141). Moreover, disparities in trends in detectable serum cotinine levels among people who do not use cigarettes over time have been observed on the basis of race/ethnicity. One analysis of NHANES data and found that from 1999 to 2012 among children ages 3–11, comparable levels of decline were observed among non-Hispanic White (percentage change: 41.2 percent) and Mexican American (percentage change: 39.0 percent) youth, but a lesser decline was observed among non-Hispanic Black youth (percentage change: 19.8 percent) (Ref. 141). A more recent analysis of NHANES data also indicated that, between 2011 and 2018, the percentage of people who do not use cigarettes with detectable serum cotinine levels increased among non-Hispanic Black youth ages 12–19 but remained stagnant among non-Hispanic White youth of the same ages (Ref. 142).

Moreover, there is also some scientific evidence supporting disparities in secondhand smoke exposure by sexual orientation. An analysis of NHANES data from 2003–2010 found that secondhand smoke exposure (defined as a serum cotinine¹⁷ levels ≥ 0.05 nanogram per milliliter) differed by sexual orientation among women 20–59 years of age (Ref. 143). This study found that among women 20–59 years of age, secondhand smoke exposure was higher among non-smoking women who identified as lesbian (56.2 percent) or who reported a lifetime experience with a same-gender partner (47.7 percent) than those women who identified as exclusively heterosexual (33.0 percent; $p < 0.001$) (Ref. 143). However, among men 20–59 years of age, exposure to secondhand smoke did not significantly differ by sexual orientation.

Disparities in the secondhand smoke exposure are found across various environmental settings. These disparities speak to the interrelated influences of individual factors (*e.g.*, age, race and ethnicity, sexual orientation, income) and existing inequities in places where members of communities disproportionately impacted by tobacco-related health disparities are likely to reside, spend time, and work (Refs. 53 and 120). For example, an analysis of NHANES data from 2017–2018 found that 87.8 percent of non-smoking persons 3 years of age and older who lived with someone who smoked inside the home was exposed to secondhand smoke based on serum cotinine values of 0.05–10.00 nanogram per milliliter compared to 21.4 percent of non-smoking persons 3 years of age and older not living with someone who smoked inside the home (Ref. 142). In terms of race and ethnicity, findings drawn from the 2013–2016 NHANES data indicate that compared to non-Hispanic White respondents, non-Hispanic Black respondents had higher odds of secondhand smoke exposure in homes other than their own (Ref. 144). An analysis of NYTS data indicates that non-Hispanic Black and non-Hispanic White students both had higher prevalence of secondhand smoke exposure at home and in vehicles than Hispanic and non-Hispanic other race/ethnicity students (Ref. 145). While secondhand smoke exposure in homes and vehicles declined from 2011 to 2018, secondhand smoke exposure in homes among non-Hispanic Black students did not change (Ref. 145). Additionally, a study using data from Wave 1 (2013–2014) of the Population Assessment of Tobacco and Health (PATH) Study found that the odds of exposure to secondhand smoke at home were higher for Black adults (OR=1.12, 95 percent CI:1.00–1.24; p -value=0.042) than White adults; and higher for those adults who self-identified as being LGBT (OR=1.30, 95 percent CI:1.11–1.52; p -value=0.001) than for heterosexual adults (Ref. 146). Home smoking bans (*i.e.*, when people decide to have their own rules that restrict or ban smoking inside their own home)—can reduce secondhand smoke exposure. For example, a study using data from the 2009–2010 National Adult Tobacco Survey (NATS) found the prevalence of exposure to secondhand smoke varied based on the presence (or absence) of smokefree rules in the home (Ref. 147). This study found that overall, 1.4 percent of people who did not smoke and had a smokefree rule at home were exposed to secondhand

smoke in their homes in the past 7 days, compared with 43.9 percent of people who did not smoke and did not have a smokefree rule at home (Ref. 147). A similar pattern was observed across age groups, race and ethnicity, and levels of educational attainment. For example, a higher percentage of Black and Hispanic people were exposed to secondhand tobacco smoke in homes with and without smokefree rules than White people. Additionally, a study using 1995–2007 TUS–CPS data found that among two parent households, higher levels of parental educational level and annual household income were associated with the higher reporting of a complete home ban as compared to lower levels of parental educational and annual household income (Ref. 148). Such findings emphasize the degree to which certain aspects of disadvantage (such as lower family income, lack of access to single-family housing, or lack of autonomy over the home environment) may compound tobacco-related health disparities.

Individuals who live in multi-unit housing, including apartments, are particularly susceptible to involuntary secondhand smoke exposure in the home, as secondhand smoke can infiltrate throughout a building along various pathways (Refs. 149 to 153). Exposures to secondhand smoke in multi-unit housing are potentially concerning given a study drawing on the 2013–2014 National Adult Tobacco Survey (NATS) found that tobacco use was higher among adults living in multi-unit housing (24.7 percent) than those in single-family housing (18.9 percent) (Ref. 154). This study also found that smoke-free home rules (*i.e.*, home smoking bans) were higher among adults living in single-family housing (86.7 percent) than those in multi-unit housing (80.9 percent) (Ref. 154). However, more than a third (34.4 percent) of multi-unit housing residents with home smoking bans have experienced secondhand smoke incursions (Ref. 154). Recent estimates indicate that approximately 80 million residents in the United States are currently living in some type of multi-unit housing (Ref. 150). Among those living in multi-unit housing with a home smoking ban, an estimated 27.6–28.9 million are exposed to secondhand smoke incursions from neighboring units and/or shared common areas (Ref. 150). Moreover, a 2013 nationally representative study conducted among U.S. adults living in multi-unit housing found that 25.2 percent of non-smoking residents who had no smoking in the home for at least 3 months and who also

¹⁶ Cotinine is an alkaloid found in tobacco leaves and is the main metabolite of nicotine. Measuring cotinine in people's blood is a reliable way to determine exposure to nicotine for both people who smoke and those exposed to environmental tobacco smoke (Ref. 140).

had a child in the home had a recent secondhand smoke incursion into their unit; 99 percent of these residents also reported being bothered by the incursion (Ref. 155). Multi-unit housing secondhand smoke incursions have also been found to be greater among specific populations that are already disproportionately burdened by tobacco-related disease and death, including women, younger adults, and non-Hispanic Black, Hispanic, and lower income populations (Ref. 154).

Workplace secondhand smoke exposure has also been shown to vary across population groups. A study using data from the 2009–2010 NATS show the prevalence of secondhand smoke exposure from employed nonsmoking adults was higher among males, non-Hispanic Black, Hispanic, and AI/AN people compared with White people, and people with low education and low income (Ref. 156). Similarly, data from the 2010 and 2015 NHIS show that exposure to secondhand smoke in the workplace was disproportionately high among non-Hispanic Black respondents, Hispanic respondents, and workers with low education and low income (Ref. 157). Additionally, the study findings indicated that “blue-collar workers” (defined as those who performed manual labor such as manufacturing, mining, sanitation, and construction) experienced higher prevalence of secondhand smoke exposure compared to “white-collar workers” (defined as those who primarily work in an office, with computer and desk setting, and perform professional, managerial, or administrative work) (Ref. 157).

The disparities observed in tobacco use, as well as disparities in secondhand smoke exposure, contribute to the disparities in tobacco-related morbidity and mortality experienced by some population groups. This proposed product standard is anticipated to reduce smoking-related morbidity and mortality for the population as a whole, including these populations that use tobacco or are exposed to secondhand smoke at disproportionately high levels.

Other combusted tobacco products, particularly those that could serve as alternatives to cigarettes if people who smoke cigarettes no longer had access to normal nicotine cigarettes (NNC), cause similar negative health effects. For example, cigar smoke contains many of the same harmful constituents as cigarette smoke, and cigar smoke may have even higher levels of several harmful compounds compared to cigarette smoke (Refs. 1, 134 and 158). For example, cigar smoke contains higher amounts of carcinogenic, tobacco-specific N-nitrosamines than

cigarette smoke due to the relatively high concentration of nitrate in cigar tobacco, which leads to formation of cancer-causing nitrosamines during the fermentation process (Refs. 1; 53 at Chapter 3; and 158). Researchers have found urinary concentrations of 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) (a hazardous tobacco-specific nitrosamine) measured in people who smoke cigars daily to be as high as those measured in people who smoke cigarettes daily (Refs. 159 and 160). Like exposure to cigarette smoke, exposure to higher levels of cigar smoke for longer time periods increases the adverse health risks caused by cigar smoking (Ref. 28).

Consequently, there is a long-standing body of research, including reports from the U.S. Surgeon General and National Cancer Institute (NCI), demonstrating that cigar use causes serious adverse health effects (Ref. 53 at p.119–155; Refs. 55; 161, and 162). NCI’s Smoking and Tobacco Control Monograph No. 9 (“Cigars: Health Effects and Trends”), which provides a comprehensive, peer-reviewed analysis of the trends in cigar smoking and potential public health consequences, as well as other research, demonstrates that cigar smoking leads to an increased risk of oral, laryngeal, esophageal, pharyngeal, and lung cancers, as well as coronary heart disease and aortic aneurysm, with the magnitude of risk a function of the amount smoked and depth of inhalation (Ref. 53 at p.119–155). Likewise, a systematic review of the mortality risks associated with cigar smoking that identified 22 studies found that people who regularly smoke cigars are at increased risk for many of the same diseases as people who smoke cigarettes, including oral, laryngeal, esophageal, and lung cancer; cardiovascular diseases; and COPD (Ref. 163).

Research indicates that most people who smoke cigars do inhale some amount of smoke, even when they do not intend to inhale, and are not aware of doing so (Refs. 54 and 55). Even when people who smoke cigars do not breathe smoke into their lungs, they are still subject to the addictive effects of nicotine through nicotine absorption (Refs. 55 and 56). This nicotine absorption occurs because cigar smoke dissolves in saliva, allowing the person smoking the cigar to absorb sufficient nicotine by holding the smoke in their mouths, even if the smoke is not inhaled (Refs. 53, 56, and 164). Cigar and/or pipe smoking causes cancers of the lung and upper aerodigestive tract, including the oral cavity, oropharynx, hypopharynx, larynx and esophagus

(Ref. 158). Additional evidence suggests that cigar and/or pipe smoking is causally associated with cancers of the pancreas, stomach, and bladder (Ref. 165). People who smoke cigars also have increased risks for coronary heart disease and COPD compared with people who never used tobacco (Ref. 166).

One study using NATS data from 2009 to 2010 found that regular cigar smoking (defined as use on at least 15 of the past 30 days) was responsible for approximately 9,000 premature deaths and more than 140,000 years of potential life lost among adults aged 35 years or older in 2010 (Ref. 134). A study of healthcare expenditures from 2000 to 2015 found that cigar-attributable healthcare expenditures for adults totaled \$1.75 billion per year, with \$284 million attributed to exclusive cigar smoking and \$1.5 billion attributed to poly tobacco use (*i.e.*, use of multiple tobacco products) involving cigar smoking plus cigarette or smokeless tobacco use (Ref. 167). In addition, overall mortality rates for all people who smoked cigars (*i.e.*, those who report inhaling as well as those who report not inhaling cigar smoke) are higher than rates for those who have never smoked, although they are generally lower than the rates observed for people who smoke cigarettes (Ref. 53 at p. 112). In an analysis of National Longitudinal Mortality Study (NLMS) data, researchers also found that the risk of dying from tobacco-related cancers is higher for people who currently exclusively use pipe tobacco and those who currently exclusively smoke cigars than for those who reported never using combusted tobacco products (Ref. 168). Another similar analysis using the restricted-use National Health Interview Survey-Linked Mortality Files (NHIS–LMF), following participants for mortality from 2000 through 2015, observed that people who currently smoked cigars daily had elevated risk of all-cause mortality compared to those who had never used tobacco (Ref. 169). In addition, researchers studying people who smoke cigars in 2009 and 2010 found that the average person who smokes cigars or pipes loses approximately 15 life years (Ref. 134).

Disparities in cigar-related health outcomes have also been observed by gender and race/ethnicity. Likely due to the greater prevalence of cigar use among men versus women, one analysis observed a significantly greater number of years of potential life lost for men than women (117,440 for men; 22,284 for women) associated with cigar use, as well as disparate monetary losses associated with cigar use (\$19.5 billion

for men; \$3.4 billion for women) based on the value of a statistical life year (Ref. 134). Studies have shown that levels of nicotine and other carcinogens in cigars can be higher than those in cigarettes and may be at levels that lead to increased risk of morbidity and mortality from conditions such as cancer, cardiovascular disease, and COPD (Refs. 134, 163, and 164). The prevalence of cigar smoking among AI/AN populations is lower than prevalence among Black populations, but higher than among Hispanic and Asian populations (Refs. 120 and 121), contributing to the disproportionate prevalence of lung cancer and cardiovascular diseases in these populations (Refs. 170 and 171).

E. Tobacco Product Marketing Has Contributed to Disparities in Use and Health Outcomes

Tobacco companies have long understood the complexities of nicotine addiction (Ref. 172) and have capitalized on the psychological and sociological aspects of tobacco use to market their products disproportionately to specific populations, such as youth and young adults, some racial and ethnic populations, individuals who identify as lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+),¹⁷ those with lower household income and educational attainment, and individuals with behavioral health conditions (Refs. 173 and 174). For example, retail advertising for tobacco products is more common in neighborhoods with greater proportions of Black residents and in lower income neighborhoods (Refs. 175 to 179). Storefront and outdoor tobacco marketing, as well as point-of-sale marketing, are all disproportionately present in Black, Hispanic/Latino, AI/AN, and low-income communities (Refs. 175, 179, 180 to 187). Higher exposure to tobacco advertisements and retailing is associated with tobacco use susceptibility and tobacco use among youth, with observed disparities impacting youth who are Black, Hispanic, or lower socioeconomic status (Refs. 188 to 192). For example, a systematic review of 35 studies found that a higher density of tobacco retailers near the home is associated with

increased combustible tobacco product use among youth (Ref. 193).

Industry marketing tactics have also included the incorporation of culture-specific imagery, traditional practices, and events that target specific racial and ethnic groups. For instance, tobacco companies have sponsored cultural events such as Cinco de Mayo celebrations, Chinese New Year celebrations, and activities related to Black History Month (Refs. 173 and 194) and have used the cultural significance of traditional tobacco to validate the authenticity of commercially available cigarettes, exploiting the traditions of Native people to encourage cigarette use (Ref. 195). Tobacco industry documents show that tobacco companies have strategically marketed their products to women with lower income, particularly Black and Hispanic women, (Ref. 196), people experiencing homelessness and people with mental illness (Refs. 197 and 198), and the LGBTQI+ community (Refs. 199 to 201). Research also demonstrates that since at least the 1960s, the tobacco industry has made strategic donations to organizations representing and affiliated with these communities (Refs. 120, 202 to 205). Internal industry documents reveal that at least one tobacco company considered such donations to be a “quid pro quo,” because they could result in the normalization of tobacco use, development of brand loyalty, and opposition to health-protective tobacco control policies (Ref. 206).

The industry’s practices have resulted in long-term consequences for communities. Tobacco marketing influences social norms around tobacco use, making it more socially acceptable and increasing the likelihood of use (Refs. 207 to 209). In communities where the tobacco industry has disproportionately marketed to historically marginalized populations over decades, these social norms are transferred through peers and family generations, perpetuating the use of harmful combusted tobacco products, and contributing to present-day tobacco-related health disparities in these populations (Refs. 207, 210, and 211). Moreover, recent scientific evidence indicates that tobacco companies continue to target populations that experience tobacco-related health disparities with tobacco marketing (Refs. 178, 180, 191, 207, 212 to 226).

Although targeted marketing is only one factor in the development and perpetuation of combusted tobacco product use and related harms, it contributes to disparities that affect public health and are of great concern to FDA. Advancing health equity is a

policy priority and an important component of fulfilling FDA’s mission to protect and promote public health. FDA and the Federal Government recognize the advancement of health equity as “both a moral imperative and pragmatic policy,” as Executive Order 13995 states. Considerations related to health equity helped inform FDA’s decision to prioritize this proposed product standard.

F. Consumer Knowledge, Attitudes, Beliefs, and Perceptions About Nicotine

The science on consumer knowledge, attitudes, beliefs, and perceptions about nicotine demonstrates that a majority of consumers correctly understand that nicotine is the substance in cigarettes that causes addiction. Nationally representative studies that examined nicotine addiction beliefs in the general population reported that the belief that nicotine is addictive was endorsed by approximately 85.8 percent of the population, and the belief that nicotine is responsible for driving continued cigarette use was endorsed by approximately 82.9 percent of the population (Refs. 227 to 233). A nationally representative survey found that 88 percent of people who currently smoke cigarettes and 91 percent of people who use e-cigarettes agreed that nicotine makes people want to smoke (Ref. 227). A nationally representative study of youth suggests that about 77.1 percent of respondents believe that nicotine definitely or probably causes addiction (Ref. 234).

However, in contrast to high rates of correct beliefs about the addictiveness of nicotine, there are high rates of incorrect beliefs about the harms of nicotine. Studies that examined nicotine harm beliefs in the general population reported that the belief that nicotine causes cancer was endorsed by 40 to 78 percent of adult participants (Refs. 227, 228, 232, 233, 235 to 245). Additionally, a nationally representative study of youth suggests that about 74.7 percent believe that nicotine definitely or probably causes cancer (Ref. 234). Multiple nationally representative studies that examined nicotine harm perceptions by tobacco use status found that 52 to 61 percent of people who currently use cigarettes and up to 84 percent of people who do not use cigarettes endorsed the belief that nicotine itself causes cancer or that nicotine is the major contributing constituent in cigarettes that causes cancer (Refs. 228, 241, and 245). A more recent qualitative study of people who currently use little cigars and cigarillos suggests that the misperception that nicotine has significant adverse health

¹⁷ Throughout this document, FDA uses the term “LGBTQI+” broadly when referring to lesbian, gay, bisexual, transgender, queer, and intersex communities. When we describe findings from the published literature, we refer specifically to the groups that are studied. For example, some authors examine tobacco-related outcomes for members who identify as lesbian, gay, bisexual, or transgender only; as such, the data are limited to those who identify as LGBT, and authors interpret the findings for those specific groups.

effects is also common among people who use these products (Refs. 228, 241, 245, and 246). Although nicotine creates and sustains addiction and therefore is the driver of the death and disease associated with smoking, it is the repeated exposure to toxicants from tobacco products that directly causes most of the serious health effects among those who use tobacco products, including fatal lung diseases, such as COPD, and cancer (Ref. 28).

Consumer misperceptions regarding the harms associated with nicotine may lead to inaccurate judgments about the risks of using products that contain nicotine, including NRT. For example, individuals who hold a misperception about nicotine may be less likely to use NRT as a smoking cessation aid. Furthermore, there is evidence that misperceptions of nicotine harm vary by gender, ethnicity, and age, and may contribute to unequal health outcomes (Ref. 233). FDA recognizes the importance of addressing nicotine misperceptions in the context of a proposed product standard that limits the level of nicotine in cigarettes and certain other combusted tobacco products in order to make those products minimally addictive or nonaddictive. FDA will continue to conduct research and develop communication tools (e.g., consumer outreach, public education initiatives, engagement with interested parties) to ensure that consumers are informed of the risks of using tobacco products that contain nicotine, including the products covered under this proposed product standard.

V. History and Perceptions of VLNC Cigarettes

A. History of LNC and VLNC Cigarettes

Tobacco companies had the technical expertise to manipulate the nicotine content in tobacco as early as the 1920s and then began to market products that may have met very low nicotine content (VLNC)¹⁸ cigarette levels throughout the late 1970s and early 1980s (Ref. 247). As discussed above, the term “VLNC cigarettes” generally refers to combusted cigarettes that have been reported to contain ≤ 1.0 mg nicotine per gram of total tobacco. For a detailed discussion of the scientific evidence that supports the technical achievability of this proposed product standard, see section VII.E of this document. In this

section, we describe some of the industry’s early and continuing efforts to develop VLNC cigarettes.

Some of the earliest VLNC cigarettes studied by academic researchers were produced by Philip Morris and marketed under the brand name “Next,” which was reported to contain 0.4 mg nicotine per gram of total tobacco (Ref. 248). Later, the National Institute on Drug Abuse (NIDA) contracted with the Ultratech/Lifetech Corporation¹⁹ to produce VLNC cigarettes for research purposes only (Refs. 249 and 250). The two types of cigarettes produced were: (1) 8.0–10.3 mg nicotine per gram of total tobacco and (2) 0.6–0.7 mg nicotine per gram of total tobacco (Ref. 250).

Commercially available Quest cigarettes were produced and marketed by Vector Tobacco in the early 2000s and utilized genetically engineered tobacco to create cigarettes with three distinct nicotine content levels (i.e., Quest 1 (12.7 mg/g), Quest 2 (7.3 mg/g), Quest 3 (0.9 mg/g)) (table 1). These cigarettes were used in much of the VLNC research conducted prior to the development of SPECTRUM Nicotine Research Cigarettes; they are no longer on the market. Philip Morris also manufactured cigarettes with varying nicotine levels for research only (Ref. 251). In a public statement issued on July, 2018, 22nd Century Group, Inc. stated that they were already using genetic engineering and plant breeding to produce VLNC tobacco for cigarettes (Ref. 252). In 2014, the company was granted patents for its process to dramatically reduce the nicotine in tobacco plants (Ref. 253). This tobacco has been used to generate low nicotine content research cigarettes, produced and distributed by RTI International, under a contract with the NIDA Drug Supply Program (Ref. 254). 22nd Century Group, Inc. acts as a vendor for RTI for this contract, manufacturing SPECTRUM Nicotine Research Cigarettes that were reported to contain 0.4 mg nicotine per gram of tobacco (Ref. 254), and they also manufacture cigarettes with other reduced levels of nicotine. These SPECTRUM Nicotine Research Cigarettes are similar in many sensory characteristics to NNC cigarettes, but with VLNC (Refs. 255 and 256).

In 2019, 22nd Century Group, Inc. received FDA marketing authorization and, in 2021, received exposure modification orders for their VLNC cigarettes under the names VLN King and VLN Menthol King. VLN cigarettes

are currently being marketed and sold to consumers in select U.S. markets as cigarettes with 95 percent less nicotine than conventional cigarettes. From January 1, 2023, to November 22, 2024, 22nd Century VLN cigarette dollar sales accounted for less than 0.001 percent of total cigarette dollar sales in any 4-week period. Menthol flavored 22nd Century VLN cigarettes over the same time accounted for less than 0.001 percent of any 4-week menthol flavored cigarette dollar sales.²⁰

Currently, these are the only authorized VLNC cigarettes. As we discuss in other parts of this document (see section VII.E), we believe the scientific evidence supports the technical achievability of the proposed standard; additionally, the tobacco industry and consumer product companies have developed a range of brands with differing nicotine levels. Thus, it appears there would be opportunities for any manufacturer who chooses to enter the market for products covered by this proposed product standard.

Although many of the studies discussed in this section investigated the effects of VLNC cigarettes, some studies also investigated the effects of cigarettes with higher levels of nicotine, often as comparators. Table 1 displays the reduced nicotine content cigarettes that were administered in studies summarized in this document and their reported nicotine levels. The nicotine content values in table 1 are approximate, and they are primarily based on published reports from the peer-reviewed scientific literature. Most studies that investigated the clinical effects of reduced nicotine content cigarettes did not chemically analyze the study cigarettes. For example, many studies that examined the effects of VLNC SPECTRUM Nicotine Research Cigarettes did not chemically characterize these cigarettes, but the authors of these studies reported that the nicotine content of the cigarettes was 0.4 mg nicotine per gram of

²⁰ FDA’s own analyses, calculations and conclusions informed in part by the NielsenIQ Retail Measurement Service (RMS) data through NielsenIQ’s RMS for the tobacco product category “Cigarettes” for the time period January 1, 2023 through November 2, 2024 for Total US Expanded All Outlets Combined (xAOC) and convenience stores are those of FDA and do not reflect the views of NielsenIQ. NielsenIQ is not responsible for, had no role in, and was not involved in analyzing and preparing the results reported herein, or in developing, reviewing, or confirming the research approaches used in connection with this report. NielsenIQ RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <https://NielsenIQ.com/global/en/> for more information.

¹⁸ As previously noted in footnote 7, the term VLNC should not be confused with the cigarette brand name “VLN.” “VLN” refers to cigarette products authorized for marketing by FDA in 2019. See <https://www.fda.gov/media/133633/download?attachment> and <https://www.fda.gov/media/133635/download?attachment>.

¹⁹ Both Ultratech and Lifetech have been reported as being the company through which NIDA manufactured research cigarettes.

tobacco. The actual nicotine content of these cigarettes is expected to vary around this value. For example, the results of one study that chemically characterized SPECTRUM Nicotine Research Cigarettes showed that the nicotine content of the sampled VLNC cigarettes ranged between 0.28 and 0.33 mg nicotine per gram (Ref. 256), which

is lower than the 0.4 mg nicotine per gram level typically reported in the literature. In 22nd Century Group, Inc.'s modified risk tobacco product applications, the company reported that after 9 years of sampling by the company, the average nicotine content of its genetically engineered VLNC tobacco is 0.6 mg nicotine per gram of

total tobacco, with a range of 0.4 to 0.7 mg nicotine per gram of total tobacco. It is likely that the Quest and SPECTRUM Nicotine Research Cigarettes, used throughout the scientific literature, also contained between 0.4 to 0.7 mg nicotine per gram of total tobacco (Ref. 257).

TABLE 1—NICOTINE CONTENT FOR NORMAL, LOW, AND VERY LOW NICOTINE CONTENT CIGARETTES USED IN THE RESEARCH STUDIES CITED IN THIS DOCUMENT

Brand	Manufacturer	Nicotine content category	Nicotine content (mg/g)
Magic ¹	22nd Century Group, Inc	VLNC	* 1.0
Next ²	Philip Morris International	VLNC	* 0.4
Philip Morris 1 mg ³	Philip Morris Tobacco Company	VLNC	* 0.7–0.9
Philip Morris 2 mg ³	Philip Morris Tobacco Company	LNC	* 2.1–2.4
Philip Morris 4 mg ³	Philip Morris Tobacco Company	LNC	* 5.0–5.6
Philip Morris 8 mg ³	Philip Morris Tobacco Company	LNC	* 9.3–10.6
Philip Morris 12 mg ³	Philip Morris Tobacco Company	NNC	* 14.4–14.7
Quest 1	Vector Group Ltd	NNC	* 12.7
Quest 2	Vector Group Ltd	LNC	* 7.3
Quest 3	Vector Group Ltd	VLNC	* 0.9
SPECTRUM 0.4 mg (NRC102–NRC105) ⁴	22nd Century Group, Inc	VLNC	0.4–0.7
SPECTRUM 1.3 mg (NRC200, NRC201) ⁵	22nd Century Group, Inc	LNC	0.9–1.3
SPECTRUM 2.4 mg (NRC300, NRC301) ⁵	22nd Century Group, Inc	LNC	1.9–2.4
SPECTRUM 5.2 mg (NRC400, NRC401) ⁵	22nd Century Group, Inc	LNC	4.6–5.2
SPECTRUM 15.8 mg (NRC600, NRC601) ⁵	22nd Century Group, Inc	NNC	15.5–17.3
Ultratech/Lifetech denicotinized ⁶	Ultratech Inc./Lifetech Corp	VLNC	* 0.6–0.7
Ultratech/Lifetech nicotine ⁶	Ultratech Inc./Lifetech Corp	LNC	* 8.0–10.3
Xodus ⁷	22nd Century Ltd., LLC	LNC	* 1.2–1.7

Abbreviations: VLNC: ≤1.0 mg nicotine per gram of total tobacco; LNC: >1.0 mg and <11.4 mg nicotine per gram of total tobacco; NNC: ≥11.4 mg nicotine per gram of total tobacco.

¹ Nicotine content from (Ref. 31).

² Nicotine content from (Ref. 248).

³ Nicotine content from (Refs. 258 and 259).

⁴ Nicotine content from (Ref. 257).

⁵ Nicotine content from (Ref. 29) (supplement).

⁶ Nicotine content estimated by FDA based on nicotine yield data from (Ref. 250).

⁷ Nicotine content from (Ref. 41).

* For these cigarettes, FDA calculated milligrams of nicotine per gram of total tobacco based on reports of milligrams of nicotine per cigarette. Calculations were based on an estimate of 0.7 grams of tobacco per cigarette.

B. Consumer Knowledge, Attitudes, Beliefs, and Perceptions Regarding VLNC Cigarettes and FDA Regulation of Levels of Nicotine in Tobacco

In this section we describe the science related to consumer knowledge, attitudes, and beliefs about reduced nicotine content (RNC)²¹ cigarettes and consumers' perceptions about a hypothetical policy reducing nicotine levels in cigarettes and certain combustible tobacco products. These concepts are important because they are

²¹ RNC cigarettes in this context refers to any cigarette with a lower amount of nicotine than NNC cigarettes. FDA notes that studies focusing on consumer perceptions of RNC cigarettes typically do not differentiate between RNC, LNC, and VLNC cigarettes. However, when describing studies that focus on consumer behavior and perceptions of VLNC cigarettes specifically, FDA uses the term VLNC cigarettes. FDA notes that studies in this domain typically use consumer perceptions of RNC cigarettes to form conclusions about consumer perceptions about VLNC cigarettes and FDA's proposed reduction of nicotine more broadly.

associated with the behavioral responses consumers believe they would take if such a policy is in effect.

The science on consumer knowledge, attitudes, beliefs, and perceptions about RNC cigarettes demonstrates that a majority of consumers perceive that RNC cigarettes are equally or more harmful than NNC cigarettes. Nationally representative studies suggest that 50 to 71 percent of consumers perceive RNC cigarettes to be as or more harmful to health than NNC cigarettes, while 25 to 35 percent perceive them to be less harmful than NNC cigarettes (Refs. 260 to 262). Recent nationally representative findings estimate that between 12 and 25 percent of people who smoke or use e-cigarettes believe RNC cigarettes are less harmful than NNC cigarettes (Refs. 227 and 236). In studies where participants actually use VLNC cigarettes, they tend to perceive them as significantly less harmful to health and

less likely to cause cancer than NNC cigarettes (Refs. 230, 263 to 265). Furthermore, there is evidence that perceptions about the harms of VLNC cigarettes relative to NNC cigarettes vary by race and age (Refs. 236, 266 to 268). The science on consumer knowledge, attitudes, beliefs, and perceptions about RNC cigarettes also demonstrates that there are widespread misperceptions about the addictiveness of RNC cigarettes relative to NNC cigarettes. Studies that use nationally representative surveys report that 60 to 77 percent of consumers incorrectly believe that RNC cigarettes are equally or more addictive than NNC cigarettes (Refs. 260 and 261). Tobacco use status does not appear to significantly change misperceptions about the addictiveness of RNC cigarettes (Ref. 228).

A 2019 nationally representative study of consumer support for a policy "requiring cigarette makers to lower the

nicotine levels in cigarettes so that they are less addictive” reported that 81 percent of study participants favored the policy (52.4 percent strongly favored, 28.6 somewhat favored) and 19 percent opposed the policy (10.3 percent somewhat opposed, 8.7 percent strongly opposed) (Ref. 269). However, consumer misperceptions about the harm and addictiveness of reduced nicotine content combustible tobacco products impact understanding of the purpose of a reduced nicotine product standard. For example, respondents in some studies did not understand why FDA would choose to remove nicotine from cigarettes or little cigars and cigarillos but not remove other chemicals that are harmful (Ref. 229, 270, and 271). Respondents also stated that they believed other chemicals besides nicotine make cigarettes addictive, and that removing nicotine from cigarettes would not eliminate their addictiveness (Refs. 229 and 270). Misperceptions may also serve as potential determinants of consumer responses to a reduced nicotine product standard. For example, one study suggests that misperceptions among people who smoke regarding the harm of RNC cigarettes is correlated with quit intentions in responses to a hypothetical government policy reducing most of the nicotine in cigarettes (Ref. 267). FDA recognizes the importance of addressing consumers’ misperceptions about the relative harm and addictiveness of VLNC cigarettes as compared to other products. FDA will continue to conduct research (e.g., assess changes over time in knowledge, attitudes, and perceptions relative to tobacco product characteristics including nicotine content) to inform regulatory decisions and other actions.

VI. Rationale for Products Covered by the Proposed Product Standard

FDA has reviewed and closely considered the comments to the Nicotine ANPRM, as well as additional evidence and information not available at the time of the ANPRM, in developing the scope of products for this proposed product standard. Specifically, we considered several factors, such as the strength and breadth of the available data on the likely effects of reducing nicotine derived from studies of VLNC cigarettes; current prevalence and initiation rates for different classes of tobacco products; the available data on product toxicity, addictiveness, and appeal; product use topography²² (including quantity,

intensity, and duration of use); and the potential for migration to different products. These data indicate that reduction of nicotine in cigarettes would reduce addiction potential, dependence levels, number of cigarettes smoked per day, and increase quit attempts among people who currently smoke cigarettes. In light of these data, FDA also expects that reduction of nicotine would prevent people who experiment with cigarettes and cigars from developing an addiction to tobacco and progressing to regular tobacco use.

This proposed product standard is intended to address one of our nation’s greatest public health challenges: the death and disease caused by combusted tobacco use. Approximately 480,000 people die every year from smoking cigarettes (Ref. 1 at p. 659) and another 9,000 die from smoking cigars (Ref. 1 at p. 659; Ref. 134). Cigarettes are the tobacco product category that causes the greatest amount of harm to the public health as a result of the prevalence of cigarette use among adults and cigarette toxicity and addictiveness. This proposed product standard is expected to increase cessation and switching to potentially less harmful tobacco products and prevent people who are experimenting with use—mainly youth and young adults—from transitioning to regular use of cigarettes. However, if the product standard were only to cover cigarettes, it would likely be less effective. Specifically, a significant number of people who are addicted to smoking cigarettes would likely migrate to similar combusted tobacco products after the standard went into effect to maintain their nicotine exposure, thereby undermining the significant health benefits of the proposed product standard (Ref. 5) (see also section VI.B of this document for further discussion of the potential for non-cigarette combusted tobacco product switching). Therefore, to increase public health benefits, FDA also is proposing to cover certain other combusted tobacco products in addition to cigarettes.

Based on these considerations, FDA is proposing to cover the following products under this product standard:

- Cigarettes (other than noncombusted cigarettes, such as HTPs that meet the definition of a cigarette),
- Cigarette tobacco,
- RYO tobacco,
- Cigars (including little cigars, cigarillos, and large cigars but excluding premium cigars), and

- Pipe tobacco (other than waterpipe tobacco).

FDA has determined that research regarding the public health impacts of potential maximum nicotine level policies applies across the tobacco products covered under this proposed product standard. As discussed in greater detail in section VII.B.12 of this document, given that cigarette tobacco, RYO tobacco, and pipe tobacco can be effectively used in cigarettes, the VLNC cigarette research discussed in this proposed rule applies to these products, and any expected benefits that would accrue as a result of instituting the proposed product standard for cigarettes would also be expected to accrue for these product categories. FDA also concludes that the VLNC cigarette research applies to cigars, given the similarities between cigarettes and most cigars (e.g., use topography). For further discussion of FDA’s findings that VLNC cigarette research applies to other covered products under this proposed product standard, see section VII.B.12 of this document. In addition, as discussed in section VI.A.3 of this document, FDA finds that the non-cigarette combusted products within the proposed scope of this rule (i.e., RYO tobacco, cigars, pipe tobacco) could function as acceptable substitutes for many people who smoke cigarettes while exposing them to similar risks and toxicity as cigarettes.

As discussed in section VIII of this document, FDA finds that the proposed product standard, with this scope, is appropriate for the protection of the public health and would provide substantial benefits for people who currently use cigarettes and certain other combusted tobacco products and for people who experiment with cigarettes and cigars and people who do not use such tobacco products. FDA seeks comments on this proposed scope, particularly on how it may affect youth initiation and use of combusted tobacco products.

A. Prevalence and Abuse Potential of Cigarettes and Other Combusted Tobacco Products

Cigarettes, the most frequently used tobacco products, are the tobacco product category that causes the greatest burden of harm to public health given that approximately 28 million adults and 380,000 youth currently smoke cigarettes (Ref. 3); the toxicity and addictiveness of these products; and the resulting tobacco-related disease and death across the population, including among people who do not smoke. Cigarettes are highly addictive and harmful tobacco products; however, the other combusted tobacco products

²² Smoking topography measures provide data on various aspects of smoking behavior, including number of puffs per cigarette, total time spent

smoking, puff volume (i.e., puff size), puff velocity (i.e., puff intensity), puff duration, and inter-puff interval (i.e., length of time between puffs).

covered in this proposed product standard are similarly addictive and harmful. If the proposed product standard covered only cigarettes, some number of people who smoke cigarettes and are addicted to nicotine would likely migrate to similar combusted tobacco products to maintain their nicotine exposure (or engage in dual use with other similar combusted tobacco products), thus reducing the positive public health impact of this proposed product standard.

Regulating the nicotine yield of cigarettes and certain other combusted tobacco products through setting a maximum nicotine level for them would make these dangerous combusted products minimally addictive or nonaddictive, making cessation easier and helping to prevent people who are experimenting with smoking from developing nicotine dependence and progressing to regular use. As stated elsewhere in this document, FDA's approach in proposing this product standard for cigarettes and certain other combusted tobacco products protects public health by reducing combusted tobacco product use (and therefore reducing exposure to harmful toxicants created through combustion) by making it considerably easier for people who want to quit cigarette use to quit all tobacco products or switch to potentially less harmful, noncombusted tobacco products which remain available. Therefore, to increase the public health benefits, FDA is focusing this proposed rule on nicotine levels in cigarettes and certain other combusted tobacco products because combusted products are responsible for the majority of death and disease due to tobacco use.

1. Cigarettes

Data from the 2024 NYTS indicate that 1.7 percent of high school students (approximately 250,000) and 1.1 percent of middle school students (approximately 120,000) reported current use of cigarettes (*i.e.*, smoked at least once during the past 30 days) (Ref. 3). In addition, 11.6 percent of adults reported that they currently smoked cigarettes in 2022 (*i.e.*, smoked at least 100 cigarettes during their lifetime and now smoke cigarettes every day or some days); this means an estimated 28.8 million adults in the United States currently smoke cigarettes (Ref. 4). Although cigarette smoking is present in all population groups in the United States, the prevalence of cigarette use differs based on sociodemographic characteristics.

Findings from the 2024 NYTS show that, among middle and high school students, 1.4 percent of non-Hispanic

White students, 0.9 percent of non-Hispanic Black students, and 1.6 percent of Hispanic students currently smoked cigarettes (Ref. 3). Additionally, data from the 2022 NHIS show differences in smoking prevalence on the basis of race/ethnicity among adults (age 18 and over). Specifically, 4.6 percent of non-Hispanic Asian, 8.0 percent of Hispanic, 12.7 percent of non-Hispanic White, 14.2 percent of non-Hispanic Black, 19.3 percent of non-Hispanic AI/AN, and 11.9 percent of non-Hispanic Other participants reported current cigarette smoking (Ref. 272). Data from the 2005 and 2015 NHIS also indicate that the prevalence of cigarette smoking has statistically significantly declined over this time period for non-Hispanic white, Black, Asian, and AI/AN adults and Hispanic adults (Ref. 273).

Data from an analysis of the 2005 and 2015 NHIS indicate that the prevalence of smoking has declined significantly over that time period among both adult male and female participants (29.9 and 25.2 percent relative decrease, respectively) (Ref. 273). Currently, according to data from the 2022 NHIS, smoking remains more prevalent among males (13.2 percent) as compared to females (10.0 percent) in the United States (Ref. 272).

Study findings indicate that individuals who identify as lesbian, gay, or bisexual are more likely to report smoking cigarettes as compared to those who identify as heterosexual (Refs. 274 to 277). Among adults in the 2022 NHIS, cigarette smoking among persons identifying as lesbian, gay, and bisexual was 12.8 percent and among those identifying as heterosexual/straight it was 11.6 percent (Ref. 272), and smoking was more prevalent among youth identifying as lesbian, gay, and bisexual (7.0 percent) in the 2020 NYTS than among those "not sure" of their sexual identity (3.5 percent) or youth identifying as heterosexual (2.7 percent) (Ref. 275). Current tobacco use for lesbian, gay, bisexual, and transgender youth in the 2022 NYTS was reported for "any" tobacco use (*i.e.*, current use of one or more of the following: e-cigarettes, cigarettes, cigars, smokeless tobacco, hookah, HTPs, nicotine pouches, pipe tobacco, or bidis), but not for individual tobacco products (Ref. 278). Pooled data from the 2015 to 2019 NSDUH indicate that compared to heterosexual/straight respondents, respondents who identified as gay males, lesbian/gay females, or bisexual females reported higher prevalence of past 30-day smoking (Ref. 279). Additionally, in data from the 2015/2016 NSDUH, relative to same-age

heterosexual men, lifetime rates of daily cigarette smoking were significantly elevated among gay men ages 18–25 (30 percent versus 23 percent) and ages 35–49 years (44 percent versus 38 percent) (Ref. 277). Similarly, relative to same-age heterosexual women, lifetime daily cigarette smoking was significantly greater among lesbian/gay women ages 18–25 (37.7 percent versus 16.3 percent), ages 26–34 (42.2 percent versus 30.3 percent), and ages 35–49 (42.7 percent versus 32.6 percent) (Ref. 277).

As evidenced in a systematic review and meta-analysis (Ref. 280), studies have consistently shown a relationship between socioeconomic status and the prevalence of cigarette smoking, such that greater levels of educational attainment and greater total family income are inversely associated with the prevalence of smoking. Specifically, in 2021 NHIS data, the prevalence of cigarette smoking was 18.3 percent for adults with a low income, 12.3 percent for those with a medium income, and 6.7 percent for those with a high income (Ref. 274). Similarly, by and large, there is an inverse relationship between educational attainment and the prevalence of smoking. For instance, according to the 2021 NHIS, the prevalence of smoking was 20.1 percent among adults with some high school education but no degree, 30.7 percent among persons with a general equivalency degree, 17.1 percent among those with a high school diploma, 13.7 percent among persons with an associate's degree, 5.3 percent among those with an undergraduate degree, and 3.2 percent among persons who had received a graduate degree (Ref. 274).

The prevalence of cigarette smoking is also higher among adults with mental health symptoms or substance use disorder (Refs. 281 to 284). Findings from the 2022 NHIS show that 27.2 percent of persons reporting severe generalized anxiety disorder (GAD) currently smoke cigarettes, as compared with 10.1 percent who report no or minimal GAD (Ref. 272). Similarly, 27.1 percent of adults who report severe depression currently smoke cigarettes, versus 10.1 percent among those who report no or minimal depression (Ref. 281). Additionally, findings from the 2021 NHIS show that 28.1 percent of persons reporting serious psychological distress also reported smoking cigarettes, compared to 10.9 percent of persons not reporting serious psychological distress (Ref. 274). Analyses of data from the 2015 NSDUH for individuals aged 12 years and over also show that cigarette smoking is significantly more prevalent among

persons who use cannabis (daily cannabis use: 54.6 percent; nondaily cannabis use: 40.2 percent) as compared to those who do not use cannabis (15.1 percent) (Ref. 282). An analysis of 2016 NSDUH data indicates that cigarette smoking is more than twice as prevalent among persons with alcohol use disorder, as compared to those without (37.8 percent versus 16.3 percent) (Ref. 283), while data from the 2014 NSDUH show that the prevalence of cigarette smoking is also more than twice as high among persons with mental health and/or substance use problems than among persons without (38.5 percent versus 15.4 percent) (Ref. 284).

2. Cigars

Cigar smoke contains many of the same constituents as cigarette smoke, including nicotine, many of which can cause significant harm to those who use cigars (Ref. 53). According to the 2024 NYTS, 330,000 middle and high school students,²³ including 1.5 percent (an estimated 230,000) of high school students (grades 9–12) and 0.8 percent (an estimated 80,000) of middle school students (grades 6–8), had smoked a cigar (cigar, cigarillo, or little cigar) on at least 1 day during the past 30 days (Ref. 3). Overall, the prevalence of cigar smoking among middle and high school students is comparable to the prevalence of cigarette smoking, with 1.7 percent (an estimated 250,000) of high school students and 1.1 percent (an estimated 120,000) of middle school students having smoked cigarettes on at least 1 day during the past 30 days (Ref. 3). Cigars are also a popular tobacco product among adults. In the 2022 NHIS, 3.7 percent of adults aged 18 or older reported currently using cigars some or every day, behind cigarettes (11.6 percent) and e-cigarettes (6.0 percent) (Ref. 272).

Evidence from national surveys—including the Monitoring the Future study and NSDUH—indicate that, similar to cigarettes, cigar use has been on the decline among U.S. youth and adults in recent years (Refs. 285 to 287). However, among youth, this decrease has not been equitably experienced. The popularity of cigar use is disproportionately high among groups such as lesbian, gay, and bisexual youth and young adults (3.2 percent among transgender youth, 3.2 percent among sexual minority females, and 3.9 percent

among sexual minority males) (Ref. 288), and youth with disabilities (7.0 percent among those who reported using little cigars and 2.6 percent among those who reported using large cigars) (Ref. 289). Cigar smoking also occurs disproportionately among specific populations of adults as well, with greater prevalence of cigar smoking reported among non-Hispanic Black adults (5.1 percent) (Ref. 274), individuals of lower educational attainment and lower annual household income (Refs. 290 and 291), and LGBTQI+ adults (Refs. 292 to 296).

Additionally, when comparing data from 2011 to 2019, while past month cigarette smoking and cigar use were both statistically significantly lower in young adults (ages 18–25), the absolute and relative declines in cigar use were less than the declines in cigarette use (33.5 percent in 2011 to 17.5 percent in 2019 for cigarettes; 10.9 percent in 2011 to 7.7 percent in 2019 for cigars) (Ref. 286). For adults (ages 26 or older), cigarette use in 2011 was statistically significantly higher compared to in 2019; however, cigar use remained relatively stable and did not significantly change (21.9 percent in 2011 to 18.2 percent in 2019 for cigarettes; 4.2 percent in 2011 to 4.0 percent in 2019 for cigars) (Ref. 286). The 2023 NSDUH found that among adults ages 26 or older in 2019, 1,847 individuals initiated cigar use each day, considerably more than the 282 who initiated cigarette smoking each day in that year (Ref. 86).

While these data indicate a high burden of current cigar smoking, the true prevalence of cigar use is likely higher. Little cigars often closely resemble cigarettes, given their shape, size, filters, and packaging, and are perceived by many as being healthier than cigarettes (Refs. 297 and 298). Several studies have shown that youth tend to underreport cigar smoking if brand name identifiers are not provided (Refs. 299 to 301). For example, in one study of Virginia high school students, the reported prevalence of cigar use nearly doubled after accounting for students who reported smoking Black & Mild (a brand name of cigarillos); in the original survey results, more than half of the students who used Black & Mild cigarillos did not report using cigars, cigarillos, or little cigars (Ref. 299).

Research indicates that most people who smoke cigars unknowingly inhale some amount of smoke, including people who smoke cigars who report that they do not inhale (Refs. 54 and 55). Youth more commonly use cigarillos and little filtered cigars that are designed to be inhaled, which may

increase their risk of poor health outcomes as well as addiction (Refs. 53 and 163). Even if people who smoke cigars do not breathe or inhale smoke into their lungs, they are still subject to nicotine's addictive effects through buccal (oral) absorption of nicotine or nicotine absorption through the lips due to cigar tobacco's alkalinity, as well as other harmful health effects (Refs. 55, 56, 302 and 303). Cigar smoke dissolves in saliva and makes it possible for people who smoke cigars to absorb sufficient amounts of nicotine to create dependence even if the user does not inhale (Ref. 56).

Nicotine can exist in protonated and freebase (unprotonated) forms. In the freebase form, it is most addictive because it is readily absorbed by the buccal mucosa, respiratory tissues, skin, and the gastrointestinal tract (Refs. 28 and 57). Freebase nicotine amounts are generally higher in cigars than cigarettes due to the higher pH of cigar smoke (Ref. 53). Nicotine absorbed across the buccal mucosa, the mouth's membrane lining, can provide sustained amounts of freebase nicotine to the person using the tobacco product (Ref. 53). Cigars can deliver nicotine much like chewing tobacco or oral snuff, with nicotine extraction absorbed directly through the buccal mucosa and lips (Ref. 53).

A 1998 NCI Monograph chapter (NCI Monograph 9) on cigar pharmacology and abuse potential concluded that the nicotine delivery characteristics and daily patterns of smoking among people who smoke cigars indicate that cigars produce dependence (Refs. 53 and 164). Since the publication of NCI Monograph 9, several in-person laboratory studies, where participants use products under observation and have outcome measures assessed, have provided additional evidence to support that nicotine exposure from cigar smoking is sufficient to create or sustain nicotine dependence among people who use cigars. Through cigar smoke, nicotine can be absorbed by inhalation (like cigarettes) or through the buccal mucosa (like smokeless tobacco). Multiple studies found that people who smoke cigars inhale (as evidenced by carbon monoxide (CO) levels and smoking topography) and that plasma nicotine levels are similar to those of people who smoke cigarettes (Refs. 304 to 308). Furthermore, using the Questionnaire of Smoking Urges, a commonly used measure of tobacco craving, several studies found that cigars reduce craving and urge to smoke to a similar magnitude as cigarettes (Refs. 306 to 308). Cigars have also been shown to decrease acute nicotine withdrawal

²³ The weighted population estimate reported in the scientific publication is 500,000 students. As noted in the scientific publication, overall population estimates might not sum to corresponding population estimates because of rounding or inclusion of students who did not self-report sex, race and ethnicity, or grade level.

symptoms (e.g., craving, anxiousness) (Ref. 304).

Several additional studies have used epidemiological data to compare nicotine dependence levels among people who use multiple tobacco products (*i.e.*, poly tobacco use), people who exclusively use cigarettes, and people who exclusively use cigars (Refs. 309 to 311). The data show that a significant proportion of people who exclusively use cigars display characteristics of tobacco dependence such as craving (Ref. 309); however, people who use multiple tobacco products and people who exclusively use cigarettes showed the highest levels of dependence, followed by people who exclusively use cigars (Refs. 309 to 311).

3. Loose Tobacco (Pipe and RYO Tobacco)

Laboratory and survey studies have provided evidence to conclude that RYO and pipe tobacco smoking is sufficient to create or sustain nicotine dependence among people who use RYO or pipe tobacco (Ref. 312). Studies show that people who use RYO and pipe tobacco inhale (as evidenced by smoking topography) (Refs. 312 to 314) and plasma nicotine levels are similar to those of people who smoke factory-made cigarettes (Ref. 313). Furthermore, RYO tobacco reduces craving and urge to smoke at a similar magnitude and is rated similarly with regard to subjective appeal as factory-made cigarettes (Ref. 313). Evidence also suggests that RYO tobacco is at least as harmful to health as factory-made cigarettes (Refs. 315 to 318).

According to data from the 2024 NYTS, 0.5 percent of high school students (or approximately 70,000 students) reported using pipe tobacco within the previous 30 days and 0.5 percent of middle school students (or approximately 50,000 students) reported pipe tobacco use in the prior 30 days (Ref. 3). Data from the 2021 NHIS indicated that 0.9 percent of adults ages 18 and older (or approximately 2.3 million adults) currently used pipes (Ref. 274). However, FDA notes that pipe tobacco prevalence data are likely an underestimate, as the NHIS survey does not include the number of people who use pipe tobacco to roll their own cigarettes.²⁴ There is also evidence that young adults who smoke cigarettes are

engaging in RYO use for financial reasons (Ref. 319). Studies of RYO tobacco use among youth are limited, but prevalence of RYO tobacco use among U.S. middle and high school students in the 2012 NYTS was 3.4 percent (Ref. 320).

The lack of data on RYO and pipe tobacco use and the limitations in how national surveys assess loose tobacco use impact our ability to draw conclusions regarding appeal of loose tobacco among youth and adults at this time. However, if such products were not included within the scope of this proposed product standard, some number of people who smoke cigarettes and/or cigars and are addicted to nicotine would likely easily migrate to such products to maintain their nicotine exposure given that RYO and pipe tobacco have the same addictive properties and health consequences as factory-made cigarettes (Refs. 168 and 321). For example, more people who smoke cigarettes could use RYO or pipe tobacco to make NNC cigarettes (or engage in dual use with certain other combusted tobacco products), reducing the positive public health impact of this proposed product standard (see section VI.B.1 of this document) (Ref. 322).

Taken together, these data demonstrate that if FDA did not include certain other combusted tobacco products within the scope of this proposed product standard, many people who smoke cigarettes likely would migrate to, or increase use of, such other tobacco products in an attempt to replace or supplement the reduction of nicotine in their VLNC cigarettes.

B. Potential for Non-Cigarette Combusted Tobacco Product Switching

Nicotine can be delivered through products that represent a continuum of risk, with combusted tobacco products at the most harmful end of this continuum. FDA's approach in proposing this product standard for cigarettes and certain other combusted tobacco products protects public health by reducing combusted tobacco product use (and therefore reducing exposure to harmful toxicants created through combustion) while potentially less harmful, noncombusted tobacco products remain available for people who have not quit all tobacco products. FDA expects that, if this proposed rule is finalized and a nicotine product standard for cigarettes and certain other combusted tobacco products is in place, many people who smoke cigarettes will either quit smoking or switch to a noncombusted tobacco product. Those who switch completely to use of a

noncombusted tobacco product may sustain their nicotine dependence and may significantly reduce their risk of tobacco-related death and disease to the extent that the products they switch to result in less harm. That is, while dependence on any tobacco product remains a health concern, nicotine alone is not directly responsible for tobacco-related cancer, lung disease, and heart disease (Ref. 323). Switching completely to a noncombusted tobacco product would reduce exposure to the chemical constituents created through combustion, which are the primary contributors of combusted tobacco-related harm (Refs. 28 and 324).

However, as discussed throughout this document, if a nicotine tobacco product standard were to apply to cigarettes only, it likely would have substantially less impact on improving health outcomes for people who use tobacco products. Specifically, FDA expects that, to maintain their nicotine exposure, some people who smoke cigarettes and are addicted to nicotine would likely migrate to other combusted tobacco products (or begin to engage in dual use with such other products) with similar toxicological risks after such a cigarette-only standard was in effect. FDA also would expect that people who use non-cigarette combusted tobacco products would continue their existing use patterns, thereby maintaining their risk of tobacco-related death and disease. To ensure maximum benefits for this nicotine tobacco product standard, FDA is proposing that it apply to cigarettes and certain other combusted tobacco products.

1. Tobacco Product Switching in Behavioral Intention and Clinical Studies

Studies involving people who currently use cigarettes predict a range of tobacco use behaviors in response to a nicotine product standard. When presented with a hypothetical nicotine reduction policy, most people who use cigarettes report that they would continue to smoke VLNC cigarettes or use other combusted tobacco products, or that they would quit; only a small portion report that they would consider switching to a noncombusted tobacco product (Refs. 262 and 264). One experimental study using a nationally representative sample examined the intended behaviors of people who currently smoke cigarettes if a nicotine product standard were put in place; overall, 30.5 percent of the participants intended to quit using all tobacco products, 5.8 percent intended to switch to noncombusted tobacco products, and 61.0 percent indicated they would

²⁴ People who smoke RYO and pipe tobacco are susceptible to similar negative health consequences as people who smoke traditional cigarettes. While there is a paucity of research examining RYO and pipe tobacco use, FDA is not aware of any data indicating that RYO cigarettes or pipe tobacco are associated with fewer adverse health consequences than traditional cigarettes.

smoke VLNC cigarettes or other combusted tobacco products (Ref. 262). An in-depth qualitative study assigned a small number of people who use cigarettes to use VLNC cigarettes for 5 days, then examined their intended behaviors in response to a nicotine product standard (Ref. 264). Most participants reported that if a product standard was put in place, they would use VLNC cigarettes if they were the only cigarettes available, and a few said that they would use VLNC cigarettes to reduce their smoking over time to eventually quit. Some participants discussed the possibility of switching to ENDS or other combusted products if a product standard was put in place. Self-reported intentions to use tobacco products are a useful predictor of individuals' future tobacco use behavior (Refs. 325 and 326) and these two studies support FDA assessments of the likelihood of switching in response to the nicotine product standard.

In clinical studies that investigated the effects of VLNC cigarettes, researchers typically instructed participants assigned to VLNC cigarette groups to use only study-provided cigarettes (*i.e.*, to refrain from using usual brand cigarettes or other tobacco products during experimental conditions). Noncompliance with these instructions during a clinical trial may also indicate the likelihood that people who smoke VLNC cigarettes would use alternative nicotine-containing products if a nicotine product standard is implemented. Several studies reviewed in this document assessed biochemical or self-reported measures of VLNC cigarette noncompliance (*i.e.*, ongoing NNC cigarette or other tobacco product use) and showed high levels of noncompliance with smoking only VLNC cigarettes during the study. Since participants were provided with VLNC cigarettes at no cost and continued to use non-study provided tobacco products (particularly NNC cigarettes), these data suggest that VLNC cigarettes have lower appeal and abuse potential compared to NNC cigarettes (Refs. 327 to 331). These findings suggest that once a nicotine product standard covering solely cigarettes is in place and VLNC cigarettes are the only cigarettes available, people are likely to use alternative nicotine-containing products including other combusted products. However, if cigarettes and certain other combusted products are covered by a product standard, people who use combusted products are likely to use non-combusted products, therefore benefitting public health.

A clinical study conducted to compare the use of alternative nicotine-

containing products (*i.e.*, smokeless tobacco, ENDS, NRT, cigars, cigarillos) and smoking behavior in 136 people who smoked cigarettes and were unwilling to quit randomly assigned participants to one of three conditions and instructed them to use only study-assigned tobacco products for 8 weeks (Ref. 5). The "LNC1" group received LNC cigarettes combined with noncombusted tobacco products (*i.e.*, smokeless tobacco, ENDS, NRT) and combusted non-cigarette tobacco products (*i.e.*, cigars, cigarillos), the "LNC2" group received LNC cigarettes combined with only noncombusted tobacco products, and the NNC cigarette group received NNC cigarettes combined with noncombusted and combusted non-cigarette products. Participants who received LNC cigarettes (both the LNC1 and LNC2 groups) used more alternative combusted tobacco products and more noncombusted tobacco products (the LNC2 group) than participants in the NNC cigarette group. However, these participants also smoked fewer total combusted tobacco products and had more quit attempts than participants in the NNC cigarette group. The findings from this study demonstrate that when people who smoke cigarettes are switched to LNC cigarettes and provided with alternative sources of nicotine, they will readily use the alternative sources of nicotine. Moreover, the LNC cigarette group (the LNC2 group) that had access to noncombusted nicotine sources only (*i.e.*, smokeless tobacco, ENDS, NRT) had statistically significantly lower biomarker levels of certain harmful constituents (N-Nitrosornicotine (NNN) and NNAL) than those who continued to smoke NNC cigarettes and had access to noncombusted and combusted non-cigarette products (the LNC1 group) (Ref. 5). The NNN and NNAL biomarker levels in the LNC1 group with access to both combusted and noncombusted tobacco products resembled the NNC group (Ref. 5).

Taken together, these findings suggest that if the proposed product standard reduces the nicotine level in cigarettes only, but people who smoke cigarettes still have access to other NNC combusted tobacco products, they likely would substitute with the NNC combusted tobacco products. This behavior would negate a significant proportion of the public health impact of the product standard. If other combusted tobacco products also are covered by this proposed product standard, however, data suggest that people who smoke cigarettes would

likely switch from combusted tobacco product use to potentially less harmful tobacco products. For further discussion of switching to a potentially less harmful nicotine delivery product, see section VIII.D.3 of this document.

2. Cigarette Price Increases

Studies investigating the effects of changes in cigarette prices on product substitution may also be used as an indicator of potential product switching in response to the proposed nicotine tobacco product standard, because a reduction in nicotine content could be conceptualized as an increase in the unit price of nicotine, as the cost to consumers is increased per unit of nicotine (Ref. 332). Therefore, studies assessing cigarette taxation may be useful because they are assessing the influence of changes in the unit price of cigarettes, through increases in cost, on behavior among people who use the products. Price increases, including taxation, represent one of the most effective tobacco control policies associated with significant declines in overall tobacco consumption as well as reductions in youth initiation rates (Ref. 333). However, taxation and price increases are also associated with a range of tax avoidance behaviors, such as substitution with a less expensive product, purchasing from low or untaxed sources, or purchasing in bulk (Ref. 334), and this behavior is more likely to occur among people who smoke and are of lower socioeconomic status (Ref. 335). It is this potential substitution that FDA is seeking to mitigate by proposing to cover certain other combusted tobacco products in addition to cigarettes. FDA expects that by reducing the nicotine in cigarettes and certain other combusted tobacco products through this proposed product standard, the effect on people who smoke will be similar to increasing the price, and, as is seen in examples of taxation and price increases, people who smoke would likely turn to alternative sources of nicotine.

An epidemiological study used data from the 2001 and 2002 New Jersey Adult Tobacco Survey (NJATS) to determine whether people who smoke cigarettes switched to cigars following an increase in the state cigarette excise tax (U.S. \$0.80 to U.S. \$1.50 per pack) (Ref. 336). In 2001, the cigarette smoking prevalence in New Jersey was 22.1 percent. Following a large cigarette excise tax increase, the cigarette prevalence decreased to 18 percent (Ref. 336). There were no statistically significant differences in the cigar smoking prevalence between 2001 and 2002; however, ever cigar use increased

statistically significantly for people who currently smoked cigarettes (50.9 percent versus 60.3 percent, respectively) and increased slightly for people who recently quit smoking (48.4 percent versus 56.4 percent, respectively). In 2001, people who currently smoked cigarettes had the highest prevalence of current cigar use (13.9 percent), while people who had recently quit cigarette use had the lowest prevalence (2.6 percent). In contrast, in 2002, while people who currently smoked cigarettes again reported the greatest prevalence of current cigar use (13.2 percent), people who had recently quit cigarette smoking had the second highest prevalence of current cigar use (11.1 percent). The authors concluded that after a cigarette excise tax increase, a small but notable proportion of people who had recently quit cigarette smoking tried cigars, substituted cigars for cigarettes, or continued using combusted tobacco products in the form of cigars (Ref. 336). Additional indirect evidence assessing trends in internet searches following the 2009 U.S. Federal tobacco tax increase showed that after the tax was announced, search queries increased for both combusted and noncombusted non-cigarette tobacco products (Ref. 337).

Similarly, several studies assessed changes in loose tobacco sales following a large tax increase in RYO tobacco and found decreases in RYO tobacco sales and increases in pipe tobacco sales as soon as the tax rate changed (Refs. 322, 338 to 340). Researchers analyzing publicly available Federal excise tax data from 2000 to 2015 found that total RYO tobacco sales statistically significantly decreased by 70.0 percent; however, total pipe tobacco sales increased by 556.4 percent (Ref. 340). Another study found a similar increase in pipe tobacco sales and decrease in RYO tobacco sales in response to tax differences between the products; however, self-reported pipe tobacco use, assessed via the NSDUH, remained consistent, and RYO consumption increased (Ref. 338). The authors suggested that people who smoke cigarettes may have bought loose tobacco labeled as pipe tobacco for use as RYO cigarettes as a tax avoidance strategy. These data suggest that following the implementation of a new tobacco control policy, manufacturers may modify their products and a significant proportion of consumers may modify their behavior to adapt to the changes (e.g., switching to a similar combusted tobacco product if a final nicotine tobacco product standard

covered cigarettes only), which would reduce the rule's potential public health effects. If cigarettes were the only product covered by the proposed product standard, a proportion of people who smoke cigarettes would likely to turn to certain other combusted products, thereby reducing the significant public health impact of this rule. Similarly, people who use certain other combusted products would not be affected by the reduction in nicotine in cigarettes and would also not benefit. Further, if cigarettes were the only product covered by the proposed product standard, the negative health effects of second- and thirdhand smoke from these other combusted products would still affect other non-smoking individuals exposed to these combusted products. However, if these certain other combusted products are covered, then the alternative products for those who switch (instead of quitting) likely would not be combusted, therefore benefitting public health.

3. Behavioral Economics Data

Behavioral economics utilizes principles of psychology and economics to predict purchasing behavior as a function of different market constraints (Ref. 341). Several studies have used real or hypothetical scenarios to investigate the impact of a change in price or availability of a given tobacco product on subsequent purchasing or use of another tobacco product. Purchasing behaviors observed in behavioral economics studies have been shown to be concordant with actual tobacco consumption and real purchase estimates (Refs. 342 to 344).

Studies have used retail sales data to investigate tobacco substitution as a function of price (Refs. 345 to 347). One study investigated relationships between purchasing patterns and price of cigarettes and little cigars. In 2013, a pack of little cigars was approximately 32 to 37 percent less expensive than a pack of cigarettes (Ref. 345). A 10 percent increase in the price of little cigars was associated with a 31.7 percent decrease in per capita little cigar sales, while a 10 percent increase in the price of cigarettes was associated with a 27.3 percent increase in per capita little cigar sales. The authors concluded that people who smoke cigarettes are price sensitive and avoided the higher cost of cigarettes by switching to little cigars. Another study estimated demand for cigarettes, little cigars/cigarillos, large cigars, e-cigarettes, smokeless tobacco, and loose tobacco using Nielsen's Convenience Track retail scanner database (Ref. 347). In this study, a 10 percent increase in the price of

cigarettes resulted in an 18.6 percent increase in e-cigarette demand, showing that e-cigarettes substituted for cigarettes (Ref. 347). Although, in this study, large cigars, smokeless tobacco, and loose smoking tobacco were not associated with increased use in response to increasing cigarette prices, Nielsen retail sales data that were analyzed in another study showed that little cigars, RYO tobacco, and pipe tobacco each serve as substitutes for cigarettes (Ref. 346).

Studies have also used hypothetical purchase tasks to investigate responses by people who smoke cigarettes to potential tobacco policy changes or price increases (Refs. 348 and 349). One study used a simulated tobacco marketplace to measure purchasing behaviors among people who smoke cigarettes (Ref. 349). Participants could purchase cigarettes, e-cigarettes, cigarillos, gum, dip, lozenges, and snus. When cigarette prices increased, e-cigarette purchasing statistically significantly increased (Ref. 349). A study conducted in the Netherlands utilized a similar hypothetical tobacco marketplace to investigate hypothetical purchases for VLNC cigarettes as a function of varying scenarios (Ref. 348). Most relevant was the scenario where participants made hypothetical purchases for VLNC cigarettes, e-cigarettes, and NRT in a marketplace where NNC cigarettes were unavailable. VLNC cigarettes had the highest rate of purchase, followed by e-cigarettes, and then NRT. Approximately 20 percent of participants reported that they would not purchase any of the products if NNC cigarettes were unavailable (Ref. 348).

These data demonstrate that people who smoke cigarettes are willing to shift consumption toward both noncombusted and combusted non-cigarette tobacco products in times of economic or product constraint. Moreover, this evidence supports the conclusion that many people who smoke cigarettes likely would switch to other combusted tobacco products that contain nicotine if a nicotine product standard covered only cigarettes. Of additional concern is the potential for increased combusted non-cigarette tobacco product substitution among certain populations that may be price sensitive, such as individuals with low socioeconomic status compared to those with higher socioeconomic status (Ref. 335). One study showed that individuals of low socioeconomic status are 85 percent more likely to report using discount brands/RYO compared to participants with higher socioeconomic status (SES) in order to avoid an increase in the cost of their

preferred product, combusted cigarettes, and therefore, these individuals have a history of and comfort with switching to alternative combusted products when available at a lower cost (Ref. 335). Given that the research highlighted above has shown that a change in the availability of a tobacco product influences subsequent purchasing or use of other tobacco products, FDA is concerned that if the proposed nicotine product standard is limited to cigarettes, a large portion of individuals will seek out alternative sources of nicotine by using other combusted tobacco products if those products are not included within the scope of this rule.

VII. Discussion of Nicotine-Related Topics

A. Approach To Limiting User Exposure to Nicotine

Nicotine is the primary addictive constituent in all tobacco products, including cigarettes. FDA is proposing a tobacco product standard that would limit nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products to make these products minimally addictive or nonaddictive, using the best available science to determine a level that is appropriate for the protection of the public health.

After consideration of the scientific literature, comments submitted in response to the Nicotine ANPRM, and the measured levels of nicotine content in research cigarettes (as reported in the literature, as well as in information submitted to FDA from industry), FDA is proposing that the maximum nicotine level in cigarettes and certain other combusted tobacco products not exceed 0.70 mg of nicotine content per gram of total tobacco in order to limit user exposure to nicotine.

Nicotine “yield” is the amount of nicotine in smoke, in other words, the amount of nicotine to which a smoker potentially is exposed. Nicotine yield is measured by a machine-generated protocol where the product is smoked by a machine in a prescribed manner and the smoke is collected in order to measure nicotine with another instrument, such as a gas chromatograph. Nicotine content refers to the total amount of nicotine present in the tobacco filler and is typically conveyed as either milligrams of nicotine per gram of total tobacco or milligrams of nicotine per product. The nicotine content of a tobacco product serves as a ceiling on nicotine yield, as it denotes the maximum amount of nicotine that a user can be exposed to when they smoke the cigarette or other

tobacco product, and it cannot be manipulated by user behavior.

Setting a limit on nicotine content and measuring that content is more effective in reducing yield (*i.e.*, the amount of nicotine the user is exposed to) than setting a limit based on a direct measurement of yield under standardized smoking-machine protocols. This is because the way yield is measured by smoking machines does not accurately capture the amount of nicotine that is taken in by a person using the tobacco products. For example, manufacturers have developed “low-yield” cigarettes designed to markedly reduce yield results as measured by the Federal Trade Commission (FTC) testing method (Ref. 350). They decreased yields by manipulating various characteristics of the cigarettes (*e.g.*, decreasing the length of the available tobacco column, increasing the burn rate of the column, increasing filter efficiency, increasing air dilution in mainstream smoke, decreasing density of tobacco, or changing the concentration of nicotine in the tobacco) (Ref. 350 at Table 2–2). Many of these design changes led to the amount of nicotine measured in the machine-generated yield being different from—and less than—the amount of nicotine received by the smoker (Ref. 350). This disconnect is a result of smoking compensatory behaviors, such as smoking more cigarettes per day, increasing the number of puffs (with a smoker’s last few puffs on a cigarette delivering disproportionately more nicotine than delivered in a smoking machine’s standardized number of puffs), increasing puff volume and frequency, inhaling more deeply, and covering ventilation holes with fingers or lips, that enable smokers to overcome, intentionally or unintentionally, many of these design changes and, thereby, increase the amount of their nicotine intake compared to the machine-generated yield. They often do this to obtain adequate nicotine to satisfy their nicotine cravings (Ref. 350).

While standardized smoking machine puffing regimes in a controlled laboratory environment are effective in producing reproducible measurements of nicotine yield, as noted above, human behavior—how people smoke, including in response to cigarette-design features—influences the nicotine intake from a cigarette and can overcome features of a cigarette that lowered the machine-generated nicotine yield. For example, combusted cigarettes that were once referred to as “light” cigarettes achieved a reduction in machine-measured nicotine yield (*e.g.*, ISO

machine smoking method, CI smoking method, FTC smoking method) through a variety of design changes to the cigarette, including the use of ventilation holes—although the actual nicotine content of the tobacco filler was not low. These design changes led to lower tar and nicotine yields in machine-generated smoke, and therefore, these products were labeled and marketed as low nicotine yield or “light,” “low,” or “mild” cigarettes. However, often unconsciously cigarette users could and did modify their use behaviors to compensate for these design changes and extract more nicotine from the products compared to the machine-generated yields, often to levels comparable to conventional cigarettes. For example, cigarette makers generally design cigarettes with ventilation holes far enough down the cigarette that they are not blocked during the FTC smoking test, but are easily blocked by users’ fingers or mouths, and larger or more frequent puffs could be taken by consumers (Ref. 351). Through such compensatory smoking behaviors, cigarette users were able to overcome the changes in ventilation in these products, resulting in no benefit to public health (Ref. 350). There is ample research demonstrating that people who use ventilated cigarettes change their smoking behavior to increase their smoke intake, including taking larger puffs, inhaling more deeply, taking more frequent puffs, or increasing the number of cigarettes they smoke per day²⁵ (Refs. 350 to 361). As a result, evidence shows that many people are exposed to higher yields of smoke constituents, including nicotine, than the yields estimated by standardized smoking machine methods (Refs. 362 to 364). Further, researchers have reviewed the extensive body of literature on filter ventilation and health effects and concluded that there is strong evidence to suggest that filter ventilation has contributed to the rise in lung adenocarcinomas among people who smoke (Ref. 365). Studies that measure nicotine pharmacokinetics have also found that the relative percentage of free nicotine in smoke may increase with percent of filter ventilation (Ref. 366), which suggests that greater filter ventilation may expose smokers to greater free nicotine levels that can lead to greater total nicotine exposure while smoking as this form of nicotine is more easily absorbed by the body.

²⁵ See section VII.B 4., Smoking Topography, of this document for further discussion of compensatory smoking and VLNC cigarettes.

In contrast, reducing the nicotine content in cigarettes and certain other combusted tobacco products places an absolute maximum limit on the amount of nicotine that can be extracted (*i.e.*, yielded) by the user. VLNC cigarettes, in contrast to low nicotine yield cigarettes generated by other design changes, are associated with minimal and transient compensatory smoking because people who smoke these cigarettes are unable to obtain adequate amounts of nicotine through these behaviors; therefore, they stop trying to do so. In sum, limiting nicotine yield through a maximum nicotine content level would be more effective in achieving the public health benefits that come from reducing the amount of the nicotine to which a user is exposed than would setting a limit based on a measurement of the maximum yield of tobacco products.²⁶

B. Scientific Evidence Supports the Target Level of Nicotine

Many studies have investigated the effects of VLNC cigarettes on behavioral outcomes, including smoking cessation, use behaviors, biomarkers of exposure, and physiological effects. Findings from these studies are discussed in this section, and they suggest that individuals who smoke VLNC cigarettes with nicotine levels similar to what FDA is proposing here are more likely to make a quit attempt, reduce smoking, demonstrate reduced exposure to harmful and potentially harmful constituents (HPHCs), and demonstrate similar or reduced physiological responses to cigarettes relative to individuals who smoke usual brand or NNC cigarettes. Results from these and other studies suggest that switching to VLNC cigarettes does not lead to compensatory smoking (see this section and VII.B.4 of this document for further discussion of compensatory smoking).

Therefore, the data reported in the scientific literature support a tobacco product standard limiting nicotine yield by setting a maximum nicotine content level in cigarettes and certain other combusted tobacco products to a maximum of 0.70 mg of nicotine per gram of total tobacco. FDA believes that this maximum nicotine level would provide the appropriate flexibility to account for variations in tobacco growing seasons and variations in analytical testing. FDA requests

comments, data, and research regarding this proposed maximum nicotine level.

1. Origin of the Proposed Product Standard

In 1994, Benowitz and Henningfield proposed the idea of Federal regulation of nicotine content in combusted tobacco products to a level too low to sustain addiction (Ref. 367). They considered the smoking habits of a small population of people who smoke cigarettes intermittently and who demonstrate reduced nicotine dependence (a group sometimes referred to as tobacco “chippers”) to inform indirect estimates of a nicotine level that they proposed would be too low to sustain addiction in most people who smoke cigarettes. Chippers are typically characterized by smoking five or fewer CPD, with limited or no withdrawal symptoms, and by being able to skip smoking for days at a time (Ref. 368). Based on their estimates of nicotine exposure among chippers, the researchers proposed a level of nicotine per cigarette—approximately 0.5 mg of nicotine per cigarette—that should be low enough to prevent or limit the development of nicotine addiction in most young people. The nicotine level proposed by Benowitz and Henningfield was an initial estimation based on observational data, and there is individual variability in dose sensitivity to all addictive substances; however, the initial estimate posed by Benowitz and Henningfield paved the way for subsequent prospective clinical studies designed to evaluate the addiction potential of VLNC cigarettes.

Several brands of commercial and research cigarettes were manufactured to contain a nicotine content similar to that originally proposed by Benowitz and Henningfield (see table 1 of this document). Using these cigarettes, researchers have consistently demonstrated that VLNC cigarettes have reduced addiction potential compared to NNC cigarettes.

22nd Century Group Inc., the company that developed SPECTRUM Nicotine Research Cigarettes and whose genetically engineered tobacco was used to make Quest cigarettes, submitted modified risk tobacco product applications to FDA that reported that the actual average value of nicotine content in its genetically engineered VLNC tobacco is 0.6 mg nicotine per gram of total tobacco, with a range of 0.4 to 0.7 mg nicotine per gram of total tobacco (see section V.A of this document for a discussion of the history of LNC and VLNC cigarettes, including the SPECTRUM Nicotine Research

Cigarettes).²⁷ The natural variation of this agricultural product resulted in the slight variation in the nicotine content of the tobacco filler within the company’s internal range of acceptable values. The average value and range were compiled by the company from 9 years of sampling data of the genetically engineered tobacco that was used to make SPECTRUM and Quest cigarettes. It is likely that the cigarettes used throughout the scientific literature, reported as having 0.4 mg nicotine per gram of total tobacco, may have, in actuality, been between 0.4 and 0.7 mg of nicotine per gram of total tobacco. This range is consistent with the scientific evidence to support a minimally addictive or nonaddictive level of nicotine content in cigarettes and certain other combusted tobacco products, and FDA took these data from 22nd Century Group Inc.’s VLNC cigarettes into consideration when determining the appropriate, technically feasible maximum level of nicotine content to propose in this product standard.

2. Smoking Cessation

A number of studies investigated the effects of VLNC or LNC cigarettes alone or in combination with NRT on smoking cessation among people who smoke but are interested in quitting (Refs. 32, 35, 41, 369 to 373) and those uninterested in quitting (Refs. 31, 40, 258, and 374). As stated throughout this document, most adults who use tobacco products wish to quit but are unsuccessful because of the highly addictive nature of these products (Refs. 1, 13, 28, 58, and 61) (see section IV.A of this document for a discussion of the addictiveness of nicotine). Taken together, results from these studies demonstrate that people who smoke and are interested in quitting who are given VLNC cigarettes are more likely to achieve initial smoking abstinence compared to those who continue to smoke their usual brand or NNC cigarettes. In addition, provision of NRT and/or behavioral intervention with VLNC cigarettes may further increase smoking cessation among individuals interested in quitting (Ref. 19).

Research demonstrates the benefits of VLNC cigarettes for those people who smoke and are interested in quitting. In one of the clinical trials that has examined the effects of VLNC cigarettes

²⁶ Consistent with the proposed limit on nicotine content, FDA is also proposing testing for nicotine content only, rather than both content and yield. This testing requirement is less burdensome yet still effective in measuring the maximum nicotine yield, *i.e.*, the maximum amount of nicotine to which a user can be exposed.

²⁷ On December 23, 2021, FDA issued exposure modification orders to 22nd Century Group Inc. for VLN King and VLN Menthol King combusted, filtered cigarettes. See <https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications>.

alone on smoking cessation in people who smoke cigarettes who were interested in quitting, 165 people who smoke were randomized to use LNC cigarettes, VLNC cigarettes, or 4 mg nicotine lozenges for 6 weeks (Ref. 32). While there were no statistically significant differences between groups in CO-verified point prevalence abstinence (*i.e.*, quit) rates at 1–4-week followup visits, abstinence rates at the week 6 followup visit were statistically significantly higher in the VLNC cigarette group (47.2 percent) and nicotine lozenge group (36.7 percent) relative to the LNC cigarette group (23.1 percent) (Ref. 32). In another randomized clinical trial (RCT), 346 people who smoked and were interested in quitting were randomized to receive 6 weeks of (1) a combination of VLNC cigarettes (nicotine was gradually reduced from NNC to LNC to VLNC cigarettes every 2 weeks) and nicotine patch (VLNC cigarettes + NRT); (2) VLNC cigarettes and a placebo patch (VLNC cigarettes only); or (3) NNC cigarettes and NRT after their quit date (NNC cigarettes + NRT) (Ref. 369). Following their quit date at week 7, the VLNC cigarettes + NRT group continued to receive NRT, the VLNC cigarettes only group received placebo patches, and the NNC cigarettes + NRT group was provided with NRT during weeks 7–10. Biochemically confirmed continuous abstinence rates were 32.8 percent in the VLNC cigarettes + NRT group, 16.4 percent in the VLNC cigarettes only group, and 21.9 percent in the NNC cigarettes + NRT group (Ref. 369), suggesting that the combination of VLNC cigarettes and NRT is more effective at promoting continuous abstinence than VLNC cigarettes alone. However, abstinence at 3- and 6-month followups could not be adequately assessed due to attrition (Ref. 369).

Many other studies conducted in individuals interested in quitting investigated the effects of LNC or VLNC cigarettes combined with NRT (Refs. 41, 35, 371 to 373, and 375). For example, in a study conducted in New Zealand, 1,410 callers to a quitline were randomized to receive VLNC cigarettes with usual quitline care (8 weeks of NRT and behavioral support via a quitline) or usual care alone (Ref. 373). Six months after the quit date, 7-day point-prevalence abstinence rates²⁸ were statistically significantly greater in participants using VLNC cigarettes with

usual quitline care (33 percent) compared to the group who received usual quitline care alone (28 percent). Continuous abstinence rates at month 6 also were statistically significantly higher for participants who received VLNC cigarettes with usual quitline care (23 percent) compared to those who received usual quitline care alone (15 percent). Likewise, in another study, 98 persons who reported heavy smoking (*i.e.*, greater than or equal to 20 CPD) received either VLNC cigarettes and a 21 mg nicotine patch or NNC cigarettes for 2 weeks prior to quitting (Ref. 372). After the quit date, all study participants wore nicotine patches for up to 8 weeks. Participants who smoked VLNC cigarettes and received patches reported less frequent and less intense cravings during the 2 weeks before and after the quit date, suggesting that use of VLNC cigarettes plus NRT may aid in cessation by reducing cigarette craving during a quit attempt. Participants in the VLNC cigarettes + NRT group had a higher self-reported quit rate compared to those in the NNC cigarettes + NRT group at 3 months (43 percent vs. 34 percent, respectively) and 6 months (28 percent vs. 21 percent, respectively), but these quit rates did not differ statistically significantly between groups, likely due to a small sample size precluding sufficient statistical power.

Several other studies have investigated the effects of VLNC or LNC cigarettes on smoking cessation among individuals uninterested in quitting (Refs. 31, 40, 258 and 374). In an RCT, participants received either NNC cigarettes or VLNC cigarettes (double-blinded, *i.e.*, neither the participants nor the researchers knew which type of cigarette participants received), and either received or did not receive a transdermal nicotine patch (open-label, *i.e.*, participants and researchers were aware of whether participants received NRT) for 7 weeks. At week 7, participants were provided a daily descending monetary bonus for refraining from using any cigarettes. Participants randomized to receive NRT were encouraged to continue using their patches. Although participants who received VLNC cigarettes smoked statistically significantly fewer total CPD than participants who received NNC cigarettes, during the abstinence period, no groups differed statistically significantly from the NNC cigarette-only group in time to lapse or number of days abstinent; however, these results were likely influenced by low adherence to VLNC cigarette use in this study (Ref. 376). In another series of studies, participants received gradually

reduced nicotine content cigarettes over a period of 6 months, beginning with NNC cigarettes and ending with VLNC cigarettes (Refs. 258 and 374). In the first study, a statistically significantly greater proportion of participants who received VLNC cigarettes considered quitting at the end of the study, compared to those in a control group who smoked their usual brand cigarettes throughout the study (Ref. 258). In a followup study in which a subset of participants was followed for 2 years, cotinine levels in the gradual nicotine reduction group rose to baseline levels or levels similar to those of the control group after 12 months during which both groups could freely smoke usual brand cigarettes (Ref. 374). Although 7.5 percent of participants in the gradual reduction group quit smoking, compared to only 2 percent of participants in the usual brand control group, this difference was not statistically significant (Ref. 374). In another study, 33 participants were randomized to receive VLNC cigarettes or to continue to smoke their usual brand cigarettes for 12 weeks (Ref. 31). The availability of VLNC cigarettes increased quit attempts in people who smoked cigarettes and had no intention of quitting (Ref. 31).

Furthermore, several extended duration VLNC studies demonstrated how VLNC cigarettes can increase cessation by assessing self-reported quit attempts as a secondary study aim. While one study showed no statistically significant differences in quit rates among people who smoke cigarettes on a nondaily basis who used VLNC or NNC cigarettes for 10 weeks (Ref. 377), other studies showed that participants who smoked VLNC cigarettes were more likely to report a quit attempt after 6 weeks of use (Ref. 29) and had a greater number of cigarette-free days after 12 (Ref. 378) and 18 weeks (Ref. 379) compared to those who smoked NNC cigarettes. However, a secondary analysis of the 18 week study (Ref. 379) found that there were no significant differences in quit rates or intention to quit at the 6-month followup timepoint (Ref. 380).

Among the studies evaluating smoking cessation following VLNC cigarette use, few utilized a randomized controlled trial design, and results were sometimes inconsistent, particularly related to long-term followup. However, the weight of evidence from these studies suggests that among people who smoke and are interested in quitting, using VLNC cigarettes can facilitate initial smoking abstinence, particularly when used along with NRT and/or behavioral intervention. Among people

²⁸ Seven-day point prevalence abstinence is a measure of, in this case, tobacco cessation outcomes for quitlines. At a given point in time (in this case, 6 months after the quit date), study participants are asked whether they have used cigarettes or other forms of tobacco in the past 7 days.

who smoke but are uninterested in quitting, VLNC cigarette use did not increase quit rates; however, it did increase quit attempts. It is important to note that studies evaluating smoking cessation following VLNC cigarette use took place in an environment where NNC cigarettes and other combusted tobacco products remained readily available. For this reason, the available data likely underestimates the likelihood of increased cessation rates following the implementation of a nicotine product standard because NNC cigarettes would no longer be available, making relapse to these cigarettes no longer possible.

3. Cigarettes Per Day (CPD)

One concern raised by some with regard to a reduced nicotine policy is whether people who smoke might alter their smoking behavior by smoking additional cigarettes in order to attempt to compensate for the lower amounts of nicotine, but studies show that extended use of VLNC cigarettes does not produce increases in CPD. Researchers typically assess CPD via participant self-reporting or by counting cigarette filters or packs returned by participants. By measuring CPD during an extended exposure trial, researchers can determine whether switching to VLNC cigarettes produces changes in CPD compared to usual brand or NNC cigarette conditions. Research conducted in the absence of the proposed standard shows that switching to LNC or VLNC cigarettes can produce modest decreases in CPD. However, as noted previously, studies evaluating changes in CPD following VLNC cigarette use took place in an environment where NNC cigarettes and other combusted tobacco products remained readily available, likely underestimating the potential reductions in CPD following implementation of a nicotine product standard because NNC cigarettes and other combusted tobacco products would no longer be legally available. These findings suggest that, if the proposed product standard were finalized and implemented, people who smoke VLNC cigarettes would not increase CPD to compensate for reduced nicotine exposure, and FDA expects that for many CPD would decrease over time.

Many studies measured VLNC CPD under conditions of extended exposure (e.g., several consecutive weeks or longer). These studies varied in sample size, duration of exposure, average CPD requirements to enter the study, participants' intentions to quit smoking, and the method in which participants transitioned from usual brand cigarettes

to VLNC cigarettes (i.e., gradual versus immediate reduction in nicotine content). Despite these differences in study methods and participant characteristics, nearly all the studies came to a similar conclusion: relative to usual brand or NNC cigarette conditions, CPD was similar (i.e., there was no compensatory smoking) (Refs. 31, 35, 329, 369, 374, 381 to 385,) or lower in VLNC cigarette conditions (Refs. 29, 32, 41, 265, 386, and 387). Notably, studies that found lower CPD while participants smoked VLNC cigarettes tended to have larger sample sizes (Refs. 29 and 379), which may have had more statistical power to detect relatively small but consistent differences in CPD across conditions.

One limitation of some studies that examined the effects of VLNC cigarette smoking on CPD is that comparisons between VLNC CPD and usual brand or NNC CPD were made without taking into account the number of non-study cigarettes smoked per day in experimental conditions. A measure of "total CPD" in VLNC cigarette conditions would include the number of study-assigned VLNC cigarettes plus the number of usual brand or non-study cigarettes smoked by participants who were not fully compliant with study procedures. Few studies have compared total CPD across VLNC and usual brand or NNC cigarette conditions. However, one study found that, relative to usual brand and NNC cigarette conditions, the combination of study- and non-study-assigned CPD was lower in VLNC and LNC cigarette conditions when nicotine content was less than or equal to 2.4 mg nicotine per gram of total tobacco, and that those participants who used VLNC cigarettes (i.e., 0.4 mg nicotine per gram of total tobacco), demonstrated reduced use and dependence with minimal evidence of withdrawal-related discomfort or safety concerns (Ref. 29). Another study found that fewer combusted tobacco products were smoked during LNC cigarette conditions relative to an NNC cigarette condition (Ref. 5). A study where participants were confined to a hotel in order to limit their access to non-study products assessed the potential effects of VLNC cigarettes on compensatory smoking behaviors (Ref. 388). Participants completed two 4-night stays; during their first stay, they were randomized to receive either NNC or VLNC cigarettes and were randomized to the other group during their second stay. Furthermore, participants were given an "account balance" where they could purchase study cigarettes from a "cigarette store" during the study. Investigators found

that by the end of the four night stays the number of cigarettes participants smoked did not differ statistically significantly between the NNC and VLNC cigarette groups, indicating that people who smoke may not engage in compensatory smoking behavior when only VLNC cigarettes are available (Ref. 388). Another study compared the effects of VLNC and NNC cigarettes on CPD in people who smoke who inhabited a residential research facility throughout the study. The results showed that when participants had access to only VLNC cigarettes for 11 days, they smoked statistically significantly fewer CPD than those who had access to only NNC cigarettes (Ref. 64).

Taken together, these studies indicate that extended use of VLNC cigarettes does not produce increases in CPD in an attempt to compensate for the reduced nicotine levels. FDA expects that this may result in reductions in CPD among people who do not quit, particularly in an environment where NNC cigarettes are not legally available.

4. Smoking Topography

Smoking topography refers to various aspects of smoking behavior, including number of puffs per cigarette, total time spent smoking, puff volume (i.e., puff size), puff velocity (i.e., puff intensity), puff duration, and inter-puff interval (i.e., length of time between puffs). Although some of these outcomes (e.g., puffs per cigarette) can be measured via direct observation, smoking topography is typically assessed with an electronic puff topography unit attached directly to a cigarette. Smoking topography measures that indicate more intense smoking behavior may be attributed to compensatory smoking. A concern raised by some with regard to a nicotine reduction policy is whether people who smoke might engage in compensatory smoking behavior to try to extract more nicotine from the cigarettes, thus increasing exposure to tobacco-related toxicants. Smoking topography study results are mixed, but the majority of studies show that individuals who smoke VLNC cigarettes demonstrate no statistically significant differences in smoking topography relative to those who smoke usual brand or NNC cigarettes, or they demonstrate changes in smoking topography measures that are associated with reductions in tobacco smoke exposure (e.g., lower total puff volume) rather than increased compensatory smoking.

Some studies found no differences in smoking topography between VLNC and NNC or usual brand cigarette conditions (Refs. 389 to 391). However, many other

studies found that smoking topography differed between cigarette conditions. Some of the more reliable findings replicated across studies were the effects of VLNC cigarettes on total puff volume and number of puffs per cigarette. Under conditions of both brief (*e.g.*, several hours) and extended (*e.g.*, several weeks) exposure, studies found that total puff volume was lower (Refs. 29, 34, 383, 384, and 392) and number of puffs per cigarette was lower (Refs. 329, 384, 392, and 393) when participants smoked VLNC cigarettes, relative to usual brand or NNC cigarettes. However, two brief exposure studies showed higher puff volumes (Refs. 393 and 394) and puff duration (Ref. 394) when participants smoked VLNC cigarettes in short laboratory sessions. Another brief exposure study conducted in adolescents showed that VLNC cigarettes produced higher numbers of puffs relative to NNC cigarettes; however, additional measures were not collected to determine whether this was a transient or lasting effect (Ref. 395). An extended exposure study showed initial decreases in puff volume when participants smoked VLNC cigarettes relative to NNC cigarettes, but these differences dissipated over the course of 7 days (Ref. 383). Finally, limited evidence suggests that VLNC cigarettes are smoked faster (Refs. 259 and 396), are smoked with increased peak velocity (Ref. 384) and may decrease inter-puff intervals when compared to NNC cigarettes (Ref. 392).

In all, while smoking topography study results are mixed, the majority of studies show that individuals who smoke VLNC cigarettes demonstrate no statistically significant differences in smoking topography relative to those who smoke usual brand or NNC cigarettes, or they demonstrate changes in smoking topography measures that are associated with reductions in tobacco smoke exposure (*e.g.*, lower total puff volume) rather than increased compensatory smoking.

5. Abuse Potential

Abuse potential refers to the ability of a product to promote continued use and the development of dependence. Choice studies are commonly used to measure abuse potential, where preference for one tobacco product over another indicates greater abuse potential. When participants are asked to make a real or hypothetical choice between VLNC cigarettes and NNC cigarettes in research studies, they reliably choose NNC cigarettes (Refs. 391, 397 to 401). Combined with data showing that VLNC cigarettes are associated with significantly lower plasma nicotine

exposure (Ref. 402) and decreased positive subjective effects compared to NNC and usual brand cigarettes (Ref. 391), these data indicate lower abuse potential of VLNC cigarettes. However, research has also shown that the choice between VLNC and NNC cigarettes can be influenced by factors such as cost or effort, such that when the effort required to obtain NNC cigarettes increases, some people who smoke cigarettes will switch their preference from NNC cigarettes to VLNC cigarettes (Ref. 398). For example, one laboratory study investigating tobacco product choice when participants were provided with an experimental income found that, although participants rated VLNC cigarettes as less satisfying than both LNC and NNC cigarettes, they purchased statistically significantly more puffs of the VLNC cigarettes when LNC and NNC cigarettes were more expensive (Ref. 403). Thus, if the proposed product standard is implemented and the cost, effort, or risk associated with obtaining NNC cigarettes increases, individual preference may shift to VLNC cigarettes or more readily available tobacco products rather than attempting to seek out illicitly marketed NNC products. If the proposed product standard were to apply only to cigarettes, these findings also indicate that people who smoke cigarettes who do not quit after a final rule goes into effect would likely be willing to switch to other NNC combusted tobacco products rather than using VLNC cigarettes. If this were the case, the public health benefit of the proposed product standard would be reduced.

Hypothetical choice tasks (*e.g.*, cigarette purchase task, multiple choice questionnaire) are used to characterize reinforcing efficacy by determining how changes in the cost of a commodity affect its consumption. These tasks typically involve prior experience with the product or brief laboratory exposure, followed by a series of questions asking participants to either (1) report how many cigarettes they would consume at a variety of escalating prices; or (2) choose between cigarettes or money at a variety of prices. Studies that used hypothetical choice tasks to assess VLNC cigarette reinforcement showed that participants find VLNC cigarettes to be less reinforcing than NNC cigarettes (Refs. 265, 343, and 391). In one study, the reinforcing efficacy of cigarettes varying in nicotine content following 6 weeks of access to the products was examined (Ref. 343). Compared to the NNC cigarette group, those in the VLNC cigarette group estimated that they

would smoke fewer cigarettes even if the cigarettes were free, spend less for the VLNC cigarettes, and quit smoking VLNC cigarettes at a lower price point (*i.e.*, a price point at which participants would continue to pay for NNC cigarettes). Responses on the hypothetical choice task were highly correlated with the actual number of cigarettes smoked during week 6 of the study.

Hypothetical choice tasks can also be used to investigate the substitutability of tobacco products. For example, another study employed a cross-price elasticity task in which the price of VLNC cigarettes was held constant while the price for usual brand cigarettes was manipulated (Ref. 404). When usual brand cigarette price increased, demand for VLNC cigarettes increased and demand for usual brand cigarettes decreased, indicating that VLNC cigarettes are a partial substitute for usual brand cigarettes (Ref. 404).

Rather than directly assessing choice between tobacco products, some studies evaluate how much people who smoke are willing to work to earn puffs from cigarettes when the number of responses required to earn a puff progressively increases (*i.e.*, a progressive ratio task). One study that used this method found that participants assigned to an NNC cigarette group were willing to work statistically significantly harder to earn puffs from their NNC cigarette than participants assigned to a VLNC cigarette group, indicating greater abuse liability (*i.e.*, ability to promote continued use and the development of dependence) of the NNC cigarette (Ref. 64).

These studies demonstrate that VLNC cigarettes are consistently shown to be of lower abuse potential compared to NNC cigarettes, as evidenced by responses to behavioral and hypothetical choice procedures. Behavioral and hypothetical choice research has also shown that the choice between VLNC and NNC cigarettes can be influenced such that some people will switch their preference from NNC cigarettes to VLNC cigarettes when the price or effort required to obtain the products increases. See section VI.B of this document for further discussion on the impact of cigarette price on switching behavior.

6. Biomarkers of Exposure

Research demonstrates that, following VLNC cigarette use, some biomarkers of exposure (*e.g.*, CO, measured as breath CO or carboxyhemoglobin (COHb)) are typically similar to those observed following NNC cigarette use, while other biomarkers (*e.g.*, total nicotine

equivalents (TNE), which are a combination of nicotine, cotinine, and other nicotine metabolites collected through plasma, saliva, or urine) are typically lower following VLNC cigarette use. However, no biomarkers of exposure are reliably observed to be higher following VLNC cigarette use relative to NNC cigarette use, meaning that study participants are not engaging in compensatory smoking behaviors.

Some of the most commonly measured biomarkers of tobacco smoke exposure are CO, plasma nicotine, cotinine (collected through plasma, saliva, or urine), TNE, and other HPHCs or their metabolites (*e.g.*, NNN, NNAL, Benzof[a]pyrene (BAP), 3-hydroxypropyl mercapturic acid (3-HPMA), S-phenylmercapturic acid (S-PMA)). While nicotine and its metabolites would be expected to decrease in individuals who switch from NNC to VLNC cigarettes, other biomarkers of exposure would be expected to remain the same if smoking behavior remained unchanged. Thus, any changes in biomarker levels observed between NNC and VLNC cigarette conditions in clinical studies may indicate differences in smoking behavior (*e.g.*, changes in CPD or smoking topography) between these two groups. Notably, due to the short half-lives of some biomarkers (*e.g.*, breath CO), decreases in smoking can produce decreases in these biomarkers during brief exposure studies. However, decreases in smoking may not produce decreases in some biomarkers (*e.g.*, NNAL) under such conditions due to the prolonged half-lives of these biomarkers.

Most studies have found no differences in CO exposure between participants who smoke VLNC cigarettes and those who smoke usual brand or NNC cigarettes (Refs. 5, 29, 32, 34, 40, 258, 374, 376, 383, 387, 388, 390, 391, 393, 395, 396, 402, 405 to 417.). This finding may be somewhat unexpected as many studies have found that participants smoke fewer CPD when they smoke VLNC cigarettes relative to NNC or usual brand cigarettes. However, although CO is positively associated with CPD, research has shown that the correlation may only be of moderate strength (Ref. 418). Furthermore, CO may be impacted by noncompliance with study cigarettes (see section VI.B of this document for a discussion about noncompliance).

Nevertheless, differences were observed between VLNC and NNC cigarette conditions in a few studies. Two brief exposure studies in which participants were given limited access to reduced nicotine content cigarettes over the course of several hours under

controlled laboratory conditions found increases in breath CO following VLNC cigarette use relative to NNC cigarette use (Refs. 419 and 420). In addition, an extended exposure study (over the course of 35 days) showed that CO levels initially increased when participants switched from usual brand cigarettes during baseline to VLNC cigarettes; however, these effects dissipated over time as CO levels eventually returned to baseline levels (Ref. 384). As discussed in section VIII.D.7 of this document, these limited increases in CO exposure may be due to changes in smoking topography. At least one extended exposure study found decreases in CO boost (the difference between measured CO levels before and after smoking a cigarette) after VLNC cigarette use compared to usual brand cigarettes (Ref. 329). In another study, one group of participants smoked NNC cigarettes throughout the study, a second group smoked study cigarettes with gradually reduced nicotine contents, and a third group immediately switched to VLNC cigarettes (Ref. 421). This study found that subjects in the immediate VLNC cigarette group had statistically significantly lower CO than did the NNC cigarette or gradual reduction groups. Breath CO for participants in the NNC cigarette and gradual reduction groups did not differ statistically significantly from each other (Ref. 421). Moreover, the only study to date that examined the effects of VLNC cigarettes on breath CO in people who smoke who inhabited a residential research facility found that when participants only had access to study cigarettes for 11 days, those who were assigned VLNC cigarettes had statistically significantly lower breath CO than those who were assigned NNC cigarettes. Furthermore, these differences increased over the course of each day such that they were much larger in the afternoon than in the morning (Ref. 64).

Notwithstanding the differing CO studies, studies that examined nicotine, cotinine, or TNE levels had overwhelming concurrence regarding the effects of either brief or extended exposure to VLNC cigarettes compared to usual brand or NNC cigarettes. VLNC cigarette use resulted in substantially lower levels of nicotine, cotinine, and TNE than usual brand or NNC cigarettes (Refs. 5, 29, 32 to 34, 40, 258, 329, 370, 374, 376, 382 to 384, 387, 388, 390, 402, 403, 406, 407, 410, 413, 417, and 419 to 425). One within-subjects laboratory study compared the nicotine pharmacokinetic profile of VLNC, LNC, NNC, and usual brand cigarettes in 12

participants who smoked cigarettes daily (Ref. 402). While each of the four cigarettes produced statistically significant increases in plasma nicotine boost (*i.e.*, peak plasma nicotine level minus baseline level) after smoking, the VLNC and LNC cigarettes had statistically significantly lower plasma nicotine boost and AUC₀₋₁₂₀ (*i.e.*, plasma nicotine area under the curve calculated for the first 120 minutes following product use, indicating extent of exposure to nicotine and its clearance rate from the body) compared to the NNC and usual brand cigarettes. These data show that although VLNC cigarettes are associated with significantly lower nicotine uptake compared to NNC and usual brand cigarettes, the cigarettes still deliver a measurable amount of nicotine.

The effects of VLNC cigarette exposure on other HPHCs were less reliable across studies. Nevertheless, studies consistently found that VLNC cigarette exposure either reduced or did not change exposure to NNN, NNAL, urinary 1-hydroxypyrene, or BAP relative to NNC or usual brand cigarettes (Refs. 5, 29, 32, 40, 258, 382, 384, and 329). Two studies also examined 3-HPMA and S-PMA levels and found that these biomarkers decreased in VLNC cigarette conditions compared to LNC and NNC cigarette conditions (Ref. 32). Another study found that an immediate switch to VLNC cigarettes statistically significantly reduced exposure to acrolein and phenanthrene tetraol (both are biomarkers of smoke exposure) throughout a 20-week study duration compared to a gradual reduction approach (Ref. 379). The reductions in biomarkers that were observed in some of these studies following VLNC cigarette exposure were typically correlated with decreases in CPD or other smoking behaviors. Thus, as expected, VLNC cigarette use resulted in fewer CPD, which resulted in overall reductions in HPHC exposure. Importantly, none of the studies found that VLNC cigarette use resulted in increases in any of these other HPHCs or their biomarkers. Taken together, these studies support that VLNC cigarette use is associated with biomarker exposure that is similar to or lower than NNC cigarette use.

7. Physiological Effects

Physiological measures may be proxy measures for the stimulant effects of nicotine. Pharmacodynamic effects of nicotine include central and peripheral nervous system stimulation, arousal, and increased heart rate or blood pressure. Nicotine is a known stimulant, but physiological effects may occur in

response to combusted tobacco products even in the absence of nicotine in those who regularly use cigarettes and certain other combusted tobacco products due to behavioral conditioning or other psychoactive chemicals in tobacco smoke. Data show that physiological effects related to VLNC cigarettes are similar or less pronounced than those produced by NNC cigarettes, suggesting that the nicotine in the VLNC cigarettes is able to produce physiological effects.

There is slight variability in the data assessing the physiological effects of VLNC cigarettes. Some studies show that, regardless of nicotine content, acute cigarette smoking is associated with an increase in baseline heart rate (Refs. 259, 407, 411, and 419); however, these increases were either less pronounced following VLNC cigarette use compared to NNC cigarette use (Refs. 259 and 407) or were less consistent (*i.e.*, observed at some but not all time points following use) (Ref. 411). Some research has shown that escalations in heart rate dissipate after repeated exposure to VLNC cigarettes but not usual brand cigarettes (Ref. 407). In contrast, other studies did not observe increases in heart rate when participants smoked VLNC cigarettes (Refs. 250, 413, 417, and 426), and several studies showed statistically significantly reduced escalations in heart rate compared to acute LNC, NNC, or usual brand cigarette administration (Refs. 64, 249, 265, 390, 405, 415, 427, and 428).

Some studies also investigated the effects of VLNC cigarettes on blood pressure. Several studies found no differences in blood pressure after smoking a VLNC cigarette compared to an LNC cigarette (Refs. 249 and 419), NNC cigarette (Ref. 259), or usual brand cigarette (Refs. 249, 259, and 419). However, other studies showed statistically significantly greater increases in blood pressure after smoking NNC or usual brand cigarettes relative to VLNC cigarettes (Refs. 265 and 390).

A small number of studies examined the effects of VLNC cigarettes on skin temperature and skin conductance (a measure of sympathetic nervous system activity indicating psychological or physiological arousal). Although one study showed that skin temperature decreased to a greater extent with NNC cigarettes compared to VLNC cigarettes (Ref. 259), another study found no differences in skin temperature as a function of nicotine content in cigarettes (Ref. 426). Another study found no statistically significant differences in skin conductance between VLNC and NNC cigarettes (Ref. 429).

Taken together, findings from these studies suggest that VLNC cigarettes produce physiological responses that are similar to or less pronounced than those produced by NNC cigarettes. These data suggest that the nicotine in the VLNC cigarettes is able to elicit physiological responses in people who smoke cigarettes, although a portion of the response may also be due to sensorimotor cues, or other stimuli associated with smoking, that may have conditioned participants to produce these physiological effects due to the historical repeated pairings with nicotine.

8. Neurological Effects

The main target of nicotine in the central nervous system is the nicotinic acetylcholine receptor (nAChR). Positron emission tomography (PET) and magnetic resonance imaging (MRI) data obtained from humans who smoke using an nAChR-specific radiotracer indicates that after smoking a VLNC cigarette, nAChR receptors located in numerous areas of the brain are occupied despite the lower nicotine content of VLNC cigarettes (Ref. 430).

Nicotine also activates the dopaminergic brain reward system, which results in dopamine release and a pleasure response. The release of dopamine also initiates an adaptive process in which an individual forms learned associations between the subjective state (*e.g.*, pleasure) and the object or context that led to that state (*e.g.*, the act of smoking a cigarette) (Ref. 389). Through this process, both nicotine administration and smoking stimuli (*e.g.*, a cigarette, a lighter) contribute to the cycle of nicotine dependence (Ref. 38). Smoking NNC cigarettes to satiety results in near-complete occupancy of nAChRs in the brain (Refs. 431 and 432). In contrast, although studies have shown there is enough nicotine in VLNC cigarettes to bind to nAChRs in the brain (Ref. 430) and to release dopamine (Ref. 389), results from these studies have also shown the effects are smaller than those observed from smoking NNC cigarettes. These differences in nAChR occupancy and dopamine release between VLNC and NNC cigarettes may explain, in part, why many studies have shown smoking VLNC cigarettes does not consistently produce the same magnitude of subjective craving and withdrawal responses observed following use of NNC cigarettes (Refs. 398, 406, 407, 411, 413, 415, 417, 419, 422, 433 to 439). Taken together, these findings demonstrate that nicotine from smoking VLNC cigarettes binds to nAChRs located in numerous areas of the brain;

however, nAChR receptor occupancy and the magnitude of craving and withdrawal responses observed following use of VLNC cigarettes are not as high as those following use of NNC cigarettes.

9. Dependence

Combusted tobacco product use can lead to symptoms of nicotine dependence, which may include tolerance to the effects of nicotine, withdrawal upon cessation of use, craving, and unsuccessful efforts to quit smoking. Because dependence may take time to develop or change, it is often measured under conditions of extended exposure. Studies typically assess dependence with questionnaires, including the Fagerström Test for Nicotine Dependence (FTND), Fagerström Test for Cigarette Dependence (FTCD), Nicotine Dependence Syndrome Scale (NDSS), and Wisconsin Inventory of Smoking Dependence Motives (WISDM). Although some studies found no evidence of a change in dependence when the nicotine content of cigarettes was gradually reduced, most studies found evidence indicating that switching to VLNC cigarettes decreases dependence. Moreover, the evidence suggests that immediate nicotine reduction is more likely to lead to decreases in dependence than gradual reduction. These findings support the hypothesis that lowering the nicotine levels in cigarettes and certain other combusted tobacco products would reduce nicotine exposure and, thereby, nicotine dependence in people who do not switch to another nicotine-containing tobacco product.

In studies that gradually reduced the nicotine content of cigarettes over the course of weeks or months, the effects of VLNC cigarettes on dependence were somewhat mixed. In a study wherein nicotine content was gradually reduced (using NNC, LNC, and VLNC cigarettes) over the course of 4 weeks, there was a trend towards statistical significance (*i.e.*, if more participants had been tested, the results may have become statistically significant) in overall reduction of dependence scores across conditions (Ref. 329). Another gradual reduction study found no difference in dependence when comparing data from baseline to week 26 in 135 participants who smoked either gradually reduced nicotine content cigarettes over the course of 6 months or their own brand cigarettes for the same duration (Ref. 258). However, when comparing only data from week 14 to week 26, while participants were primarily smoking VLNC cigarettes, there was a statistically

significant decrease in dependence in the group that received gradually reduced nicotine content cigarettes (Ref. 258). A secondary analysis of data from 51 people who smoke demonstrated that participants with higher FTND scores at baseline were more likely to demonstrate signs of dependence during the study, regardless of the nicotine content of their study cigarettes (Ref. 381). In a followup study, participants assigned to receive gradually reduced nicotine content cigarettes were given VLNC cigarettes for an additional 6 months, and no statistically significant changes in dependence were observed (Ref. 374).

In studies that immediately reduced the nicotine content of cigarettes by switching participants from usual brand cigarettes to LNC or VLNC cigarettes, dependence decreased in people who smoked cigarettes who were not interested in quitting compared to those who smoked NNC or usual brand cigarettes for 6 weeks (Ref. 29), 10 weeks (Ref. 30), or 12 weeks (Ref. 31). In smoking cessation studies in which participants endorsed wanting to quit, VLNC cigarettes were also associated with reductions in nicotine dependence over time (Refs. 32 to 35). Conversely, a trial in which people with serious mental illness who smoke and were not seeking smoking cessation treatment were randomized to use either VLNC or NNC cigarettes for 6 weeks showed no statistically significant differences in FTCD scores across VLNC and NNC cigarette groups (Ref. 440). However, these results may be explained by the high level of noncompliance (*i.e.*, ongoing use of NNC cigarettes or other tobacco products) reported in the VLNC cigarette condition (Ref. 440) (see section VI.B of this document for further discussion of noncompliance).

To date, one study compared the effects of gradual versus immediate nicotine reduction on FTND and WISDM dependence scores (Ref. 379). In a 20-week double-blind, parallel design study, adults who smoke cigarettes ($n=1,250$) were randomized to an immediate reduction group that received VLNC cigarettes, a gradual reduction group that received cigarettes containing progressively decreased nicotine content every 4 weeks (15.5, 11.7, 5.2, 2.4, and 0.4 mg nicotine per gram of total tobacco, respectively), or a control group that received NNC cigarettes. At the conclusion of 20 weeks, the immediate reduction group showed statistically significantly lower FTND and WISDM dependence scores compared with the gradual reduction group and the NNC cigarette control group; no statistically significant

differences in dependence scores were observed between the gradual reduction and control groups. These results suggest that immediate nicotine reduction is associated with reduced nicotine dependence compared to gradual reduction or continued use of NNC cigarettes (Ref. 379).

The delay to smoking the first cigarette of the day is a strong predictor of dependence. In the only study to date that examined the effects of VLNC cigarettes on latency (*i.e.*, delay) to smoke in participants inhabiting a residential research facility, time to first cigarette was statistically significantly longer among people who smoke who only had access to VLNC cigarettes for 11 days compared to those who only had access to NNC cigarettes, supporting the potential for less dependence over time among those who switch to VLNC cigarettes (Ref. 64).

Accordingly, despite some mixed results in studies using a gradual decrease in nicotine content, most evidence shows that switching to VLNC cigarettes decreases dependence among people who smoke cigarettes. The evidence also suggests that immediate nicotine reduction is more likely than gradual reduction to lead to decreases in dependence. For more discussion of the scientific evidence supporting an immediate nicotine reduction approach, see section VII.C of this document.

10. Subjective Effects of VLNC Cigarettes

Self-reported subjective effects (*e.g.*, drug “liking,” “satisfaction”) are widely used measures of reinforcing efficacy and abuse liability of drugs and tobacco products. Drug “liking” is associated with drug self-administration and has been shown to be the most sensitive and reliable subjective effects measure of abuse liability (Ref. 441). Many studies have compared the subjective effects of VLNC, LNC, NNC, and participants’ usual brand cigarettes using self-reported measures of drug effects (*e.g.*, Cigarette Evaluation Scale, Smoking Effects Questionnaire, Visual Analogue Scale items). These studies typically found that VLNC cigarettes are “liked” less than NNC and usual brand cigarettes and, therefore, subject to lower abuse potential than NNC cigarettes.

Under conditions of brief exposure when participants were given limited access to cigarettes that varied in nicotine content, typically over the course of several hours under controlled laboratory conditions, studies generally found that VLNC cigarettes were rated lower in cigarette “liking” compared to NNC or usual brand cigarettes (Refs.

265, 383, 398, 399, 403, 410, 413, 428, 435, 437, 440, 442 to 448). However, a few studies found no statistically significant differences in “liking” as a function of nicotine content in cigarettes (Refs. 415, 419, 420, and 449). Many studies also have evaluated other subjective effects (such as “good” or “positive” effects and “bad” or “negative” effects) and found that they vary together with drug “liking.” A number of studies have shown that VLNC cigarettes were rated lower on other positive subjective effects items (*e.g.*, “satisfaction,” “pleasure,” “taste,” “strength,” “stimulation”) compared to LNC cigarettes (Refs. 265, 412, 419, and 450), NNC cigarettes (Refs. 265, 394, 396, 437, and 451) and usual brand cigarettes (Refs. 390, 407, 413, and 452). VLNC cigarettes were also rated lower on effects such as “aversiveness,” “sickness,” and “dizziness” (Refs. 390, 396, 414, 453, and 454), and higher on items such as “dislike” and “unpleasant” compared to NNC or usual brand cigarettes (Refs. 265 and 383). These seemingly contradictory findings are likely due to the constructs that these subjective effects measure; “aversiveness,” “sickness,” and “dizziness” are used to measure direct sensory and physical effects of nicotine, while “dislike” and “unpleasant” are used to measure general product liking.

Although often assumed, recent findings confirm that greater immediate positive subjective effect ratings (*e.g.*, “liking,” “satisfaction”) predict greater acute reinforcing effects of cigarettes of varying nicotine content (Ref. 455). Several factors have been shown to influence subjective effects ratings of VLNC and NNC cigarettes. These factors include participants’ ability to discriminate the nicotine content of cigarettes. For example, NNC cigarettes have increased ratings of positive subjective effects when participants are able to discriminate them from VLNC cigarettes (Refs. 400 and 401). Individuals who smoke menthol cigarettes rated both VLNC and NNC cigarettes higher in positive subjective effects compared to people who smoke nonmenthol cigarettes (Ref. 456). In addition, positive subjective effects ratings are higher when participants are told that they are receiving a nicotine-containing cigarette, regardless of the actual nicotine content of the cigarette (Refs. 428, 435, 444, 445, and 457).

Several studies assessed subjective effects of VLNC cigarettes following extended exposure when participants were given less restricted access to cigarettes of varying nicotine content in their natural environments (*e.g.*, homes, workplaces), typically over the course of

several weeks. Findings from these studies were relatively similar to findings from brief exposure studies. On average, VLNC cigarettes were rated as less appealing (e.g., lower ratings of “liking,” “satisfaction,” or “pleasure”) compared to LNC and NNC cigarettes (Refs. 249 and 384). However, at least one study found no differences in subjective effects as a function of cigarette nicotine content (Ref. 258). Positive subjective effects ratings for VLNC cigarettes were shown to remain constant or decrease over time (Refs. 249 and 373).

In a study where people who smoke inhabited a residential research facility, during 11 days of exposure, participants who received NNC cigarettes rated positive subjective effects lower and negative subjective effects higher than baseline subjective effects of usual brand cigarettes (indicative of a general dislike of research cigarettes); however, subjective ratings of NNC study cigarettes increased and were similar to usual brand cigarettes by the end of the study (Ref. 64). In contrast, participants assigned to the VLNC cigarette group rated positive subjective effects of cigarettes (e.g., “enjoyable”) lower and negative subjective effects (e.g., “unpleasant”) higher than baseline subjective effects of usual brand cigarettes throughout the entire study period (Ref. 64).

Finally, gender may influence differences in subjective effects. In one study, women rated all cigarettes as more flavorful than men, and an interaction was observed between gender and nicotine content such that women demonstrated less sensitivity than men to the differential subjective effects of NNC and VLNC cigarettes (Ref. 447). Another study found that women reported increased satisfaction with VLNC or LNC cigarettes alone, while men reported greater satisfaction when these cigarettes were combined with NRT (Ref. 458). Finally, one study found that women reported higher psychological reward than men across all nicotine contents tested (Ref. 459).

In sum, subjective effects data consistently show that VLNC cigarettes have equal or lower abuse potential compared to NNC and usual brand cigarettes under conditions of brief and extended exposure. FDA is not aware of any studies that found that VLNC cigarettes had greater abuse potential than NNC or usual brand cigarettes.

11. The Effects of VLNC Cigarettes on Relief From Craving and Withdrawal Symptoms

Symptoms of nicotine and tobacco withdrawal may include irritability,

depression, insomnia, headache, and increased craving. Although craving is often characterized as a symptom of nicotine and tobacco withdrawal, it is also a symptom of dependence, and it can occur in the absence of other withdrawal symptoms. Thus, craving is usually measured and reported separately from withdrawal. Studies typically assess craving and withdrawal using the Questionnaire of Smoking Urges (QSU), QSU-Brief, Minnesota Nicotine Withdrawal Scale (MNWS), Shiffman-Jarvik Withdrawal Scale, and Visual Analogue Scale items. Despite their lower nicotine content, VLNC cigarettes typically do not produce greater reports of craving or other withdrawal symptoms. Although findings from some brief exposure studies are mixed, the results of many studies suggest that brief and extended exposure to VLNC cigarettes can suppress craving and withdrawal just as effectively as NNC and usual brand cigarettes. The ability of VLNC cigarettes to suppress craving and withdrawal in people who smoke cigarettes is likely at least partially due to the long history of pairings between nicotine and the sensorimotor stimuli associated with smoking. Through conditioning, these stimuli can suppress craving and some other withdrawal symptoms even in the absence of nicotine (Ref. 38).

In brief exposure studies where participants were given limited access to reduced nicotine content cigarettes, typically over the course of several hours under controlled laboratory conditions, VLNC cigarettes suppressed craving and withdrawal relative to baseline measures that were typically assessed following overnight abstinence (Refs. 452, 460 to 467). Furthermore, many studies showed that VLNC cigarettes can reduce craving and withdrawal as much as usual brand or NNC cigarettes (Refs. 391, 406, 407, 411, 413, 415, 417, 419, 422, 433 to 439). However, some studies observed that suppression of craving and withdrawal was lower after smoking VLNC cigarettes compared to usual brand or NNC cigarettes (Refs. 265, 396, 388, 402, 427, 440, 453, 454, 468, and 469). In addition, results from a few studies suggest that VLNC cigarettes influence craving more than withdrawal. One study found that VLNC cigarettes suppressed craving similarly to NNC cigarettes, but also produced an increase in other withdrawal symptoms (Ref. 470). Other studies have found no effects of VLNC cigarettes on withdrawal symptoms (Refs. 414, 428, and 448). Notably, some of these brief

exposure studies reported differences between genders and generally found that females who smoke experienced greater reductions in craving (Refs. 265, 463 and 464) or withdrawal (Refs. 436 and 462) compared to males who smoke after smoking VLNC cigarettes. However, another study found that, after smoking VLNC cigarettes, males who smoke had greater reductions in craving compared to females who smoke (Ref. 435).

During extended exposure studies, when participants smoked VLNC cigarettes from 4 days to 1 year, ratings of withdrawal (Refs. 249 and 258) and craving (Refs. 249 and 383) were generally similar to ratings observed in usual brand and NNC cigarette conditions. In one study, researchers found that, after switching to VLNC cigarettes from usual brand cigarettes for 1 week, withdrawal symptoms increased with no reported change in craving (Ref. 32). However, these effects were relatively brief, and, within 6 weeks, withdrawal symptoms returned to baseline levels, and craving steadily decreased below baseline levels. Results from another study showed that VLNC cigarettes can produce persistent reductions in craving characterized by participants as “moderate” or “a lot” after 3 and 6 weeks of exposure; however, some participants reported that no relief from craving occurred during the 6-week study (Ref. 373). In addition, one study demonstrated that 6 weeks of exposure to LNC and VLNC cigarettes resulted in less craving and no difference in other withdrawal symptoms compared to NNC cigarettes (Ref. 471). Finally, during week 1 of a 20-week trial, people who smoke and were randomized to immediately reduce nicotine with VLNC cigarettes reported statistically significantly more withdrawal symptoms compared to those who gradually reduced nicotine content every 4 weeks (15.5 (NNC), 11.7 (NNC), 5.2 (LNC), 2.4 (LNC), and 0.4 (VLNC) mg nicotine per gram of total tobacco, respectively) and compared to a control group using NNC cigarettes (Ref. 379). However, at the conclusion of 20 weeks, the immediate reduction group reported statistically significantly lower smoking urges compared with the gradual reduction group and the NNC cigarette control group. No statistically significant differences in smoking urges were observed between the gradual reduction group and the NNC cigarette control group, suggesting that gradual reduction may be less effective than immediate reduction in reducing urge to smoke. Similar to findings from brief exposure studies, female participants

experienced a reduction in craving after switching to LNC cigarettes for 1 week, whereas male participants showed no change in craving upon switching. Overall, withdrawal symptoms increased in both males and females who smoke cigarettes after 1 week. However, these differences from baseline were short-lived. Ratings of both craving and withdrawal symptoms were no different than baseline over the remaining 6 weeks of the study (Ref. 458).

Craving and withdrawal were also assessed in several smoking cessation studies wherein participants were provided VLNC cigarettes along with pharmacotherapies (*e.g.*, NRT, varenicline) before a designated quit date. In these studies, participants who received VLNC cigarettes plus a nicotine patch experienced less severe cravings, with no statistically significant difference in withdrawal (Ref. 472), a greater reduction in craving and withdrawal (Ref. 35), and less frequent and less intense cravings before and after the quit date (Ref. 372) compared to those who received NNC cigarettes before the quit date. Another study found that LNC cigarettes plus either varenicline or NRT resulted in decreases in craving compared to pharmacotherapy alone, with no differences in withdrawal across groups (Ref. 371).

Accordingly, findings from these studies suggest that the maximum nicotine level in this proposed product standard, consistent with VLNC cigarette levels, would not result in substantial increases in craving or other withdrawal symptoms.

12. VLNC Cigarette Data Applies to Other Covered Products Under This Proposed Product Standard

Research regarding the public health impacts of this proposed maximum nicotine level applies across the tobacco products covered under this proposed product standard. People who smoke cigarettes who have lower SES have a greater likelihood of choosing to use RYO tobacco as a cheaper alternative to factory-made cigarettes (Ref. 312, Ref. 319). Also, literature shows that tobacco manufactures reformulate or re-label pipe tobacco as “dual purpose” and sell it for RYO use to capitalize on disparities between tax rates on different types of tobacco products (Ref. 322). Given that cigarette tobacco, RYO tobacco, and pipe tobacco can be effectively used in cigarettes, the VLNC cigarette research applies to these products, and any expected benefits that would accrue as a result of instituting the proposed product standard for

cigarettes also would be expected to accrue for these product categories.

While the current published literature regarding very low nicotine products discusses only cigarettes, the many similarities between cigarettes and most cigars (in both appearance and use topography) support the application of VLNC cigarette research to the coverage of these cigars. For example, little cigars are often indistinguishable from cigarettes given their shape, size, filters, and packaging, and are perceived as being healthier than cigarettes (Refs. 297 and 298). Little cigars and certain cigarillos also “are packaged and consumed in a manner similar to cigarettes” (Ref. 473 at p. 584). The close resemblance of little cigars and many cigarillos to cigarettes have led consumers, particularly children and young adults, to mistake them for cigarettes (Ref. 474). Because they are physically similar to cigarettes, little cigars are generally smoked the same way as cigarettes, with deeper inhalation than large cigars (Refs. 53 and 475). Secondhand smoke from cigars also contains many of the same toxins and carcinogens as cigarette smoke, including carbon monoxide, nicotine, ammonia, benzene, nitrosamines, and formaldehyde, all of which are on FDA’s list of HPHCs (HPHC Established List, 77 FR 20034 (2012)). Moreover, people who smoke cigarettes who switch to products like cigars to sustain their addiction tend to engage in deeper inhalation, making them even more susceptible to the dangers associated with tobacco product use (Ref. 53).

Studies also suggest that people smoke some cigarillos like cigarettes, inhaling and smoking them every day (Refs. 53 and 475). Research has found that little cigars deliver nicotine levels similar to, and sometimes higher than, cigarettes, as well as similar or higher levels of carcinogens compared to cigarettes (Refs. 476 and 477). Large cigars can deliver as much as ten times the nicotine of a filtered cigarette (Ref. 53). Even if people who smoke cigars do not breathe or inhale smoke into their lungs, they are still subject to nicotine’s addictive effects through buccal absorption of nicotine or nicotine absorption through the lips due to cigar tobacco’s alkalinity (Refs. 54 to 56, 302 and 303). Cigar smoke dissolves in saliva and makes it possible for people who smoke cigars to absorb sufficient amounts of nicotine to create dependence (Ref. 56). People who smoke cigars regularly are at increased risk for many of the same diseases as people who smoke cigarettes, including oral, esophageal, laryngeal, and lung

cancer; cardiovascular diseases; and COPD (Ref. 163). Accordingly, FDA believes it is appropriate to bridge these VLNC cigarette studies to cigars.

C. An Immediate Nicotine Reduction Approach Is Strongly Supported by Scientific Evidence

Two approaches have been suggested for implementing a nicotine product standard that would limit nicotine yield by establishing a maximum level of nicotine content in cigarettes and certain other combusted tobacco products. One is a gradual reduction approach, which decreases the nicotine content in the tobacco products over time until it reaches minimally addictive or nonaddictive levels. The other is an immediate reduction approach, or single target approach, which would immediately reduce the nicotine content to minimally addictive or nonaddictive levels. Available research indicates that both approaches are associated with noncompliance (*i.e.*, use of NNC cigarettes) when participants reach the VLNC cigarette phase of the intervention, which supports findings from other studies that show people who use VLNC cigarettes are more likely to use alternative nicotine-containing products when such products are concurrently available. However, the available scientific evidence suggests that the gradual approach can lead to compensatory smoking during the intermediate steps when people are smoking products with low to moderate nicotine content.

Based on scientific evidence, as well as comments and information submitted in response to the Nicotine ANPRM, FDA is proposing an immediate reduction approach to reach the maximum nicotine level in this proposed product standard. We expect that there would be very little compensatory smoking with an immediate reduction approach and that any compensatory smoking would be self-limiting and transient (*i.e.*, research shows that people who smoke would be unable to obtain their nicotine dose from VLNC cigarettes no matter how they smoked them and would quickly stop trying to do so), which would increase the benefits of the proposed product standard. We anticipate most people who smoke will maintain usual smoking behavior during these 2 years. An attempt to taper nicotine intake could involve switching to VLNC cigarettes already on the commercial market (*i.e.*, VLN® cigarettes), reducing the number of cigarettes smoked per day, or switching to another tobacco product. Tapering nicotine intake while

NNC cigarettes are on the market may facilitate abstinence in smokers by increasing motivation to quit and quit attempts. However, we do not expect most people who smoke to switch to VLNC cigarettes while NNC cigarettes are available. We request comments, data, and information regarding the selection of an immediate reduction approach.

Several studies have investigated the effects of a gradual approach to reducing cigarette nicotine content on compensatory smoking (Refs. 40, 258, 329, and 384). In these studies, participants were not interested in quitting and did not receive NRT or alternative tobacco products. For example, a pilot study and a clinical trial examined whether a gradual reduction in cigarette nicotine content would increase exposure to tobacco smoke toxins due to compensatory smoking (Refs. 40 and 258). Participants smoked their usual brand cigarettes during baseline and then were switched to five types of research cigarettes containing gradually reduced nicotine content (*i.e.*, 10.3 (NNC), 6.5 (LNC), 3.9 (LNC), 1.7 (LNC), and 0.5 (VLNC) mg nicotine per cigarette). In the 10-week pilot study, participants were switched weekly, and in the 6-month trial, participants were switched monthly (Refs. 40 and 258). Little change in smoking behavior was observed; however, plasma cotinine concentration (a biomarker of nicotine exposure) decreased as a function of cigarette nicotine content, such that cotinine was lowest while participants were smoking VLNC cigarettes. The smaller pilot study showed little evidence of compensation, as calculated based on cigarette consumption, CO, and polycyclic aromatic hydrocarbon (PAH) metabolites (Ref. 40); however, the 6-month trial showed a slight increase in compensatory smoking, as measured by CO and CPD, while participants were in the intermediate phase of the study. This increase was no longer evident once participants reached the VLNC cigarette phase of the study (Ref. 258).

Another study showed that compensatory smoking may increase when participants smoke cigarettes with intermediate levels of nicotine (*e.g.*, LNC cigarettes) compared to usual brand cigarettes (Ref. 384). Taken together, these studies demonstrate that people who smoke cigarettes may engage in compensatory smoking during the early stages of a gradual reduction approach by smoking more intensely in an attempt to obtain their desired level of nicotine (Refs. 258, 329, and 369).

Several studies have investigated whether an immediate reduction

approach to nicotine reduction would increase compensatory smoking (Refs. 29 and 31). Like the gradual reduction studies discussed in this section, participants in these immediate reduction studies were not interested in quitting and did not receive NRT or alternative tobacco products. In the most comprehensive immediate nicotine reduction study to date, 839 participants were randomized to one 6-week condition, during which they smoked their usual brand cigarettes or immediately switched to research cigarettes containing either 15.8 (NNC), 5.2 (LNC), 2.4 (LNC), 1.3 (LNC), or 0.4 (VLNC) mg nicotine per gram of total tobacco (Ref. 29). Participants assigned to the LNC or VLNC cigarette groups, who received cigarettes with nicotine content less than or equal to 2.4 mg nicotine per gram of total tobacco, smoked statistically significantly fewer CPD than participants assigned to the usual brand and NNC cigarette groups. Those who received LNC or VLNC cigarettes containing 5.2 mg nicotine per gram of total tobacco or less had statistically significantly lower urinary TNE than those who received NNC cigarettes. There were no differences in breath CO measures, an indicator of compensatory smoking, between the cigarette groups. The total puff volume at week 6 was statistically significantly lower among participants who smoked VLNC cigarettes compared to those who smoked NNC cigarettes. However, much like the gradual reduction studies, a secondary analysis showed that noncompliance (*i.e.*, ongoing use of NNC cigarettes or other tobacco products) was high in participants randomized to the VLNC cigarette group, suggesting that VLNC cigarettes have lower appeal and abuse liability compared to NNC cigarettes and that people who smoke VLNC cigarettes are likely to obtain nicotine from other tobacco product use (Ref. 330).

In another study, 33 participants were randomized to receive VLNC cigarettes at no charge or to continue smoking their usual brand cigarettes for 12 weeks (Ref. 31). Overall, participants in both groups smoked a similar total number of CPD, even though only the participants in the VLNC cigarette group received free cigarettes. These data demonstrate that an immediate reduction in cigarette nicotine content is unlikely to lead to significant compensation or increased toxicant exposure.

A secondary analysis pooled data from five clinical studies to examine the relationship between compensatory smoking and gradual versus immediate nicotine reduction approaches (Ref. 387). Two of the studies utilized a

gradual reduction approach, and three of the studies utilized an immediate reduction approach. CPD, breath CO, and cotinine levels were compared between the immediate reduction group, the gradual reduction group, and a control group that received usual brand cigarettes. Relative to baseline, statistically significant decreases in CPD were observed in participants in the gradual reduction groups (5 percent decrease in CPD) and immediate reduction groups (11 percent decrease in CPD), whereas statistically significant increases in CPD were observed in participants in the usual brand groups (12 percent increase in CPD). Although statistically significant changes in breath CO were not observed relative to baseline in any group, statistically significant decreases in cotinine were observed among both gradual and immediate reduction groups, but not in the usual brand group.

The largest study designed to directly investigate gradual versus immediate nicotine reduction on toxicant exposure was a 10-site, randomized, double-blind clinical study in 1,250 adults who smoke and had no intention to quit (Ref. 379). Participants were randomly assigned to an immediate reduction group that received VLNC cigarettes for 20 weeks, a gradual reduction group that received cigarettes containing progressively decreased nicotine content every 4 weeks (15.5, 11.7, 5.2, 2.4, 0.4 mg nicotine per gram of total tobacco) for 20 weeks, or a control group that received NNC cigarettes for 20 weeks. Notably, in this study (and virtually all clinical studies of reduced nicotine content cigarettes), research cigarettes were free to participants. Any changes in biomarker levels observed between these two groups would indicate differences in smoking behavior (*e.g.*, CPD, smoking topography). Completion rates were statistically significantly lower for the immediate reduction group (68 percent) compared to the gradual reduction group (81 percent) and control group (86 percent). The immediate reduction group had statistically significantly lower levels of three primary biomarker outcomes (*i.e.*, CO, 3-HPMA, and *r*-1,*t*-2,3,*c*-4-tetrahydroxy-1,2,3,4-tetrahydrophenanthrene) compared to the gradual reduction group, which did not differ from the control group. In addition, statistically significantly lower levels of other biomarkers (*i.e.*, TNE, NNAL, 2-cyanoethylmercapturic acid, 3-hydroxy-1-methylpropylmercapturic acid, S-PMA) were observed in the immediate reduction group compared to the gradual reduction and the control

groups. The immediate reduction group smoked cumulatively fewer CPD over the course of the 20-week study and had lower nicotine dependence scores compared to the gradual reduction group, with no statistically significant differences in CPD or dependence in the gradual reduction versus control groups. While there was no statistically significant difference between the immediate and gradual reduction groups in the proportion of participants with any “cigarette-free days” during the study, the immediate reduction group had a statistically significantly higher number of “cigarette-free days” compared to the gradual reduction group. The immediate reduction group had statistically significantly higher withdrawal scores at week 1 compared to the gradual reduction group; however, these differences dissipated after the first week. The immediate reduction group had higher rates of noncompliance with non-study cigarette use and a higher drop-out rate, which may have impacted the various outcome measures (e.g., biomarkers of exposure). Additionally, the immediate reduction group had an increased number of adverse events (predominantly related to withdrawal) compared to the gradual reduction group. Nevertheless, this study provides further evidence that immediate nicotine reduction is associated with reduced toxicant exposure and nicotine dependence and increased smoking abstinence compared to gradual nicotine reduction. This suggests that with immediate nicotine reduction, the potential health benefits could occur sooner than gradual nicotine reduction. While the immediate reduction group had increased levels of nicotine withdrawal, this effect was time-limited, dissipating after 1 week (Ref. 379).

Higher study attrition and noncompliance with study cigarettes are common within VLNC cigarette conditions in clinical studies (Refs. 327, 329, and 330), especially studies such as the one described above (Ref. 379), wherein participants are not interested in quitting smoking, and they are asked to refrain from using alternative sources of nicotine. Because of the lower abuse liability of VLNC cigarettes, participants in these studies may drop out or use non-study cigarettes that contain nicotine. These conditions would not exist if the proposed product standard is implemented. People who smoke would not be able to readily obtain NNC cigarettes, but they would be able to obtain alternative noncombusted products with nicotine content that they

could switch to or use with VLNC cigarettes.

In sum, evidence from studies involving VLNC cigarettes suggests it is likely that there would be very little or no compensatory smoking with an immediate reduction approach to a maximum nicotine level, which would increase the public health impact of a nicotine reduction policy. Additionally, FDA believes an immediate reduction approach would have a lesser impact on manufacturers as compared to a gradual approach by limiting any changes necessary for compliance to a single occasion. Although FDA believes this is a benefit of the immediate reduction approach, it is not a determinative factor given the strength of the scientific evidence.

D. Scientific Evidence Supports the Use of an Analytical Test Method To Determine Nicotine Level

In its considerations regarding the use of an analytical test method, FDA determined that any analytical method to measure compliance must accurately and reliably detect nicotine at low concentrations (i.e., below 0.70 mg nicotine per gram of total nicotine). In addition, FDA determined that it is important that the proposed product standard permit comparison of test results among finished tobacco products and testing facilities. FDA also concluded that it is important that the test method demonstrate its suitability and reliability in accurately measuring a range of nicotine concentrations across a wide variety of tobacco blends and products. Accordingly, FDA is proposing to require manufacturers use an analytical test method that would satisfy these preceding factors and demonstrate that the test method was validated in an analytical test laboratory. In lieu of requiring a specified test method, we are recommending manufacturers consider using one of the three following analytical test methods FDA has determined satisfy the preceding factors: FDA’s Tobacco Products Laboratory method (Ref. 478), Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) Recommended Method (CRM) No. 62 (Determination of nicotine in tobacco and tobacco products by gas chromatographic analysis; (Ref. 479)), or CRM No. 87 (Determination of nicotine in tobacco products by gas chromatography-mass spectrometry (GC-MS); (Ref. 480)). However, an analytical test method that meets the requirements of the regulation, even if it is not one of the recommended methods, would be acceptable.

FDA’s Tobacco Products Laboratory, located in Atlanta, Georgia, has developed an analytical test method, entitled “Quantitation of Nicotine in Tobacco Products—Update to LIB No. 4550” (LIB #4692), that is capable of quantifying nicotine levels that include concentrations well above and below the proposed nicotine standard level and also meets formal intralaboratory validation criteria (Ref. 478). The method utilizes GC-MS with a run time of 4.1 minutes. Analysis is conducted on extracted tobacco or spiked surrogate matrix samples treated with a base (sodium hydroxide) to obtain the total nicotine content for each sample. Quinoline is used as the internal standard. Tomato leaves are used as a surrogate matrix for tobacco to examine recovery amounts for spiked samples. Validation was performed using Moonlight brand VLN Menthol King ground tobacco and NIST 1573a (Tomato Leaves) as a blank spiking matrix. The range of the method was 0.1 to 2.0 mg of nicotine per gram of total tobacco, meaning nicotine concentrations in this range can be accurately measured. Tobacco samples with nicotine concentrations expected to be higher than 2.0 mg nicotine per gram of total tobacco were analyzed after dilution of the extraction sample by a factor of ten. The method detection limit is 0.05 mg nicotine per gram of total tobacco, which is more than an order of magnitude below the proposed maximum nicotine concentration of 0.70 mg per gram of total tobacco. The limit of quantitation is 0.1 mg nicotine per gram of total tobacco, which is also well below the limit of the proposed product standard. Furthermore, this method was proven to be applicable to a wide range of tobacco products. Tobacco filler and total tobacco from various marketed tobacco products including cigarettes, large cigars, cigarillos, little cigars, RYO cigarettes and pipe tobacco were analyzed successfully using FDA’s Tobacco Products Laboratory method.

CORESTA updated CRM No. 62 (Determination of Nicotine in Tobacco and Tobacco Products by Gas Chromatographic Analysis) in December 2021 and CRM No. 87 (Determination of Nicotine in Tobacco Products by Gas Chromatography-Mass Spectrometry (GC-MS)) in April 2020 to extend the scope of the methods to include VLNC tobacco by lowering the calibration range for these analytical test methods (Refs. 479 and 480). A study determined that the updated versions of CRM No. 62 and CRM No. 87 are suitable for the analysis of nicotine content in VLNC

tobacco and tobacco products (Ref. 481). These methods can reliably measure nicotine content as low as 0.117 mg per gram of total tobacco.

FDA's Tobacco Products Laboratory method, entitled "Quantitation of Nicotine in Tobacco Products—Update to LIB No. 4550" (LIB #4692), is publicly available at <https://www.fda.gov/science-research/field-science-and-laboratories/laboratory-information-bulletins>. In addition to the Tobacco Products Laboratory method, CRM No. 62 (<https://www.coresta.org/determination-nicotine-tobacco-and-tobacco-products-gas-chromatographic-analysis-29185.html>) and CRM No. 87 (<https://www.coresta.org/determination-nicotine-tobacco-products-gc-ms-33537.html>) are also publicly available methods that include the proposed nicotine level in the range of concentrations that can be accurately measured. FDA recommends manufacturers use one of these analytical test methods to demonstrate compliance with this proposed product standard.

It is reasonable to expect some manufacturers may prefer to use other test methods. If developed and validated, such methods may have different advantages in ease of use, upper and lower bounds of detection, equipment, and expertise. We would evaluate data from analytical test methods as part of a premarket submission in accordance with section 910 of the FD&C Act.

FDA requests comments, including data or other scientific support, regarding FDA's Tobacco Products Laboratory method, CRM No. 62, CRM No. 87, or other available methods, that could test the proposed scope of tobacco products at the proposed maximum nicotine level.

E. Scientific Evidence Supports the Technical Achievability of the Proposed Maximum Nicotine Level Target

While FDA has analyzed various methods of technical achievability for this proposed product standard, section 907(b)(1) of the FD&C Act also requires FDA to consider information submitted in connection with the proposed product standard regarding the technical achievability of compliance. Therefore, pursuant to section 907(d)(2) of the FD&C Act, FDA requests comments by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with this proposed product standard, including information concerning the existence of patents that may impact the ability to comply by the proposed 2-year effective

date of this proposed rule (see section XI of this document).

The tobacco industry has developed a range of brands with differing nicotine levels. Tobacco product manufacturers have extensive experience blending tobaccos with different nicotine levels to ensure that products will have precise levels of nicotine and using continuous quality testing throughout the entire process to ensure that nicotine levels vary only minimally within cigarette packs and from pack to pack (Ref. 482). A cigarette is an inexpensive and extremely effective nicotine delivery system that maximizes the cigarette's addicting and toxic effects (Ref. 61).

In fact, the tobacco industry has had programs in place since the 1960s to obtain "any level of nicotine desired" (Ref. 2) (see section V.A for a detailed discussion). Indeed, the tobacco industry conducted research on consumer perceptions of RNC cigarettes to determine the optimal amount of nicotine in cigarettes to maintain appeal. Reviews of industry documents indicate that user experience, such as poor taste and reduced throat sensations, impacted the commercial viability of VLNC cigarettes (Refs. 247, 483, and 484). Internal industry strategies to mitigate these issues and maintain VLNC cigarette appeal to consumers included adding menthol to enhance the flavor of RNC cigarettes (Ref. 484) and maintaining or increasing tar levels to improve taste (Ref. 483).

As discussed in this section, there are numerous methods for altering the concentration of nicotine in cigarettes and certain other combusted tobacco products, and FDA anticipates that manufacturers and tobacco farmers may choose to use a variety of approaches to meet the proposed maximum nicotine concentration. Significant reduction of nicotine in the tobacco products covered by this proposed product standard can be achieved principally through tobacco blending, chemical extraction, or genetic engineering. Other practices such as modified growing conditions (e.g., discontinue the practice of topping where the flowering head of the tobacco plant is removed to produce leaves with a significantly higher nicotine content, increase plant density, decrease nitrogen application), as well as more recent novel techniques, can also help to reduce nicotine levels. One or a combination of these processes can be used to achieve the nicotine target concentration in this proposed product standard.

1. Genetically Engineered Tobacco

Tobacco industry scientists have long recognized the potential for genetic engineering to control nicotine content (Ref. 485). The first practical application of biotechnology by a major tobacco manufacturer was the development of low nicotine content tobacco in the 1980s, which led to the receipt of a patent for biotechnology for altering nicotine in tobacco plants (Refs. 483 and 486). Other tobacco researchers and major manufacturers also recognized the value of biotechnology for developing low nicotine content tobacco for cigarettes, including for use as part of a smoking cessation program (Ref. 487).

In the 1930s, some Havana and Cuban cigar tobacco varieties were discovered to have naturally lower nicotine levels. Genetic analysis of these low nicotine containing plants identified a mutation in the *nic1* and *nic2* genes that are responsible for the production of reduced nicotine in some tobacco variety leaves (Ref. 488). These varieties of low nicotine content cigar tobacco were crossbred with burley tobacco to produce varieties of cigarette tobacco with low nicotine content to meet the health demands of the time (Ref. 489).

Several American and international tobacco companies genetically engineered low-nicotine strains in the 1960s and 1970s (Refs. 490 to 493), including a strain with a nicotine concentration as low as 0.15 percent (i.e., 1.5 mg nicotine per gram of total tobacco), which was much lower than the 3.15 percent (31.5 mg nicotine per gram of total tobacco) observed in the comparator strain (Ref. 492). During that time period, the Kentucky Tobacco Research Board worked on genetic strains of low nicotine content tobacco (with a nicotine content of 0.2 percent) to be used for experimental studies on the role of nicotine in smoking behavior (Refs. 493 to 497). In addition, Canadian researchers examined low nicotine strains of tobacco, particularly in association with efforts to develop a strain of flue-cured or air-cured tobacco that would be suitable as the base material for reconstituted tobacco (Refs. 493, 498, and 499). Although the early strains of low-nicotine tobacco that were developed by these researchers and companies contained far less nicotine than strains that were traditionally used to make cigarettes, the nicotine content is even lower in strains that have been developed more recently through genetic engineering.

Genetic engineering has resulted in up to a 98 percent reduction in nicotine levels (Ref. 483). In 2003, Vector Tobacco began marketing the Quest

cigarette produced from genetically modified tobacco containing only trace amounts of nicotine (this product is no longer on the market) (Ref. 483). In 2014, the U.S. Patent and Trademark Office granted a patent for two genes that may be suppressed to substantially decrease nicotine in tobacco plants (Ref. 500). Additionally, in 2020, the U.S. Patent and Trademark Office granted another patent for methods of manipulating plant metabolism and alkaloid levels by controlling transcription factor NbTF7, which regulates the nicotinic alkaloid biosynthetic pathway in the *Nicotiana tabacum* plant (Ref. 501). This method appears to be able to introduce very low nicotine traits in any variety of *Nicotiana tabacum*; therefore, this method may be applicable to other combusted tobacco products that use *Nicotiana tabacum* (e.g., cigars).

Significant progress has been made in the genetic modification of nicotine and other alkaloid production in tobacco. One powerful gene editing technology, CRISPR-Cas9, has been used to delete or silence various genes involved in the production of nicotine in tobacco plants resulting in several ultra-low nicotine CRISPR tobacco lines that have been grown experimentally (Ref. 502). However, challenges have presented themselves in transitioning these ultra-low nicotine content tobacco plants to fields, such as severely stunted plants and high insect infestation rates (Ref. 503). Studies on the impact of genetically engineered low-level nicotine are ongoing and this method has not been accomplished on a large scale.

FDA is aware that genetically engineered tobacco seed has been created and may be available for purchase on the market. If this proposed rule is finalized, licensing agreements may be needed to support production of VLNC tobacco, at least initially. FDA notes that similar agreements with tobacco manufacturers are common within the tobacco industry.

2. Chemical Extraction

Another method to achieve lower nicotine concentrations in tobacco products is through chemical extraction technology. By the 1970s, tobacco manufacturers were regularly practicing nicotine extraction as a method to control nicotine delivery (Refs. 493 and 504 to 506). Extraction methods include water extraction (coupled with steam or oven drying), solvent extraction, and extractions of nicotine without usable leaf (Ref. 493). For example, one company, Ultratech, Inc., produced VLNC cigarettes by extracting nicotine

with an alkaline solution (Ref. 507). Supercritical fluid extraction (which extracts chemical compounds using supercritical carbon dioxide instead of an organic solvent) also yielded success in the 1990s, allowing for optimum extraction times and the elimination of more time-consuming steps (Ref. 508). FDA notes that existing patents for chemical extraction reveal that more than 96 percent of nicotine can be successfully extracted from tobacco while retaining “a strong characteristic aroma . . . not different from the unextracted blend,” achieving a product that “was subjectively rated as average in nicotine characteristics” (Refs. 509 and 510). A major tobacco manufacturer also has used a high-pressure carbon dioxide process similar to the process used to decaffeinate coffee. In this process, tobacco leaf is treated with ammonium salt, and then treated with carbon dioxide/water vapor, to achieve a 95 to 98 percent reduction in nicotine (Refs. 483 and 511).

Water extraction also can be used for nicotine reduction. Although some manufacturers believe that some water extraction practices may have rendered the tobacco “unsuitable for use” in cigarettes, other water extraction projects have yielded suitable smoking material with sizeable nicotine reductions (80 to 85 percent reduction in leaf nicotine) (Refs. 493, 505, 512, and 513).

3. Tobacco Farming Practices

Different types of farming practices also can lower nicotine concentrations in tobacco plants. One example is alkaloid-minimizing farming practices. Industry studies have shown that changes to growing and harvesting practices affect the development of tobacco chemistry, including nicotine content (Ref. 493). Some manufacturers have revised their agricultural practices specifically to meet new product development goals, such as the production of low nicotine content tobacco (Ref. 493). For example, one manufacturer evaluated how various experimental agricultural practices including bulk-curing, once-over harvesting, and high plant density could affect the tobacco’s chemistry (Refs. 493 and 514). In other cases, chemical agents were observed to reduce nicotine content (Refs. 493, 515 to 517).

Modification of tobacco growth practices can result in reduced levels of nicotine in tobacco plants. In traditional tobacco production, plants are topped and suckered (removing the growth at the apex and axillary buds) to slow the ripening rate of the leaves resulting in increased nicotine content. Therefore,

discontinuing these practices results in a significant decrease in nicotine production (Ref. 518). It has been found that plant density is conversely correlated to nicotine production in the plant as increased plant density creates a competition for resources, particularly nitrogen. Therefore, higher plant densities lead to lower nitrogen availability and stunted plant growth, thus resulting in lower nicotine tobacco (Ref. 519).

Nightshades are a botanical family that naturally contain alkaloids, including nicotine. In addition to tobacco plants, tomatoes, eggplants, potatoes, and peppers are in the nightshade category. Nicotine synthesis begins in the root of the tobacco plant and researchers have studied whether replacing tobacco root with other nightshades via grafting could affect nicotine biosynthesis (Ref. 519). Studies have been performed where grafting tobacco shoots on rootstocks of eggplant was shown to reduce nicotine production drastically without significant changes to the development of the plants (Ref. 520). Eggplant grafting results in differential expression of hundreds of genes involved in the nicotine biosynthetic pathway (Ref. 520). In these studies, no significant differences in plant height, leaf length, leaf width, or stalk circumference were observed between the tobacco/tobacco and tobacco/eggplant groups up to 80 days after grafting. However, the grafted tobacco/eggplant leaves resulted in a 95 percent reduction in nicotine content as compared to the tobacco/tobacco control plants (Ref. 520).

4. Tobacco Blending/Crossbreeding

One way to achieve lower nicotine concentrations in tobacco products is to selectively blend the tobacco filler. Most cigarettes sold in the United States are blended from several different types of tobacco (Ref. 359). A tobacco industry executive previously testified that the main component of a cigarette that contributes to nicotine delivery is the tobacco blend, and year-to-year crop variation does not determine the nicotine content in a cigarette (Ref. 521). The term “leaf blending” describes the selection of tobaccos to be used in a product by tobacco type (e.g., flue-cured, burley, oriental), geographical origin, year, and tobacco grade (Ref. 493). Blend differences can produce significant variations in nicotine concentration in the tobacco rod, leading to differences in smoke composition and yield (Ref. 82 at p. 469).

Many tobacco strains are available, including approximately 1,000 different

tobacco varieties (Ref. 359). The tobacco industry has used breeding and cultivation practices to develop high nicotine tobacco plants to give manufacturers greater flexibility in blending and in controlling the amount of nicotine to be delivered (Ref. 522 at 41694). These practices could be used to develop low nicotine content tobacco plants as well. Tobacco industry documents show that in the 1960s, tobacco companies recognized the increasing demand for low nicotine content tobacco and began instituting projects that found low nicotine content cigarettes can be made by selecting grades of tobacco with low nicotine content (Refs. 523 and 524).

Because the nicotine content of tobacco plants varies, manufacturers could replace more commonly used nicotine-rich varieties like *Nicotiana rustica* with lower nicotine varieties (Ref. 525). For example, oriental Turkish-type cigarettes also deliver substantially less nicotine than cigarettes that contain air-cured burley tobacco (Refs. 82 and 526). Even without this selective breeding, manufacturers could use careful tobacco leaf purchasing plans to control the nicotine content in their products (Ref. 522 at 41694). By maintaining awareness of the differences and monitoring the levels in purchased tobacco, companies could produce cigarettes with nicotine deliveries consistent to one-tenth of 1 percent (despite annual variations of up to 25 percent in the nicotine content of the raw material grown in the same area) (Ref. 522 at 41694).

Grading, which is used to evaluate and identify differences within tobacco types, is a function of both plant position (*i.e.*, higher or lower leaf position on the stalk) and quality (*i.e.*, ripeness), and segregation of grades by nicotine content has become common practice (Ref. 493). The position of leaves on the plant stalk affects nicotine levels: tobacco leaves located near the top of the plant can contain higher concentrations of nicotine, and lower stalk leaves generally contain lower nicotine levels (Refs. 493, 525, and 527). For example, flue-cured tobacco leaves harvested from the lowest stalk position may contain from 0.08 to 0.65 percent nicotine (*i.e.*, 0.8 to 6.5 mg nicotine per gram of total tobacco), whereas leaves from the highest positions may contain from 0.13 to 4.18 percent nicotine (*i.e.*, 1.3 to 41.8 mg nicotine per gram of total tobacco) (Refs. 359, 528 and 529). Therefore, substituting leaves found lower on the plants (commonly called “priming”) could reduce the nicotine content of tobacco products (Ref. 525).

Internal tobacco industry documents describe the use of leaf blending and tobacco selection to control cigarette nicotine content (Ref. 493). For example, one company project determined that manufacturers could reduce cigarette nicotine content by selecting grades of tobacco with naturally low nicotine content (Ref. 523). Another observed that the demand for low nicotine content tobacco has increased worldwide and necessitated a shift in purchasing standards (Ref. 524).

5. Other Practices

After tobacco is harvested, it is cured and aged before being used in tobacco products. The aging process naturally changes the chemistry of the tobacco, including some reduction in nicotine content (Ref. 493). At least one manufacturer has explored efforts to speed the tobacco aging process, in part to alter or limit the changes in chemistry that naturally occur (Refs. 493 and 530). Other approaches to curing and fermenting tobacco have been explored as methods for altering nicotine content. For example, in one manufacturer’s report, researchers observed that the properties of tobacco, including nicotine content, could be altered without the need for nontobacco additives by modifying curing practices (Ref. 531). In addition, manufacturers have explored other approaches to identify microbial bacteria that actively degrade nicotine while leaving other components of the leaf intact (Refs. 532 and 533). Consumer product testing showed that the “product acceptability” of that tobacco was equal to that of untreated tobacco (Ref. 534).

Researchers also have developed novel approaches to reducing the nicotine in tobacco products in recent years. An example of one such approach is enzymatic digestion utilizing glucose oxidase harvested from the salivary excretion produced by a specific species of herbivorous caterpillar, *helioverpa zea* (Ref. 535). The extracted enzyme is applied to the harvested tobacco leaves, reducing the nicotine in the tobacco leaf by up to 75 percent, providing an “effective and economical system for producing tobacco products which contain about 0.01 mg nicotine per cigarette or less . . . while maintaining the other desirable ingredients for good taste and flavor” (Ref. 535). Another novel approach is the use of microwave-assisted technology to extract nicotine from tobacco, including cigar filler (Ref. 536), that also could be effective for reducing the nicotine content for other tobacco products such as RYO tobacco and pipe tobacco.

By using one or a combination of methods described above, FDA concludes there is ample evidence of the technical feasibility of complying with this proposed product standard to reduce the nicotine level in cigarettes and certain other combusted tobacco products.

6. Applicability to Other Combusted Tobacco Products and Smaller Manufacturers

FDA anticipates that manufacturers of non-cigarette tobacco products covered by this proposed product standard may also choose to use a variety of approaches to meet the proposed maximum nicotine level. Given the similarities between the tobacco used in cigarettes and in other combusted tobacco products that FDA proposes to include within the scope of this product standard, FDA expects that it is similarly technically feasible for non-cigarette tobacco products to comply with the proposed maximum nicotine level. FDA requests comments, data, and research regarding the feasibility of using the techniques discussed in this section, or other nicotine reduction techniques, for the non-cigarette products covered under this proposed product standard.

Although industry documents contain little information regarding feasibility of VLNC levels for non-cigarette products, an early 1962 patent does indicate a tobacco storage process that dramatically reduced nicotine levels, including in shade-grown Connecticut tobacco used for cigars, from 0.85 percent to 0.075 percent nicotine content (*i.e.*, from 8.5 to 0.75 mg nicotine per gram of total tobacco) (Ref. 537). In 1975, a large tobacco manufacturer also discussed development of a low nicotine cigar or cigarillo, including processed low nicotine content tobaccos such as a burley filler in the range of 0.34 percent nicotine (*i.e.*, 3.4 mg nicotine per gram of total tobacco) and methods for reducing nicotine in the cigar wrapper (Ref. 538).

FDA expects that smaller manufacturers may use a variety of methods to comply with the proposed product standard, including purchasing tobacco blends that are lower in nicotine or have already undergone extraction. FDA believes that the supply chain should be capable of adapting to the purchasing needs of smaller manufacturers as well as larger manufacturers, particularly given the prevalence of genetically engineered tobacco, as discussed in this section. FDA requests comments, including data and research, regarding the methods and

options smaller manufacturers may use to comply with this proposed product standard.

F. Proposal Does Not Seek To Limit Nicotine to Zero

Section 907(d)(3) of the FD&C Act expressly prohibits FDA from requiring the reduction of the nicotine yield of a tobacco product to zero, and consistent with that provision FDA is not seeking to do so. However, section 907(a)(4)(A)(i) of the FD&C Act expressly authorizes FDA to establish product standards with provisions “for nicotine yields,” which includes the authority to include a provision, such as the one in this proposed rule, to require reduction of nicotine yield to a level other than zero. The information provided in this section demonstrates that the proposed product standard does not require the level of nicotine to be zero. The level of nicotine proposed in this product standard is measurable in the tobacco filler and in the smoke yield. Research shows that after use of VLNC cigarettes, nicotine is measurable in the body via biomarkers of exposure and neurological receptor occupancy.

1. Nicotine Biomarkers of Exposure

Studies have shown that levels of nicotine biomarkers increase in people who smoke cigarettes containing nicotine equivalent to FDA’s proposed nicotine level, thereby demonstrating exposure to nicotine from smoking VLNC cigarettes (Refs. 259, 402, and 539). Short-term studies that measure nicotine exposure in people who smoke cigarettes who smoke one or two VLNC cigarettes have generally found increases in plasma nicotine levels that follow similar, but less dramatic, patterns seen following smoking regular nicotine cigarettes. For example, one study evaluated plasma nicotine exposure before and repeatedly after smoking a single NNC, LNC, VLNC, or usual brand cigarette (Ref. 402). While the LNC and VLNC cigarettes were associated with lower plasma nicotine levels compared to the NNC and usual brand cigarettes, all cigarettes were associated with statistically significant increases in plasma nicotine compared to baseline levels (Ref. 402). Similarly, 22nd Century Group, Inc. submitted modified risk tobacco product applications to FDA containing data from two clinical studies showing that peak plasma nicotine levels following use of a single VLNC cigarette ranged from 0.4–0.5 nanograms of nicotine per milliliter of plasma and total nicotine levels (*i.e.*, plasma nicotine area under the curve calculated using the trapezoidal rule to 180 minutes) ranged

from 26.2–30.4 nanograms of nicotine per milliliter of plasma (Ref. 539). Researchers observed similar effects among participants who smoked a single VLNC cigarette made by Philip Morris for research purposes only (Ref. 259).

Studies with longer exposure to VLNC cigarettes have also found evidence of nicotine exposure within study participants. For example, studies showed that after several days or weeks of smoking VLNC cigarettes, biomarkers of nicotine exposure—such as urinary cotinine and TNE (*i.e.*, the sum of nicotine and various nicotine metabolites)—in people who smoke cigarettes were drastically reduced but were still detectable (Refs. 32 and 265). Notably, if participants in these studies were noncompliant with study-assigned cigarettes, then some of the biomarkers of nicotine exposure could be attributed to the use of other tobacco products. However, evidence from studies in which participants were confined to hotels or residential research facilities without access to other tobacco products also demonstrate that extended exposure to VLNC cigarettes produces biomarkers of nicotine exposure and physiological responses consistent with nicotine exposure (Refs. 64 and 423). Taken together, these data consistently show that levels of nicotine biomarkers of exposure in people who smoke VLNC cigarettes are still detectable. For further discussion of biomarkers of exposure, see section VII.B.6 of this document.

2. Receptor Occupancy and Cerebral Response From the Use of VLNC Cigarettes

Studies have shown that the nicotine provided by VLNC cigarettes is enough to occupy sufficient numbers of nicotine receptors in the brain (*i.e.*, $\alpha 4\beta 2$ nAChRs) to mitigate feelings of withdrawal and craving. PET and MRI data obtained from people who smoke cigarettes indicate that after smoking a VLNC cigarette, nicotine receptors located in numerous areas of the brain are occupied despite the lower nicotine content of VLNC cigarettes, and these participants reported a statistically significant reduction in craving compared to before smoking the VLNC cigarette (Ref. 430). In another study that compared VLNC and NNC cigarettes, exposure to both types of cigarettes resulted in the binding of nicotine to receptors in the brain and the release of dopamine (Ref. 425). However, the magnitude of subjective craving or withdrawal responses observed following use of VLNC cigarettes was lower than use of NNC cigarettes (Refs. 425 and 461). For

further discussion of receptor occupancy, see section VII.B.8 of this document.

3. VLNC Cigarette Nicotine Smoke Yield

Nicotine “yield” refers to the amount of nicotine in tobacco smoke as measured through machine-generated smoking methods (*e.g.*, ISO machine smoking method, CI smoking method, FTC smoking method), and is typically measured and reported in milligrams per cigarette. The maximum level of nicotine set by this proposed product standard would result in nicotine yield in tobacco smoke that is at detectable levels above zero. For example, SPECTRUM NNC cigarettes that contain 15.8–16.6 mg of nicotine per gram tobacco filler have machine-measured nicotine yields of 0.7–0.8 mg of nicotine per cigarette. SPECTRUM VLNC research cigarettes that contain 0.3–0.4 mg of nicotine per gram tobacco filler have quantifiable machine-measured nicotine yields greater than zero, ranging from 0.03–0.04 mg of nicotine per cigarette (Ref. 254). Similarly, Quest® 3 VLNC cigarettes had quantifiable machine-measured nicotine yields of approximately 0.03 mg of nicotine per cigarette (Ref. 540).

In summary, the data indicate that nicotine is measurable in both the tobacco filler and the smoke yield of VLNC cigarettes and therefore does not equal zero. After using VLNC cigarettes, nicotine exposure has been shown to occur as evidenced by studies measuring biomarkers of nicotine exposure and neurological receptor occupancy. Consequently, FDA finds that the proposed product standard would not require the reduction of nicotine yields to zero.

VIII. Determination That the Standard Is Appropriate for the Protection of the Public Health

The Tobacco Control Act authorizes FDA to adopt tobacco product standards by regulation if it finds that such tobacco product standards are appropriate for the protection of the public health (section 907(a)(3)(A) of the FD&C Act). The notice of proposed rulemaking (NPRM) for such a product standard must set forth this finding with supporting justification, which FDA is providing here (section 907(c)(2)(A)) of the FD&C Act.

In order to make this finding, FDA must consider scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and

- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

Section 907(a)(3)(B)(i) of the FD&C Act.

FDA has considered scientific evidence related to all three factors. Based on these considerations, as discussed below, we find that the proposed standard is appropriate for the protection of the public health because it would increase the likelihood that many people who currently smoke cigarettes and/or certain other combusted tobacco products would stop smoking altogether, yielding significant health benefits from smoking cessation. Additionally, we find that the proposed standard is appropriate for the protection of the public health because it would decrease the likelihood that people who do not smoke cigarettes and/or use certain other combusted tobacco products—including youth and young adults—who experiment with combusted tobacco products will become addicted to these products, thereby decreasing progression to regular use, resulting in reduced tobacco-related morbidity and mortality associated with combusted tobacco product use. Increased cessation, as well as decreased initiation, progression to regular use, and consumption would lead to lower disease and death in the U.S. population, due to decreased use of cigarettes and certain other combusted tobacco products. Furthermore, the rule is appropriate for the protection of the public health because the population as a whole would likely experience additional health benefits as a result of reduced secondhand smoke exposure, smoking-related fires, and smoking-related perinatal conditions.

A. Approach To Estimating Impacts to the Population as a Whole

Current evidence shows that, while nicotine itself is not the direct cause of most smoking-related diseases, addiction to the nicotine in tobacco products is the proximate driver of tobacco-related death and disease because it sustains tobacco use (Refs. 1, 28, 58, and 61). The addiction caused by nicotine in tobacco products is critical in the transition of people who smoke cigarettes from experimentation to sustained smoking and in the maintenance of smoking for those who want to quit (Refs. 1 at p. 113 and 28). Combusted tobacco products, including cigarettes, are responsible for the overwhelming burden of disease and

death from tobacco product use (Refs. 1 and 28). As a result, FDA expects that making cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive would reduce tobacco-related harms by promoting smoking cessation or complete migration to alternative, potentially less harmful noncombusted tobacco products and by reducing initiation. In this section, we summarize the approach used to estimate the possible impact of a potential nicotine tobacco product standard to the population as a whole and present the findings of this analysis.

To assess the potential public health impacts of a nicotine product standard, FDA developed a population health model using inputs derived from available empirical evidence and expert opinion to estimate the impact of changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States. Details of this modeling approach have been previously published in two peer-reviewed publications (Refs. 47 and 48), which describe the overall model in terms of the inputs, transition behaviors, and outputs that it contains, along with results from simulation studies. In preparation for this proposed product standard, FDA updated the model published previously (Ref. 47), which describes the impact of a potential product standard that limits the level of nicotine in cigarettes, RYO tobacco, non-premium cigars, and pipe tobacco so that they are minimally addictive or nonaddictive.²⁹ The details of this analysis are presented in an updated modeling document, entitled “Methodological Approach to Modeling the Potential Impact of a Nicotine Product Standard on Tobacco Use, Morbidity, and Mortality in the U.S.” (Ref. 42). We estimated the potential impacts of a nicotine product standard by modeling a baseline scenario of use of cigarettes and noncombusted tobacco products including smokeless tobacco, e-cigarettes, HTPs, and oral nicotine products. We then compared the baseline scenario to a product standard scenario characterized by the introduction of a potential nicotine product standard that would apply to

cigarettes, RYO tobacco, non-premium cigars, and pipe tobacco. FDA’s modeling framework and methodological approach and the associated inputs and assumptions have been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 49), FDA revised the modeling document, and the final modeling document is available in the docket for this proposed rule (Ref. 42). FDA’s modeling work informed the development of this proposed product standard. FDA requests comments on the methodology and analysis (including the overall model in terms of the inputs, transition behaviors, and outputs) presented in the scientific modeling document.

FDA’s population health model incorporates the following tobacco use transitions to estimate the impact of the policy: (1) cigarette smoking cessation; (2) people who smoke cigarettes switching to noncombusted tobacco products rather than quitting tobacco use entirely; (3) people who continue to smoke cigarettes beginning dual use of cigarettes and noncombusted tobacco products; (4) people who do not smoke initiating regular cigarette smoking; and (5) people who do not smoke who have been dissuaded from smoking cigarettes and certain other combusted tobacco products, who instead initiate use of a noncombusted tobacco product. The model, based on input parameters derived from empirical evidence and expert estimates, projected the impact of a potential nicotine product standard on four main outcomes: (1) prevalence of cigarette smoking and noncombusted tobacco use; (2) tobacco-attributable mortality; (3) life years lost due to tobacco use; and (4) quality-adjusted life years (QALYs) lost due to cigarette smoking-attributable morbidity in the U.S. population over time. The model explores various baseline scenarios via sensitivity analyses, including with and without projections that incorporate implementations of other future tobacco product standards (e.g., flavored cigar and menthol cigarette product standards).

More detailed information regarding modeling study methodology, including descriptions of the model inputs, data sources, and assumptions used to derive estimates of the potential impact of a nicotine product standard on population health can be found in FDA’s modeling document (Ref. 42). Briefly, the simulation began with an initial population that reflected the sex and age (based on 2021 U.S. Census Bureau estimates) and cigarette use distribution (i.e., never, current, former

²⁹ The policy scenario presented in Apelberg et al. 2018 (Ref. 47) did not define a specific level of nicotine as minimally addictive or nonaddictive. Rather, the policy scenario simulated implementation of a hypothetical standard in which cigarettes and certain other combusted tobacco products were made minimally addictive or nonaddictive, informed by a formal expert elicitation process, and used to estimate the impact of decreasing the addictiveness of cigarettes on certain tobacco use behaviors.

use; estimated from the 2020 NHIS data and 2020 NYTS data) in the U.S. population. Next, we incorporated sex-specific rates for smoking initiation and cessation for year 2021 modeled using cigarette smoking histories for birth cohorts reconstructed from NHIS data by Cancer Intervention and Surveillance Modeling Network (CISNET) researchers (Ref. 541). Recent analyses using data from the Population Assessment of Tobacco and Health (PATH) Study (Ref. 542) provide data on initiation of ENDS from Wave 4 (2016–2017) to Wave 5 (2018–2019); however, those estimates are related to transitions from never use to ever use of a specific product at the current wave, rather than transitions to established use, as defined in the population model. In the absence of up-to-date estimates of exclusive noncombusted product initiation rates from the published scientific literature, data regarding exclusive initiation of noncombusted tobacco products and dual use were derived by scaling the sex- and age-specific smoking initiation rates from CISNET using youth (ages 9–17) prevalence estimates from the 2017–2020 NYTS, and young adult (ages 18–24) prevalence estimates from the 2020 NHIS (Ref. 542). NYTS prevalence estimates for noncombusted product use correspond to frequent use, defined as use at least 20 days in the past 30 days.³⁰ Additional details regarding the estimation of scaling factors to compute noncombusted product initiation rates can be found in FDA's modeling document (Ref. 42). CISNET sex- and age-specific cigarette smoking cessation rates derived from NHIS data were utilized as cessation rates for all product categories, including noncombusted tobacco use. Age-specific rates of switching from cigarettes to noncombusted tobacco products were derived from prior research (Ref. 543). Overall U.S. death rates from 2019 vital statistics data were used to reflect the death rates at baseline for individuals under age 35 who never smoked, since smoking-related mortality is minimal before this age (Ref. 544). For ages 35 and older at baseline, FDA estimated annual death rates from 2019 NHIS–LMF data among participants who have never smoked in NHIS from 1997 through 2018 who were followed for

mortality through linkage with the National Death Index from 2002 through 2019 (Ref. 545). NHIS–LMF never-user death rates are adjusted for low mortality in the NHIS's civilian noninstitutionalized population, due to the survey's exclusion of people in institutionalized settings such as long-term care institutions (e.g., nursing homes, hospitals for the chronically ill or physically or intellectually disabled, wards for abused or neglected children), persons in correctional facilities (e.g., prisons or jails, juvenile detention centers, halfway houses), and U.S. nationals living in foreign countries. The adjustment was done by using the ratio of U.S. death rates from the 2019 vital statistics data to NHIS–LMF death rates by sex and age (Ref. 546). Death rates for people who have never smoked cigarettes are projected for the period from 2022 through 2100 using mortality scaling factors obtained from the Lee-Carter mortality forecasting method (Refs. 547 to 549). To estimate mortality for e-cigarettes and other noncombusted tobacco products, we apply the same risks that are used for smokeless tobacco. Our assumptions about all-cause mortality risk among people who use smokeless tobacco in the United States were informed by the first NHANES, Cancer Prevention Study I (CPS–I), and Cancer Prevention Study II (CPS–II). Mortality probabilities for people who currently use and formerly used tobacco are obtained by multiplying never-user probabilities of dying by relative risk according to tobacco use status.

Quantitative inputs for tobacco use transitions following implementation of the proposed product standard were obtained through a formal expert elicitation process that was first conducted in 2015 and then repeated in 2018. FDA is conducting another expert elicitation to obtain updated quantitative inputs for tobacco use transitions and intends to publish the results for public review and comment. For the 2015 and 2018 expert elicitations, the methodology used to identify experts, develop the protocol, conduct the elicitation, and summarize the findings can be found in a previous peer-reviewed publication (Ref. 47) and in FDA's modeling document (Ref. 42). Briefly, the initial elicitation process centered around three online conferencing sessions held during January and February 2015, following a written protocol designed to elicit opinions using a structured, standardized approach. Briefing books with key papers on the topics of interest as well as background data on tobacco

use and policy were provided to a panel of eight experts prior to the conference sessions. Experts were asked to identify any other relevant information to share with the panel. Detailed written questionnaires were completed by each expert as independent take-home exercises. To maintain the independence of the experts and encourage open discussion, involvement of FDA staff was limited. This general process was repeated in 2018 to ensure that estimates reflected the experts' current assessment of the research literature and potential effects of a hypothetical product standard. Seven of the original eight experts agreed to participate in the second elicitation. Participants received updated briefing materials, and an online workshop was held in April 2018. The experts, once again, subsequently completed a detailed questionnaire.

To explore the possible impact of a hypothetical policy reducing nicotine levels, the experts were asked to assume that combusted tobacco products that could be viewed as highly likely to serve as substitutes for traditional cigarettes (*i.e.*, RYO tobacco, pipe tobacco, non-premium cigars) would be included in the policy, while other tobacco products (*i.e.*, premium cigars, waterpipe/hookah, e-cigarettes, smokeless tobacco) would be excluded. While the policy scenario presented in FDA's modeling document (Ref. 42) is based on a reduction of the nicotine level in cigarettes, cigarette tobacco, RYO tobacco, certain cigars and pipe tobacco, the estimated population impact in the main analysis is solely based on reductions in cigarette smoking. Cigarettes are the only one of these combusted products to be incorporated directly in the model, given that cigarette smoking is responsible for the bulk of morbidity and mortality caused by combusted tobacco product use. Estimates of mortality benefits due to reductions in non-premium cigar and pipe tobacco use are derived from model outputs, as explained below, although these estimates would not include other population health benefits such as reduced morbidity.

The experts were asked to predict and quantify the anticipated impact of the policy on the following model parameters: (1) cigarette smoking cessation rates; (2) switching from cigarette smoking to other tobacco products excluded from the hypothetical policy scenario (*i.e.*, premium cigars, waterpipe/hookah tobacco, smokeless tobacco, e-cigarettes or other ENDS); (3) dual use rates; (4)

³⁰ While past 30-day use is the conventional definition of current use of a tobacco product in the NYTS, we utilized the corresponding definition of frequent use (20 or more days of use in past 30 days) to correspond with initiation of regular use that is more closely associated with longer-term health outcomes. In this context, we have scaled the initiation rates to reflect the initiation of regular, longer-term use. This approach is consistent with that for adult initiation to regular use and long-term cessation as defined by CISNET.

cigarette smoking initiation rates; and (5) initiation rates for other tobacco products excluded from the hypothetical policy scenario. Each of the experts was asked to provide his or her best estimate of the parameters' true value, estimates of the minimum and maximum plausible values, and estimates of the 5th, 25th, 75th, and 95th percentile values. Experts were asked first about impacts in the first year immediately following the potential product standard's implementation and then about impacts in the years following the first full year of implementation. Experts had the option of providing separate estimates of impacts for males and females for the initial and subsequent years. For each question, experts were asked to provide the factors they considered pertinent to answering the question, including the studies and research findings most influential to informing their views, and to rate their familiarity with the relevant literature. The elicitation process provided the experts with opportunities to interact and discuss divergent views, from which each expert generated their initial and final estimates. In the updated elicitation, experts were also asked to assess the potential effects of an alternative product standard that would only apply to cigarettes, cigarette tobacco, and RYO tobacco, although they were not required to provide quantitative estimates of the effects of such a standard.

While parameter estimates and their probability distributions varied somewhat among participants, most experts had the view that making cigarettes and certain other combusted tobacco products minimally addictive would lead to substantial initial and long-term increases in smoking cessation among people who smoke cigarettes and decreased initiation among people who do not smoke cigarettes. The experts' parameter estimates fell within a broad range, although the updated estimates were often somewhat more consistent and found greater effects from the potential policy than in the original elicitation. In general, estimates of the effects of a nicotine product standard on use behaviors such as smoking cessation, product switching, and smoking initiation were greater in magnitude in the 2018 expert elicitation than in the previous 2015 elicitation. For example, the median estimates of smoking cessation were 36 percent in the first year following implementation of a nicotine product standard and 34 percent in subsequent years in the 2018 elicitation, compared to 25 and 22

percent, respectively, in 2015. For product switching (from cigarettes to noncovered tobacco products), the median estimates were 56 and 58 percent in the first and subsequent years following implementation in the 2018 expert elicitation and 41 and 40 percent in 2015. Median estimates of reductions in smoking initiation were 63 and 65 percent in the first and subsequent years in the 2018 elicitation, and 46 and 49 percent in 2015. Overall, the experts' estimates indicate that the proposed product standard would introduce substantial changes in tobacco use behaviors which would result in substantial public health benefits. Given the inherent uncertainty associated with projecting the long-term impact of a future regulatory action, FDA conducted a range of analyses to examine the impact of uncertainty around key model inputs and assumptions on tobacco use prevalence and premature mortality. First, in the main analysis, we examined uncertainty in the behavioral responses to a potential nicotine product standard by conducting a Monte Carlo simulation (Ref. 550). For the product standard scenario, a Latin hypercube sampling design with 1,000 simulations was conducted for each set of expert-defined distributions, resulting in a total of 7,000 simulations (Ref. 551 at p. 524). The resulting outputs were aggregated to create an overall set of output distributions, and distribution percentiles were calculated across all 7,000 simulations. For each simulation, the policy scenario was compared to the baseline scenario to estimate changes in the outcomes. Key distribution responses in FDA's modeling document highlight the positive impacts to the public health of the proposed product standard (Ref. 42). More information on this topic can be found throughout this document.

In addition, we conducted sensitivity analyses to assess the impact of specific data input assumptions, including those related to baseline trends in noncombusted product use, noncombusted product mortality risk, dual product use mortality risk, and switching to non-covered combusted products. Specifically, we conducted sensitivity analyses to examine the impact of increased initiation of noncombusted tobacco product use among those who would otherwise not have used tobacco; the impact of an increase in switching from cigarettes to noncombusted tobacco product use; the impact of a varying mortality risk associated with dual use of cigarettes and noncombusted tobacco products; the impact of lower and higher

noncombusted tobacco product risk; and the effects of a nicotine product standard, accounting for the emergence of an illicit market for normal nicotine content cigarettes. Additional detailed information concerning these sensitivity analyses can be found in FDA's modeling document (Ref. 42). Overall, the results from FDA's population health modeling, even accounting for the impacts of the factors utilized in FDA's sensitivity analyses, clearly demonstrate the public health benefit of the proposed product standard.

In 2022, FDA issued proposed product standards to prohibit menthol as a characterizing flavor in cigarettes (87 FR 26454, May 4, 2022) and to prohibit all characterizing flavors (other than tobacco) in cigars (87 FR 26396, May 4, 2022). If finalized, these rules are anticipated to reduce overall youth initiation and increase cessation among individuals who smoke cigarettes and non-premium cigars. In sections VIII.E and VIII.F of this document, we describe how we adjusted our model by utilizing estimates of the likely population health impact of these rules, quantified in peer-reviewed publications and discussed in the proposed rules, to adjust the baseline inputs for initiation of combusted and noncombusted products, as well as cessation of combusted products and likelihood of switching to incorporate the impact of the rules in this proposed nicotine product standard.

B. The Likelihood That Nonusers Would Start Using Cigarettes or Other Combusted Tobacco Products

Nicotine is an addictive chemical and the primary constituent in cigarettes and other tobacco products that causes and maintains addiction. It is a significant contributor to youth and young adult initiation of smoking cigarettes and other combusted tobacco products. In section IV.A of this document, we summarize evidence from multiple study designs, incorporating findings from experimental and laboratory-based studies, clinical trials, and pre-clinical research that illustrate the role that nicotine plays in facilitating initiation of and addiction to cigarettes and other combusted tobacco products. As discussed in section IV.B of this document, scientific research demonstrates that adolescence is a period of development when individuals who experiment with tobacco products are more susceptible to developing nicotine dependence and progressing to regular use of such products. Indeed, almost 90 percent of adults who currently and regularly smoke initiated smoking by age 18, and

98 percent initiated smoking by age 26, which is notable given that 25 is the approximate age at which the brain has completed development (Refs. 1 and 17 to 19). The developing brain is more vulnerable to developing nicotine dependence than the adult brain is, and the earlier an individual begins smoking the less likely they are to quit (Ref. 20). Compounding this are the findings described in section IV.C of this document that demonstrate that many youth and adults who smoke want to quit smoking but have difficulty doing so. Further, the scientific literature on relapse in those who try to quit confirms the powerful addictive properties of nicotine in tobacco products, a principal factor limiting a person who smokes' ability to quit, and further underscores the public health importance of decreasing the addictiveness of these products, particularly to reduce susceptibility to addiction for youth and young adults who experiment with smoking. In this section, we discuss how, given this scientific evidence, as well as the findings from our population health model, FDA expects the proposed nicotine product standard for cigarettes and certain other combusted tobacco products would decrease experimentation and progression to regular use of these products among people who currently do not use these products.

Data from the 2023 NSDUH found that, in the United States, approximately 452,000 youth (ages 12–17) smoked their first cigarette and approximately 245,000 youth tried a cigar for the first time during 2023 (Ref. 86 Table A.13A). The 2023 NSDUH also found that approximately 945,000 young adults (ages 18 to 25) initiated with cigarettes and 1,065,000 young adults initiated with cigars in 2021 (Ref. 552 see Table 4.7B). Additionally, nearly 90 percent of U.S. adults who currently smoke cigarettes daily report having smoked their first cigarette by age 18 (Ref. 1). Given that nicotine is highly addictive and present in all cigarettes and cigars, as people who experiment with cigarettes and cigars continue to use these products, there is a substantial risk of the development of nicotine

dependence and progression to regular use. Nicotine is a highly addictive substance, and multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among people who infrequently use the products (Refs. 24, 93, and 553). Although the majority of adolescents who smoke daily meet the criteria for nicotine dependence, one study found that the most susceptible youth lose autonomy (*i.e.*, independence in their actions) regarding tobacco within 1 or 2 days of first inhaling from a cigarette (Ref. 93). Another study found that 19.4 percent of adolescents (initially aged 12–13 years and followed over 6 years) who smoked weekly were dependent on nicotine (Ref. 95). In a study regarding nicotine dependence among adolescents who recently initiated smoking (9th and 10th grade students), adolescents who smoked cigarettes at the lowest levels (*i.e.*, smoking on only 1 to 3 days of the past 30 days) experienced nicotine dependence symptoms such as loss of control over smoking (42 percent) and irritability after not smoking for a while (23 percent) (Ref. 96). Researchers in a 4-year study of 6th grade students also found that “[e]ach of the nicotine withdrawal symptoms appeared in some subjects *prior* to daily smoking” (Ref. 93) (emphasis added). Ten percent of the study participants showed signs of tobacco dependence within 1 or 2 days of first inhaling from a cigarette, and half had done so by the time they were smoking seven cigarettes per month (Ref. 93). Moreover, nicotine can disrupt brain development and have long-term consequences for executive cognitive functioning (*e.g.*, decreased attention and working memory and increased impulsivity) and increases the risk of developing a substance use disorder and various mental health problems—particularly affective disorders such as anxiety and depression—as an adult (Refs. 554 to 556). Therefore, progressing to regular use during adolescence can have lasting consequences and signs of nicotine dependence are evident in youth who smoke cigarettes. Taken together, this

research suggests that even infrequent experimentation can lead to early signs of dependence, which underscores the public health importance of decreasing the likelihood of cigarette experimentation among youth and young adults in the United States. If this proposed rule is finalized, cigarettes and the other combusted tobacco products covered would be rendered minimally addictive or nonaddictive, thereby breaking the link between experimentation, nicotine dependence, and progression to regular use. As a result, FDA expects a significant reduction in youth initiation and progression to regular cigarette smoking and use of other combusted tobacco products, which would ultimately protect youth from a lifetime of addiction, disease, and premature death attributable to combusted tobacco use. To the extent that youth and young adults in the United States who would have initiated use of cigarettes and other combusted tobacco products covered by the scope of this proposed rule do not initiate with such tobacco products, the proposed standard would prevent future cigarette- and combusted tobacco product-related disease and death. Findings from FDA’s population health model, previously described in section VIII.A of this document and in the docket (Ref. 42), estimate the likelihood that youth and young adults who do not smoke would initiate regular cigarette smoking use under the proposed standard. Table 2 provides an estimated projection of the cumulative number of youth and young adults who would not initiate regular cigarette use as a result of implementation of this proposed product standard over time (Ref. 42 Appendix J for annual estimates). Since a sustained decrease in smoking initiation rates is expected, the cumulative number of people dissuaded from initiating smoking would continue to increase over time. By 2100, we estimate that, as a result of this proposed nicotine product standard, over 47 million youth and young adults who would have otherwise initiated smoking would not start smoking.

TABLE 2—PROJECTED CUMULATIVE NUMBER OF YOUTH AND YOUNG ADULTS WHO WOULD NOT INITIATE SMOKING AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027

[Millions]

Year	Median	(5th, 95th percentiles)
2028	1.3	(0.4, 1.7)
2030	2.6	(0.7, 3.4)
2040	8.6	(2.3, 11.5)
2050	14.8	(4.0, 19.8)
2060	21.1	(5.6, 28.3)

TABLE 2—PROJECTED CUMULATIVE NUMBER OF YOUTH AND YOUNG ADULTS WHO WOULD NOT INITIATE SMOKING AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027—Continued

[Millions]

Year	Median	(5th, 95th percentiles)
2070	27.5	(7.3, 37.0)
2080	34.1	(9.1, 45.9)
2090	40.8	(10.8, 54.9)
2100	47.6	(12.6, 64.1)

For these reasons, FDA expects that establishing a maximum limit of the nicotine content in cigarettes and certain other combusted tobacco products, as described in this proposed rule, would reduce the likelihood that youth and young adults would initiate with and progress to regular cigarette smoking and use of other combusted tobacco products, thereby protecting many youth and young adults from a lifetime of addiction and disease, and premature death, attributable to the use of combusted tobacco (see section VIII.D of this document for a discussion of life years gained and other public health benefits as a result of decreased initiation). Thus, from the expected impact on people who would not initiate smoking cigarettes, especially youth and young adults, this proposed product standard is appropriate for the protection of public health.

C. The Likelihood That Existing Users Would Reduce Cigarette and Other Combusted Tobacco Product Consumption or Stop Smoking

In addition to the long-term public health benefits that would accrue from the prevention of cigarette smoking and other combusted tobacco use among youth and young adults, FDA anticipates that the proposed standard also would increase the likelihood that many people who currently smoke cigarettes and certain other combusted tobacco products would stop smoking altogether, yielding health benefits from smoking cessation. FDA expects that the proposed standard would result in substantial changes in tobacco use patterns among people who currently use tobacco. Given that tobacco products are addictive primarily due to the presence of nicotine, FDA expects that the proposed standard would lead many people who currently smoke cigarettes and certain other combusted tobacco products to: (1) quit using these tobacco products altogether, (2) transition to dual use of cigarettes or other combusted tobacco products with other potentially less harmful tobacco products, or (3) transition completely to

use of other potentially less harmful tobacco products.

As discussed in section IV of this document, the scientific evidence is clear that nicotine is an addictive chemical and is the primary constituent that causes and maintains addiction to cigarettes and other combusted tobacco products. The U.S. Surgeon General has concluded that there is a causal relationship between smoking and addiction to nicotine (Ref. 1), and the earlier that individuals begin smoking, the less likely they are to successfully quit (Ref. 27). FDA expects that, if this proposed rule is finalized, many people who smoke cigarettes will either quit smoking entirely, switch to a noncombusted tobacco product entirely, or transition to dual use. As discussed previously, those who switch completely to a noncombusted product may sustain their nicotine dependence but would significantly reduce their risk of tobacco-related death and disease to the extent that the products they switch to result in less harm. That is, while dependence on any tobacco product remains a health concern, the vast majority of tobacco-related cancer, lung disease, and heart disease is due to exposure to constituents of tobacco smoke (Ref. 323). Switching completely to a noncombusted tobacco product would reduce exposure to the chemical constituents created through combustion (Ref. 8).

There are multiple sources of evidence to inform FDA's analysis of how the proposed standard would affect the likelihood that people who smoke would reduce cigarette and combusted tobacco product consumption or stop smoking altogether. Findings from clinical studies offer insight into tobacco product switching, as well as cigarette smoking cessation behaviors occurring following the implementation of the proposed product standard. As described previously in section VI.B of this document, a clinical trial intended to assess the use of noncombusted and non-cigarette combusted tobacco products among participants randomized to receive LNC and NNC cigarettes found that participants who

received LNC cigarettes used alternative combusted and noncombusted tobacco products on a statistically significantly higher percentage of days compared to those who received NNC cigarettes (Ref. 5). Another analysis of switching behavior in the context of a clinical study examined the influence of LNC cigarette use on alternative tobacco product use in participants who did not smoke cigarettes daily. Among participants who did not use e-cigarettes at baseline, new use of e-cigarettes was statistically significantly more prevalent in the LNC cigarette group compared to the NNC cigarette group (Ref. 377). Both findings suggest that people who smoke cigarettes, and do not quit tobacco use altogether, are likely to seek alternative sources of nicotine once a nicotine product standard for combusted tobacco products is in place.

As discussed in section VII.B.2 of this document, numerous studies have investigated the effects of VLNC or LNC cigarettes—alone or in combination with NRT products—on smoking cessation among people who smoke cigarettes and are interested in quitting (Refs. 32, 35, 41, 369 to 373), as well as among samples of people who smoke cigarettes and are not interested in quitting (Refs. 31, 40, 258, and 374). Taken together, results from these studies demonstrate that people who smoke cigarettes and are interested in quitting who are given VLNC cigarettes are more likely to achieve initial smoking abstinence compared to those who continue to smoke their usual brand or NNC cigarettes. In addition, provision of NRT and/or behavioral intervention with VLNC cigarettes can further increase smoking cessation among individuals interested in quitting (Ref. 19).

Estimates from FDA's population health model—described in section VIII.A of this document—indicate that in the first year following the implementation of the proposed standard in 2027, smoking prevalence would decline from 9.1 percent in the baseline scenario to a median of 4.5 percent in the product standard scenario, due to the large increase in

smoking cessation in the first year after implementation. In subsequent years, the difference in smoking prevalence between the scenarios would continue to grow due to sustained increases in cessation and decreases in initiation relative to baseline. The projected smoking prevalence drops to 0.2 percent under the product standard scenario by 2050, compared to 5.3 percent under baseline. By 2100, smoking prevalence is estimated at 0.2 percent in the product standard scenario, compared to 4.6 percent under baseline. Estimates of the projected cumulative number of people who quit smoking are depicted in table 3. Within the first year of the proposed standard implementation, 12.9 million additional people who smoke

cigarettes are estimated to either quit tobacco altogether or switch from cigarette smoking to using noncombusted tobacco products, signifying a considerable gain over the estimated 1.6 million people who smoke that would have quit under the baseline scenario. The mortality risk of switching is greater than quitting all tobacco products, therefore the public health model assumes the risk for people who switch to noncombusted products as 8 percent higher than the risk for those who quit tobacco use entirely based on evidence in the literature (Ref. 557), see section VIII.D of this document for a more detailed discussion. The number of additional people who quit smoking would increase to approximately 19.5

million within 5 years after the implementation of the proposed standard, representing a gain of more than the 7.3 million people who quit smoking than would be anticipated under the baseline scenario. The median estimates grow closer to the 95th percentile estimates than to the 5th percentile estimates over time. A closer analysis of this pattern indicates that the 5th percentile estimates are affected by lower estimates given by two experts in the expert elicitation. Those estimates indicate that a lower percentage of people who currently use cigarettes will quit smoking cigarettes, following a nicotine product standard's implementation.

TABLE 3—CUMULATIVE NET PEOPLE WHO QUIT SMOKING ¹ (MILLIONS) AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027

Period	Median	(5th, 95th percentiles)
Within 1st year (2027)	12.9	(0.8, 24.8)
Within 2 years (2027–2028)	17.5	(1.2, 24.1)
Within 3 years (2027–2029)	19.3	(1.6, 23.2)
Within 4 years (2027–2030)	19.8	(1.8, 22.3)
Within 5 years (2027–2031)	² 19.5	(2.0, 21.4)

¹ Net people who quit smoking cigarettes (including those who switch to noncombusted tobacco products), defined as people who quit smoking cigarettes in addition to baseline, is computed as: (number of people who quit smoking cigarettes under the nicotine product standard scenario) – (number of people who quit smoking cigarettes under baseline scenario).

² Cumulative net people who quit smoking declines slightly in year 5 of the simulation because there are more people who quit smoking cigarettes in the baseline scenario compared with the product standard scenario. Since there are millions of fewer people smoking cigarettes in the product standard scenario as the years continue, eventually there are fewer people available to quit smoking cigarettes compared to baseline.

We also examined the potential for an illicit market for NNC cigarettes to develop in response to the proposed product standard (see section IX.D of this document for a discussion on illicit trade). In order to examine the potential impact of such an illicit market, sensitivity analyses were conducted for the effects of diversion from cessation to illicit trade, and initiation into illicit products, on the estimated benefits of a nicotine product standard. These

analyses demonstrate that increasing the assumed proportion of people who smoke who may divert to the use of illicit NNC cigarettes (for purposes of illustration, we use a low-end estimate (3.8 percent), a midpoint estimate (5.9 percent), and a high-end estimate (21.0 percent)),³¹ and allowing youth and young adults (who would have otherwise initiated NNC cigarette use) to initiate into illicit NNC cigarette use (0 percent, 2.6 percent, and 10 percent)³²

under the proposed nicotine standard, resulted in reductions in the projected cumulative net people who quit smoking following the implementation of the nicotine product standard policy (table 4). However, even in the case of significant diversion to illicit NNC cigarettes, the number of people projected to quit smoking remains substantial.

³¹ We use 3.8 percent as a low-end estimate based on 2017 estimates of illicit trade volume in cigarettes from (Ref. 558). This estimate excludes interstate smuggling for purposes of tax avoidance. For a midpoint estimate, using findings from the International Tobacco Control United States Survey (Ref. 559), we estimate that 5.9 percent of U.S. people who use cigarettes last purchased cigarettes from low-tax locations. We use these figures as proxies for the proportions of people who use cigarettes who may actively seek out illicit NNC cigarettes under a nicotine product standard, although we note that the product standard would be implemented nationwide, avoiding disparate pricing/availability between states. We use 21.0

percent as a high-end estimate based on the difference in non-compliance rates between reduced nicotine intervention groups (78 percent) and control groups assigned to NNC cigarettes (57 percent) in clinical trial data from (Ref. 29, Ref. 330). This estimate of 21.0 percent also represents the high-end of the range estimated in (Ref. 560), which reflected the methodology of the pack return survey by (Ref. 561). While FDA uses this 21.0 percent high-end estimate for the purpose of analyzing potential impacts, we note that it represents a highly unlikely upper bound, because for such a substantial percentage of people who use cigarettes to acquire NNC cigarettes, convenient and consistent access to an illicit market would be

needed, which is highly unlikely. We also note that basing a high-end estimate on non-compliance rates found in studies (where NNC cigarettes are legally available outside the confines of the study environment) is not equivalent to real-world conditions where NNC cigarettes would not be legally available in the U.S. marketplace.

³² We use findings from an expert elicitation developed to gauge the impact of a menthol cigarette and cigar prohibition in the United States (Ref. 562), which indicates that among people ages 12–24 who would have otherwise initiated menthol cigarette use, 2.6 percent would initiate illicit menthol cigarette use (estimate ranged from 0 percent to 10 percent).

TABLE 4—CUMULATIVE NET PEOPLE WHO QUIT SMOKING COMBUSTED CIGARETTES (MILLIONS) AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027 UNDER ILLICIT TRADE SCENARIOS. MEDIAN (5TH, 95TH PERCENTILES) ESTIMATES

Period	Illicit trade impact scenarios			
	Main scenario (no impact)	Low Impact ¹	Medium Impact ²	High Impact ³
Within 1st year (2027)	12.9 (0.8, 24.8)	12.4 (0.7, 24.6)	12.1 (0.7, 24.4)	9.9 (0.3, 22.6)
Within 5th year (2027–2031)	19.5 (2.0, 21.4)	19.3 (1.7, 21.3)	19.2 (1.5, 21.4)	18.1 (0.3, 21.4)

¹ Low Impact: 3.8 percent people who smoke would divert to use illicit NNC cigarettes, and 0 percent youth and young adults would initiate illicit NNC cigarettes.

² Medium Impact: 5.9 percent people who smoke would divert to use illicit NNC cigarettes, and 2.6 percent youth and young adults would initiate illicit NNC cigarettes.

³ High Impact: 21.0 percent people who smoke would divert to use illicit NNC cigarettes, and 10.0 percent youth and young adults would initiate illicit NNC cigarettes.

The sum of the available evidence—including the current use of cigarettes by millions of Americans, findings from studies assessing the effects of VLNC or LNC cigarettes on smoking cessation, and findings from FDA's population health model—supports FDA's finding that the proposed product standard would increase the likelihood that many people who smoke cigarettes and/or other combusted tobacco products would stop smoking altogether, yielding significant health benefits from smoking cessation. Additionally, we find that the proposed standard is appropriate for the protection of the public health because it would decrease the likelihood that people who do not smoke cigarettes and/or use certain other combusted tobacco products—particularly youth and young adults—who experiment with combusted tobacco products will become addicted to these products, thereby decreasing progression to regular use, resulting in reduced tobacco-related morbidity and mortality associated with combusted tobacco product use. As of 2021, more than 48 million people in the United States ages 12 and older used tobacco products within the past 30 days (Refs. 25 and 274). Further, in 2021, 35.6 million U.S. adults (14.5 percent) and nearly 1 million middle and high school students (3.2 percent) used any combustible tobacco product (Ref. 274). Thus, even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease caused by smoking.

D. Benefits and Risks to the Population as a Whole

We expect that the proposed nicotine product standard, if finalized, would reduce tobacco-related harms. As discussed in section IV of this document, nicotine is the primary constituent in cigarettes and other tobacco products that causes and maintains addiction. By enacting a

product standard that would seek to limit the nicotine content in cigarettes and certain other combusted tobacco products to minimally addictive or nonaddictive levels, FDA anticipates that reductions in population harm would be realized through long-term health benefits resulting from prevention of cigarette uptake and progression to regular cigarette smoking among young people, as well as shorter-term health benefits resulting from increased cessation of cigarette smoking among people who currently smoke. Each of these impacts alone would result in significant health benefits to the U.S. population. In totality, they provide overwhelming evidence that the proposed standard would result in substantial health benefits over both the short- and long-term. In this section, we summarize the health benefits of never progressing to regular cigarette smoking and combusted tobacco product use, the health benefits of quitting smoking, the population health benefits of switching from cigarettes to potentially less harmful tobacco products, and the health benefits of not being exposed to secondhand smoke. We also describe additional public health benefits of the proposed standard not addressed in FDA's population health model. Finally, we describe potential risks or limiting effects of the product standard, including risks of compensatory smoking. Based on the available evidence, FDA concludes that any such potential risks or limiting effects would be significantly outweighed by the anticipated substantial benefits of this proposed nicotine product standard.

1. Given the Harmful Effects of Cigarette Smoking and Combusted Tobacco Use, Never Progressing to Regular Smoking Prevents Death and Disease and Improves Quality of Life

Never progressing to regular cigarette smoking prevents death and disease caused by smoking. Any effects of a

nicotine product standard in cigarettes and certain other combusted tobacco products on preventing youth, young adult, and even adults who have never smoked from initiating/experimenting and progressing to regular cigarette smoking will have a population health benefit. Youth and young adults would experience the greatest benefits from a nicotine product standard, because it is likely that most of them would not progress beyond experimentation or occasional use and, therefore, may not experience the dangerous and deadly tobacco-related health effects associated with combusted tobacco product use. Fetuses and children also would benefit if their parents quit smoking or using most combusted tobacco products, given the negative health consequences to the fetus of a smoking mother and the dangers of secondhand smoke (Ref. 19). Children of parents who smoke, when compared with children whose parents do not smoke, have an increased frequency of respiratory infections like pneumonia and bronchitis (Ref. 563). Smoking cessation reduces the rates of these respiratory symptoms and of respiratory infections among children (Ref. 63 at p. 467). Children exposed to tobacco smoke in the home also are more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (thick or sticky fluid behind the eardrum) (Ref. 563). If parents were more readily able to quit because these products were minimally addictive or nonaddictive, the incidence of these health problems among youth would be expected to decline. Additionally, such health problems would not occur in future years, as fewer individuals would initiate and progress to regular smoking.

According to the 2014 Surgeon General's Report, which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of disease and death

in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (Ref. 1). As stated in the report, “cigarette smoking has been causally linked to disease of nearly all organs of the body, to diminished health status, and to harm to the fetus” and “[t]he burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products” (Ref. 1). The 2014 Surgeon General’s Report estimates that 16 million people live with diseases caused by smoking cigarettes (Ref. 1). Additionally, the burden of tobacco-related addiction and disease disproportionately impacts certain populations, such as individuals experiencing poverty, those of lower educational attainment, in historically marginalized racial and ethnic groups, in the LGBTQI+ community, people living with a mental health condition, in the military, and in certain geographic areas (Ref. 120). In particular, Black individuals experience the highest rates of incidence and mortality from tobacco-related cancers compared to people from other racial and ethnic groups (Refs. 102 and 103). Additionally, mortality related to other tobacco-related diseases such as heart disease, stroke, and hypertension is higher among Black individuals than

other racial and ethnic groups (Refs. 105, 106, 108 to 110, and 123). Moreover, when comparing mortality to morbidity, for every person who dies from smoking, 30 more are living with a smoking-attributable disease (Ref. 1). Smoking is causally associated with a number of diseases affecting nearly all organs in the body, such as numerous types of cancer, heart disease, stroke, lung diseases such as COPD, and diabetes, in addition to putting individuals at increased risk for tuberculosis, certain eye diseases, and immune system issues (Ref. 1). One study estimated that individuals in the United States have had 14.0 million major smoking-attributable medical conditions, including more than 7.4 million cases of COPD, nearly 2.3 million heart attacks, 1.8 million cases of diabetes, nearly 1.2 million stroke events, more than 300,000 cases of lung cancer, and nearly 1 million cases of other smoking-attributable cancers (bladder, cervix, colon/rectum, kidney, larynx, mouth, tongue, lip, throat, pharynx, stomach) (Ref. 564). Therefore, increased smoking cessation, reduced cigarette consumption, and lower progression to regular use would reduce not only the mortality from smoking, but also the enormous burden of cigarette-attributable disease in the United States. In addition to the years of life gained due to reduced premature mortality

from tobacco, the substantial reductions in smoking initiation and increases in smoking cessation will result in improvements in quality of life for those who quit or do not initiate smoking because of the product standard. To estimate the potential impact of the proposed standard on morbidity and mortality, we used estimates from FDA’s population health model, which is described in section VIII.A of this document. Table 5 presents cumulative estimates of mortality and morbidity avoided as a result of the proposed nicotine product standard, for certain years in the simulation period (Ref. 42 at Appendix J). By 2060, we estimate that approximately 1.8 million deaths due to tobacco would be avoided, rising to 4.3 million by the end of the century. The reduction in premature deaths attributable to the proposed product standard would result in 19.6 million life years gained by 2060 and 76.4 million life years gained by 2100. Based on previously reported quality of life scores derived for people who do and do not smoke, stratified by age group (Ref. 565), we estimate that the proposed nicotine product standard would result in 24.0 million QALYs gained by 2060 due to reduced smoking morbidity. By 2100, this estimate is projected to increase to 53.1 million QALYs gained due to reduced smoking morbidity (Ref. 42 at Section 2.3).

TABLE 5—PROJECTED NUMBER OF TOBACCO-ATTRIBUTABLE DEATHS AVOIDED, LIFE YEARS GAINED, AND QALYs GAINED DUE TO REDUCED SMOKING AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027

Year	Scenario	Cumulative tobacco-attributable deaths avoided (millions)	Cumulative life years gained (millions)	Cumulative QALYs gained due to reduced smoking morbidity (millions)
2040	Median (5th, 95th)	0.4 (0.1, 0.5)	2.0 (0.2, 2.7)	9.6 (2.7, 10.0)
2060	Median (5th, 95th)	1.8 (0.4, 2.0)	19.6 (3.6, 22.7)	24.0 (10.1, 24.7)
2080	Median (5th, 95th)	3.1 (1.0, 3.4)	47.4 (12.5, 52.5)	38.2 (18.5, 39.2)
2100	Median (5th, 95th)	4.3 (1.6, 4.6)	76.4 (26.5, 82.5)	53.1 (27.5, 54.4)

In addition to the main analyses concerning projected death and disability, we examined the sensitivity of modeled results to underlying assumptions related to baseline product use projections and mortality risk estimates. Sensitivity analyses accounted for the following: an increase in noncombusted product initiation; different assumptions of people who smoke switching to noncombusted products per year; decrease in smoking initiation; lower and higher noncombusted product mortality risk compared to baseline; different assumptions for dual product use mortality risk; changes in baseline

mortality rate projections; and the potential impact of a substantial illicit market for NNC cigarettes. Changes to baseline inputs of noncombusted product use trajectories and health risks had minimal impact on smoking prevalence and attributable morbidity and mortality, and the nicotine product standard still resulted in substantial public health benefits. Assuming increasing initiation rates for noncombusted product use until year 2030 implies that the number of people who use tobacco will be higher under the baseline and nicotine product standard scenarios, with a higher

proportion being people who use noncombusted tobacco products. In terms of mortality risk, we applied a relative risk of 1.18 for people who use noncombusted tobacco products as compared with people who have never smoked (*i.e.*, the risk of death associated with noncombusted tobacco use is assumed to be 1.18 times greater than the risk of death associated with never smoking). For combusted cigarette smoking, the relative mortality risk varies with age, but is generally around 2.5, as compared to people who have never smoked (*i.e.*, the risk of death associated with smoking is estimated to be 2.5 times greater than the risk of

death associated with never smoking). Mortality risk for people who have never used tobacco is 1, so the excess mortality risk of using a product beyond that of those who have never used tobacco, and therefore related to the

product used, can be calculated by subtracting 1 from the mortality risk (*i.e.*, excess mortality risk for noncombusted tobacco use is $1.18 - 1 = 0.18$, and for combusted cigarette use it is $2.5 - 1 = 1.5$). Thus, in our main

modeling projections, we apply an excess risk of using noncombusted tobacco products that is 12 percent that of the excess risk associated with cigarette smoking (*i.e.*, $100 \times (0.18/1.5) = 12$ percent).

TABLE 6—IMPACT OF VARYING BASELINE ASSUMPTIONS ON PROJECTED SMOKING PREVALENCE AND AVOIDED MORTALITY AND MORBIDITY BY 2100. MEDIAN (5TH, 95TH PERCENTILES) ESTIMATES

Scenario	Projections through year 2100			
	Cigarette smoking prevalence (%)	Cumulative tobacco-attributable mortality avoided (millions)	Cumulative life years gained (millions)	Cumulative QALYs gained from reduced smoking morbidity (millions)
Main scenario	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	76.4 (26.5, 82.5)	53.1 (27.5, 54.4)
Baseline noncombusted tobacco product trajectory				
Increased noncombusted initiation	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	76.5 (26.7, 82.5)	53.1 (27.5, 54.4)
50% increased complete switching	0.13 (0.06, 1.7)	4.2 (1.7, 4.5)	74.9 (28.6, 80.7)	51.9 (29.0, 52.9)
100% increased complete switching	0.12 (0.06, 1.5)	4.2 (1.8, 4.4)	73.6 (30.3, 79.0)	50.8 (30.2, 51.6)
Baseline smoking initiation trajectory				
25% decrease in smoking initiation during the period 2021–2030	0.13 (0.1, 1.6)	4.1 (1.5, 4.4)	72.9 (24.3, 79.0)	45.2 (22.9, 46.4)
Baseline smoking cessation				
10% increase in smoking cessation	0.15 (0.1, 1.8)	4.0 (1.5, 4.3)	70.9 (24.9, 76.4)	50.1 (26.3, 51.2)
Baseline noncombusted mortality relative risk (RR)				
Higher RR than main scenario (RR = 1.3)	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	75.0 (26.0, 81.4)	53.1 (27.5, 54.4)
Lower RR than main scenario (RR = 1.1)	0.2 (0.1, 1.9)	4.4 (1.6, 4.7)	77.2 (26.9, 83.2)	53.1 (27.5, 54.4)
Baseline dual use RR				
Dual use RR is 18% greater than for cigarette smoking	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	75.9 (25.0, 82.4)	53.1 (27.5, 54.4)
Dual use RR is the average of cigarette and noncombusted use RR	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	77.0 (28.6, 82.6)	53.1 (27.5, 54.4)
Dual use RR is equal to the noncombusted use RR	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	77.6 (30.7, 82.7)	53.1 (27.5, 54.4)
Baseline mortality rate projections				
Keep mortality rates constant starting at 2060	0.2 (0.1, 2.0)	4.7 (1.9, 5.1)	77.9 (28.2, 83.9)	53.0 (27.4, 54.2)

As shown in table 6, varying baseline input parameter values had very small effects on estimates of the potential population health effects of a nicotine product standard. Assuming a 25 percent decrease in cigarette smoking initiation during the period from 2021 to 2030 resulted in modest decreases in smoking prevalence and health benefits, in particular reductions in morbidity due to smoking, by 2100 in the policy scenario compared to the main analysis. Increases in baseline complete switching to noncombusted tobacco product use resulted in similar small decreases in smoking prevalence and health benefits in terms of life years gained and reduced smoking morbidity by 2100 compared to the main analysis. Different assumptions about baseline relative risks also produced modest

changes in differences in life years gained. Additional details regarding the sensitivity analyses can be found in FDA's modeling document (Ref. 42).

Sensitivity analyses were also conducted examining assumptions about the potential effect of the nicotine product standard on smoking cessation. In addition to the modeling results obtained through expert-derived inputs, we also generated projections based on results from clinical studies of VLNC cigarette use and cessation. Based on these studies, we applied a two-fold increase in cessation (estimates ranged from 6.4 percent to 19.8 percent), as compared to the baseline cessation rate (estimates ranged from 3.2 percent to 9.9 percent), as an alternative estimate of the long-term impact of the proposed product standard on cessation, while

maintaining the median of the expert-derived values for the other parameters (Ref. 42 at Section 2.3). Given the wide variation in the expert-derived cessation rates, the projected health impacts assuming a two-fold increase in cessation fell within the range of results obtained from expert-derived inputs (see table 6).

Additionally, increasing the assumed proportion of people who smoke who may divert to the use of illicit NNC cigarettes (3.8 percent, 5.9 percent, and 21.0 percent),³³ and allowing youth and

³³ We use 3.8 percent as a low-end estimate based on 2017 estimates of illicit trade volume in cigarettes from Euromonitor International (Ref. 558). This estimate excludes interstate smuggling for purposes of tax avoidance. Using findings from the International Tobacco Control United States Survey, we estimate that 5.9 percent of U.S. people

young adults (who would have otherwise initiated NNC cigarette use) to initiate into illicit NNC cigarette use (0 percent, 2.6 percent, and 10 percent)³⁴ under the proposed nicotine standard resulted in reductions in the projected

cumulative attributable morbidity and mortality outcomes following the implementation of the policy (table 7). It is noteworthy that significant benefits in terms of reduced morbidity and mortality are realized as a result of this

product standard, even in a scenario in which greater proportions of the population who smoke are assumed to divert to use of illicit NNC cigarettes.

TABLE 7—PROJECTED HEALTH BENEFITS AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027 UNDER ILLICIT TRADE SCENARIOS

[Median (5th, 95th percentiles) estimates]

Year	Illicit trade impact scenarios			
	Main scenario (no impact)	Low impact ¹	Medium impact ²	High impact ³
Tobacco-Attributable Deaths Avoided (Millions)				
2040	0.4 (0.1, 0.5)	0.4 (0.04, 0.5)	0.4 (0.04, 0.5)	0.4 (0.01, 0.5)
2060	1.8 (0.4, 2.0)	1.8 (0.4, 2.0)	1.8 (0.3, 2.0)	1.7 (0.1, 2.0)
2080	3.1 (1.0, 3.4)	3.1 (0.8, 3.4)	3.1 (0.8, 3.4)	3.0 (0.4, 3.3)
2100	4.3 (1.6, 4.6)	4.3 (1.5, 4.6)	4.3 (1.4, 4.6)	4.2 (0.9, 4.5)
Cumulative Life Years Gained (Millions)				
2040	2.0 (0.2, 2.7)	2.0 (0.1, 2.7)	2.0 (0.1, 2.7)	1.8 (0.01, 2.6)
2060	19.6 (3.6, 22.7)	19.4 (3.2, 22.6)	19.3 (3.0, 22.6)	18.4 (1.2, 22.0)
2080	47.4 (12.5, 52.5)	47.1 (11.4, 52.4)	46.9 (10.7, 52.3)	45.3 (5.3, 51.5)
2100	76.4 (26.5, 82.5)	76.0 (24.6, 82.3)	75.8 (23.4, 82.2)	73.9 (13.7, 81.3)
Cumulative QALYs Gained from Reduced Smoking Morbidity (Millions)				
2040	9.6 (2.7, 10.0)	9.6 (2.5, 10.0)	9.5 (2.4, 10.0)	9.2 (1.5, 9.9)
2060	24.0 (10.1, 24.7)	24.0 (9.6, 24.7)	23.9 (9.2, 24.7)	23.4 (6.5, 24.6)
2080	38.2 (18.5, 39.2)	38.2 (17.7, 39.2)	38.0 (17.0, 39.2)	37.3 (12.6, 39.0)
2100	53.1 (27.5, 54.4)	53.0 (26.6, 54.4)	52.8 (25.5, 54.3)	51.9 (19.3, 54.1)

¹ Low Impact: 3.8 percent people who smoke would divert to use illicit NNC cigarettes, and 0 percent youth and young adults would initiate illicit NNC cigarettes.

² Medium Impact: 5.9 percent people who smoke would divert to use illicit NNC cigarettes, and 2.6 percent youth and young adults would initiate illicit NNC cigarettes.

³ High Impact: 21.0 percent people who smoke would divert to use illicit NNC cigarettes, and 10.0 percent youth and young adults would initiate illicit NNC cigarettes.

As previously discussed, nicotine is the primary driver of addiction in tobacco products and facilitates progression to regular cigarette smoking and other regular combusted tobacco product use. FDA anticipates that establishing a maximum level of nicotine in cigarettes and certain other combusted tobacco products will prevent a substantial number of youth and young adults who experiment with combusted tobacco products from developing an addiction to these products, thereby decreasing progression to regular use, resulting in reduced tobacco-related morbidity and mortality associated with combusted tobacco product use.

2. Given the Harmful Effects of Cigarette Smoking and Other Combusted Tobacco Product Use, Quitting Smoking Reduces Death and Disease

Although the health benefits are greater for people who stop smoking at earlier ages (Refs. 63 and 563), researchers estimate that people who regularly smoke can gain years of additional life expectancy no matter when they quit (Ref. 566). Quitting cigarette smoking and use of other combusted tobacco products substantially reduces the likelihood of tobacco-related death and disease. As stated in the 2004 Surgeon General's Report, "[q]uitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by

smoking and improving health in general" (Ref. 63). The 2020 Surgeon General's Report also concluded that "[s]moking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life." (Ref. 19). As previously noted, FDA expects that, if this proposed rule is finalized, there will be a significant increase in smoking cessation in the U.S. population (see section VIII.C of this document).

The benefits associated with smoking cessation happen quickly (Ref. 63). Within 2 to 12 weeks of quitting smoking, an individual's lung function and blood circulation improve (Ref. 63). During the first 1 to 9 months following cessation, coughing and shortness of breath decrease (Ref. 63). Within several

who use cigarettes last purchased cigarettes from low-tax locations (Ref. 559). We use these figures as proxies for the proportions of people who use cigarettes who may actively seek out illicit NNC cigarettes under a nicotine product standard, although we note that the product standard would be implemented nationwide, avoiding disparate pricing/availability between states. We use 21 percent as a high-end estimate based on the

difference in non-compliance rates between reduced nicotine intervention groups (78 percent) and control groups assigned to NNC cigarettes (57 percent) in clinical trial data (Refs. 29 and 330). This estimate of 21 percent also represents the high-end of the range estimated by the National Research Council, which reflected the methodology of the pack return survey by Fix, et al. (Refs. 560 and 561).

³⁴ We use findings from an expert elicitation developed to gauge the impact of a menthol cigarette and cigar prohibition in the United States, which indicates that among people ages 12–24 who would have otherwise initiated menthol cigarette use, 2.6 percent would initiate illicit menthol cigarette use (estimate ranged from 0 percent to 10 percent) (Ref. 562).

months of quitting smoking, individuals can expect further improvement in lung function (Ref. 63). Additionally, the benefits of cessation continue for those who remain smoke-free. Smoking cessation reduces the risk of cancers and other diseases (Ref. 19). For example, the risk of fatal lung cancer in adults over age 55 is about 25 times higher among people who smoke cigarettes relative to people who have never smoked (Ref. 567). After 10–15 years of abstinence from smoking, the risk of lung cancer is about 50 percent of the risk for individuals who continue to smoke (Ref. 19). The risk of cancer of the mouth, throat, esophagus, stomach, bladder, cervix, pancreas, liver, kidney, colon, and rectum, and the risk of acute myeloid leukemia also decreases (Refs. 19 and 568). The evidence is also sufficient to infer that the risk of stroke decreases after smoking cessation and approaches that of people who have never smoked cigarettes over time (Ref. 569). Furthermore, the evidence is sufficient to infer that the relative risk of coronary heart disease among people who formerly smoked cigarettes falls rapidly after cessation and then declines more slowly (Ref. 19).

In addition, smoking cessation substantially reduces the risk of other dangerous diseases that can lead to death or disability and cause a financial strain on healthcare resources. For example, quitting smoking substantially reduces the risk of peripheral artery occlusive disease (which can cause complications that lead to loss of limbs) (Ref. 563). It also reduces the relative risk of coronary heart disease and stroke morbidity and mortality among people who formerly smoked compared with people who have never smoked (Ref. 19). People who formerly smoked cigarettes also have half the excess risk of experiencing an abdominal aortic aneurysm compared to people who currently smoke cigarettes (Ref. 563). Furthermore, cigarette smoking complicates many diseases (*e.g.*, people who smoke and have diabetes have higher risk of complications, including heart and kidney disease, poor blood flow in the legs and feet, retinopathy, and peripheral neuropathy), and smoking cessation can alleviate those complications as well (Ref. 28).

Even people who smoke and quit smoking after the onset of a life-threatening disease experience significant health benefits from cessation. Quitting smoking after a diagnosis reduces the chance of recurrences and future health problems. For example, people who quit smoking after having a heart attack can reduce their chances of having a second heart

attack by 50 percent (Ref. 568). For those persons who have already developed cancer, quitting smoking reduces the risk of developing a second cancer (Refs 563, 570 to 572). Additionally, quitting smoking after a diagnosis of lung cancer reduces the risk of cancer progression and mortality (Ref. 573). Researchers also estimate that for people who currently smoke and have been diagnosed with coronary heart disease, quitting smoking reduces the risk of death overall and reduces the risk of recurrent heart attacks and cardiovascular death by 30 to 40 percent (Refs. 19 and 563). The 2020 Surgeon General's Report concluded that quitting smoking reduces the risk of fatal and non-fatal stroke, and earlier reports have also stated that it is reasonable to assume that quitting smoking would reduce the risk of recurrent strokes (Refs. 19 and 563). Quitting smoking helps the body tolerate the surgery and treatments, such as chemotherapy and radiation, associated with certain smoking-related diseases, and quitting also improves the likelihood of responding to those treatments (Refs. 63, 563, 570, and 574) and reduces the risk of respiratory infections compared to continued smoking (Refs. 563 and 575).

Given the reduction in risk of smoking-related death and disease associated with cessation, those who successfully quit smoking also increase their life expectancy. Using data from the CPS-II—an ongoing study of 1.2 million adults—scientists have found that, among men who smoke cigarettes, men who smoked at age 35 and continued to smoke until death had a life expectancy of 69.3 years, compared with a life expectancy of 76.2 years for those who stopped smoking at age 35 (Ref. 576). After adjusting for the subsequent quit rate among people who currently smoke cigarettes at baseline (to account for the possibility that some people who currently smoke at baseline quit smoking or some people who formerly smoked relapsed during followup and, thus, were incorrectly classified as people who continue to smoke in the unadjusted analysis), the life expectancy for males who formerly smoked increased to 77.8 years (a life extension of 8.5 years) (Ref. 576). Women who smoked at age 35 and continued to smoke until death had a life expectancy of 73.8 years, compared with a life expectancy of 79.7 years for those who stopped smoking at age 35 (Ref. 576). After adjustment for the subsequent quit rate among people who currently smoke at baseline, the life expectancy for females who formerly smoked increased to 81 years (a life

extension of 7.7 years) (Ref. 576). Furthermore, a man aged 60–64 years who smokes 20 cigarettes (one pack) or more per day and then quits smoking reduces his risk of dying during the next 15 years by 10 percent (Ref. 563).

While cessation is beneficial for people of all ages, the health benefits are greatest for people who stop smoking at earlier ages (Refs. 63 and 563). Scientists in the United Kingdom found that people who quit smoking at age 30 reduce their risk of dying prematurely (*i.e.*, dying before their expected average life expectancy) from smoking-related diseases by more than 90 percent (Refs. 544 and 577). Those who quit at age 50 reduce their risk of dying prematurely by 50 percent compared to those who continue to smoke (Ref. 544). Using NHIS data, researchers also estimated that life expectancy in the United States would increase by 4 years among people who smoke who quit at ages 55–64, and 10 years among people who smoke who quit at ages 25–34 (Ref. 566). Scientists using the CPS-II data (while accounting for the possibility that some people who currently smoke at baseline quit smoking and some people who formerly smoked relapsed during followup) found that even people who smoke who quit at age 65 had an expected life increase of 2 years for men and 3.7 years for women (Ref. 576).

The benefits continue for those who remain smoke-free. At year one, an individual's risk of coronary heart disease becomes half that of a person who smokes cigarettes (Refs. 219 and 578). Beginning 2 and 5 years after cessation, an individual's stroke risk is reduced to that of a person who does not smoke cigarettes (Refs. 19 and 578). In addition, the risk of cancers of the mouth, throat, esophagus, and bladder for a person who formerly smoked is halved within 5 years (Ref. 578). By 10 years post-cessation, an individual's risk of cancers of the kidney and pancreas decreases (Ref. 578). The risk of coronary heart disease becomes that of a person who does not smoke after 15 years of abstinence (Ref. 578). FDA anticipates that limiting nicotine yield by setting a maximum level of nicotine in cigarettes and certain other combusted tobacco products would improve smoking cessation outcomes in adults who smoke and result in longer life expectancies for more individuals. Additionally, FDA anticipates that this proposed product standard will benefit populations that use tobacco products at disproportionately high levels by reducing tobacco-related morbidity and mortality by improving quitting and cessation among these populations.

Research has shown that people from specific population groups who smoke cigarettes bear a disproportionate burden of tobacco-related morbidity and mortality. Black individuals, and in particular Black men, experience the highest rates of incidence and mortality from tobacco-related cancers compared to people from other racial and ethnic groups (Refs. 102 and 103). Additionally, mortality due to tobacco-related disease such as heart disease, stroke, and hypertension is higher among Black individuals compared to other racial and ethnic groups (Refs. 105, 106, 108 to 110, 123, and 579). Furthermore, individuals with symptoms of mental health disorders and persons who have substance use disorders smoke cigarettes in disproportionately large numbers (Refs. 128, 580 to 585), resulting in increased risk for tobacco-related morbidity and mortality (Ref. 585). Based on these collective findings, FDA anticipates that the proposed product standard will improve smoking cessation outcomes across the U.S. population, including among populations at increased risk for tobacco-related morbidity and mortality, leading to a reduction in adverse tobacco-related health effects.

3. Given the Harmful Effects of Cigarette Smoking, Switching to a Potentially Less Harmful Nicotine Delivery Product May Reduce Death and Disease

Some people who smoke and who want to quit use NRT products, or other smoking cessation products that do not contain nicotine, that FDA has approved as safe and effective for smoking cessation. These products have been shown to significantly increase the success of smoking cessation (Ref. 586). FDA continues to be committed to enabling the development of safe and effective drug product innovations that help smokers quit combustible cigarettes and improve their health.

FDA also recognizes, however, that other people may seek to switch from cigarette smoking to using other noncombusted tobacco products that deliver nicotine. People who smoke and switch completely to a potentially less harmful noncombusted tobacco product to maintain their nicotine dependence also could, to the extent that use of those products result in less harm, significantly reduce their risk of tobacco-related death and disease (Ref. 8).

As described in section VI.B of this document, studies have reported on the ways in which people who use tobacco have predicted how their patterns of tobacco use would change in response to the implementation of a nicotine

product standard. While most people who use tobacco in these studies indicated that they would continue to smoke cigarettes—or other combusted products—or simply quit tobacco use, some participants reported that they would switch to using or increase use of a noncombusted product (Refs. 262, 264, and 587).

One clinical trial compared use of NRT and alternative tobacco products (*i.e.*, smokeless tobacco, e-cigarettes, cigars, cigarillos) among people who smoke cigarettes and were randomized to one of three groups (Ref. 5). One group received LNC cigarettes along with access to NRT, noncombusted tobacco products (*i.e.*, smokeless tobacco, e-cigarettes), and combusted non-cigarette products (*i.e.*, cigars, cigarillos); a second group received LNC cigarettes, and NRT, and noncombusted tobacco products only; and a third group received NNC cigarettes along with NRT, noncombusted tobacco products, and combusted tobacco products. Overall, those who received the LNC cigarettes used more alternative combusted and noncombusted tobacco products as well as NRT. These participants also smoked fewer total combusted tobacco products and had a greater number of quit attempts. Tobacco toxicant levels in participants who received LNC cigarettes and only NRT and noncombusted products were statistically significantly lower than those of participants who received NNC cigarettes, while toxicant levels in those who received LNC cigarettes and had access to NRT, combusted, and noncombusted products did not differ from the NNC cigarette group (Ref. 5). Findings demonstrate that when people who smoke cigarettes are switched to LNC cigarettes and are provided with alternative sources of nicotine, they will readily use the alternative sources of nicotine. Moreover, the LNC cigarette group that had access to NRT and noncombusted nicotine sources only had statistically significantly reduced biomarker levels of certain harmful constituents (NNN and NNAL) compared to those who continued to smoke NNC cigarettes (Ref. 5). The LNC cigarette group with access to NRT and both combusted and noncombusted tobacco products resembled the NNC cigarette group (Ref. 5).

Moreover, in general, the high levels of noncompliance with study-issued VLNC cigarettes in the context of clinical trials, and continued use of non-study provided tobacco products (particularly NNC cigarettes), suggest that VLNC cigarettes have lower appeal and abuse potential compared to NNC cigarettes (Refs. 327 to 331). As a result,

these findings suggest that people who smoke VLNC cigarettes are likely to use alternative nicotine-containing products, if such products are concurrently available, once a nicotine product standard for combusted tobacco products is in place.

Under FDA's population health model's product standard scenario, an increase in noncombusted product use would occur concurrently with a dramatic reduction in cigarette smoking. Although the model assumes that noncombusted product initiation would remain constant until the end of the projection period (*i.e.*, 2100), the product standard scenario shows that noncombusted use continues to climb due to higher switching rates from combusted products as compared to the baseline scenario. This is because the number of people who start using noncombusted tobacco products would be much higher compared to the number of people who quit using noncombusted products. That is, there would be more people who currently use noncombusted tobacco products every year than people who quit using noncombusted products, which would cause an increase in noncombusted tobacco use prevalence throughout the projection period. According to the model, adult noncombusted tobacco use would increase from 7.7 percent in the baseline scenario to 12.8 percent in the product standard scenario within 1 year after policy implementation, due to the increase in switching from cigarette smoking and dual use as a result of a nicotine product standard. The prevalence of noncombusted tobacco use would remain higher in the product standard scenario over time due both to increased uptake among people who smoke and increased initiation due to some dissuaded initiation of cigarette use, compared to those individuals taking up noncombusted products instead.

Under the product standard scenario in the model, dual use of cigarettes and noncombusted tobacco products also would increase immediately, since a greater proportion of people who continue to smoke cigarettes would take up noncombusted products than in the baseline scenario, but this pattern would not continue over time with dual use prevalence reaching levels below 0.1 percent by the year 2035. Although the increase in noncombusted tobacco product use trend changes over time (*i.e.*, results showed a spike increase in noncombusted use prevalence within the first 3 years after implementation of a nicotine product standard), the decrease in smoking prevalence becomes greater than the increase in

noncombusted use following the implementation of a nicotine product standard. Consequently, overall tobacco use under the product standard scenario would remain lower than in the baseline scenario.

As described in section VIII.A of this document, in addition to the aforementioned main analyses, FDA conducted a series of sensitivity analyses to examine the impact of key modeling assumptions on the main outcome metrics of interest. In these analyses, we examined the sensitivity of modeled results to underlying assumptions related to baseline product use projections and mortality risk estimates. Sensitivity analyses included examining the impact of increased initiation of noncombusted tobacco product use among those who would otherwise not have used tobacco, the impact of an increase in switching from cigarettes to noncombusted tobacco product use, the impact of a varying mortality risk associated with dual use of cigarettes and noncombusted tobacco products, the impact of lower and

higher noncombusted tobacco product risk, and the emergence of an illicit market for full nicotine content cigarettes.

In general, changes to baseline inputs of noncombusted product use trajectories and health risks had minimal impact on smoking prevalence and attributable morbidity and mortality and the nicotine product standard policy scenario still resulted in substantial public health benefits. In the main modeling analysis, we account for people who would have initiated on smoking cigarettes initiating on noncombusted tobacco products instead because of the product standard. It is also possible that there could be increased initiation of noncombusted tobacco use among those who would otherwise not have used tobacco under the product standard scenario; for example, due to increased marketing of noncombusted products because of the policy or changes in public perceptions of the harms of noncombusted products. In a sensitivity analysis, starting at 2027 (year of the proposed standard

implementation), we assumed a 20 percent increase in the initiation of noncombusted tobacco products among those who would otherwise have not used tobacco. Table 8 provides the projected impacts on tobacco-related mortality and morbidity through the year 2100. Compared with the main results, a 20 percent increase in initiation of noncombusted tobacco use had minimal impact in mortality outcomes given the substantial reduction in adverse health effects projected under a potential nicotine product standard. For example, by year 2100, cumulative life years gained decreased by less than 1 percent compared with the main results, while cumulative tobacco-attributable deaths avoided remained almost the same. It is important to note that, because we only have data on the effect of cigarette smoking (and not noncombusted product use) on quality of life, the projected changes in QALYs gained from reduced smoking morbidity are not affected by increasing noncombusted product use initiation.

TABLE 8—IMPACT OF INCREASED INITIATION OF NONCOMBUSTED TOBACCO PRODUCTS AS A RESULT OF THE PROPOSED NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027 ON PROJECTED SMOKING PREVALENCE AND TOBACCO-RELATED MORTALITY AND MORBIDITY BY 2100

[Median (5th, 95th percentiles) estimates]

Scenario	Projections through year 2100			
	Noncombusted tobacco use prevalence (%)	Cumulative tobacco-attributable mortality avoided (millions)	Cumulative life years gained (millions)	Cumulative QALYs gained from reduced smoking morbidity (millions)
Main scenario	14.1 (12.7, 14.9)	4.3 (1.6, 4.6)	76.4 (26.5, 82.5)	53.1 (27.5, 54.4)
20% increased initiation of noncombusted products	15.4 (14.0, 16.1)	4.3 (1.6, 4.6)	75.9 (26.1, 82.1)	53.1 (27.5, 54.4)

Taken together, findings from prior research, as well as FDA's population health model, suggest that if the proposed product standard reduces the nicotine yield by setting a maximum level of nicotine in cigarettes only, but people who smoke cigarettes still have access to other NNC combusted tobacco products, they likely would substitute with the NNC combusted tobacco products and negate a significant proportion of the public health impact of the product standard. If other combusted tobacco products also are covered by this proposed product standard, however, data suggest that people who smoke may switch from combusted tobacco product use to potentially less harmful tobacco products. Moreover, findings indicate that switching from combusted cigarette use to noncombusted tobacco product use has the potential to impart

significant health-related benefits on a population level. The population health model estimates that on average approximately 50 percent of people who smoke cigarettes will switch to noncombusted tobacco products use per year, and although we estimate that such switching carries an 8 percent higher risk than quitting tobacco use entirely (based on findings from Henley et al. 2007 (Ref. 557)), this is still a significant health-related benefit compared to continuing to use combusted tobacco products.

4. Having Fewer People Smoke Cigarettes and Other Combusted Tobacco Products Will Reduce Death and Disease Associated With Secondhand Smoke Exposure

Cigarettes and other combusted tobacco products also have deadly effects on people who do not smoke

because they produce secondhand smoke. It is well-established that secondhand tobacco smoke causes premature death and disease in children and in adults who do not smoke (Ref. 15 at p.11). Secondhand smoke exposure is currently estimated to be responsible for over 41,000 deaths annually in the United States (Ref. 1). For example, an estimated 7,300 lung cancer deaths and nearly 34,000 coronary heart disease deaths annually can be attributed to secondhand smoke (Ref. 1). Additionally, productivity losses due to secondhand smoke-attributable deaths are estimated to cost the United States \$5.6 billion each year (Ref. 1).

Children are one group disproportionately exposed to and impacted by secondhand smoke. The 2014 Surgeon General's Report estimated that secondhand smoke is

associated with 150,000 to 300,000 lower respiratory tract infections in infants and children under age 18 months, 790,000 doctor's office visits related to ear infections per year, and 202,000 asthma cases each year (Refs. 1 and 137). In 2014, the U.S. Surgeon General reported that 400 sudden infant death syndrome (SIDS) deaths annually are related to perinatal smoking or exposure to secondhand smoke; the "Reproductive Outcomes" section describes the impact of perinatal smoking (Ref. 1). Children of parents who smoke, when compared with children of parents who do not smoke, have an increased frequency of respiratory infections like pneumonia and bronchitis (Ref. 563). Children exposed to tobacco smoke in the home are also more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (fluid behind the eardrum) (Ref. 563). More recent data from the 2013–2014 NHANES estimates that approximately 58 million Americans who do not smoke (1 in 4) were exposed to secondhand smoke, including 14 million children (Ref. 588). Approximately half of all U.S. children ages 3–18 are exposed to cigarette smoke regularly at home or other locations that still permit smoking (Ref. 1). In 2019, approximately one-quarter of middle and high school students reported breathing in secondhand smoke in their homes or in a vehicle (Ref. 145).

The burden of secondhand smoke exposure is experienced disproportionately among members of some racial and ethnic groups and lower income groups. Among people who do not smoke and were ages 3 and older, findings from 2011 to 2018 NHANES data indicate that non-Hispanic Black persons and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 (Ref. 139). From 1999 to 2012, the

percentage of people who do not smoke and were age 3 and older exposed to secondhand smoke (defined in the study as levels 0.05–10 nanogram per milliliter) declined across all racial and ethnic groups (Ref. 141). However, a significantly higher proportion of non-Hispanic Black persons who do not smoke continued to have detectable serum cotinine levels compared to Mexican American and non-Hispanic White persons who do not smoke. For example, in 2011–2012, nearly 50 percent of non-Hispanic Black people who do not smoke had detectable serum cotinine levels, compared with 22 percent of non-Hispanic White and 24 percent of Mexican American people who do not smoke (Ref. 141). Additionally, disparities in secondhand smoke exposure are found across various environmental settings, including homes, vehicles, workplaces, and public places. These disparities speak to the interrelated influences of individual factors (e.g., age, race and ethnicity, income) and existing inequities in places where members of communities impacted by tobacco-related health disparities are likely to reside, spend time, and work (Ref. 174). The proposed product standard is anticipated to reduce smoking-related morbidity and mortality for specific population groups that do not smoke that are disproportionately exposed to secondhand smoke, especially youth.

Moreover, there is also some scientific evidence supporting disparities in secondhand smoke exposure by sexual orientation. An analysis of NHANES data from 2003–2010 found that secondhand smoke exposure (defined as a serum cotinine¹⁷ levels ≥0.05 nanogram per milliliter) differed by sexual orientation among women 20–59 years of age (Ref. 143). This study found that among women 20–59 years of age, secondhand smoke exposure was higher among non-smoking women who identified as lesbian (56.2 percent) or who reported a lifetime experience with a same-gender partner (47.7 percent) than those women who identified as exclusively heterosexual (33.0 percent;

p<0.001) (Ref. 143). However, among men 20–59 years of age, exposure to secondhand smoke did not significantly differ by sexual orientation.

FDA anticipates that the overall public health benefits of this proposed nicotine product standard would be far greater than those described above once we account for the impacts of reduced cigarette smoking on secondhand smoke exposure. As evidenced by evaluations of smoke-free policies, decreasing exposure to secondhand smoke will decrease smoking-related death and disease among people who do not smoke (Refs. 589 and 590).

To estimate the potential impact of the proposed standard on morbidity and mortality, FDA evaluated the existing scientific literature as well as findings from our population health model, which is described in section VIII.A of this document. Estimation of the mortality benefits of a nicotine product standard for secondhand smoke exposure used a similar approach. This approach relied on scaling the estimate of 437,400 deaths annually attributable to direct cigarette smoking from 2005–2009 (Ref. 1), to the number of deaths attributed to secondhand smoke exposure. That ratio was then applied to the model-derived projected changes in avoided cigarette-attributable deaths under the main product standard scenario to project the number of avoided deaths over time from secondhand smoke exposure. In the population health model, the impacts of a nicotine product standard on mortality from secondhand smoke exposure were estimated by first calculating the ratio of secondhand smoke (41,280 deaths; (Ref. 1)) to primary smoking-attributable deaths. That value, 9.4 percent, was then applied to the projections of cigarette-attributable deaths avoided yielding an estimate of approximately 169,000 cumulative deaths from secondhand smoke exposure avoided by 2060, rising to approximately 415,600 cumulative deaths avoided by the end of the century (see table 9).

TABLE 9—PROJECTED NUMBER OF TOBACCO-ATTRIBUTABLE DEATHS AVOIDED FOR SECONDHAND SMOKE AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027

Year	Scenario	Cumulative secondhand smoking-attributable deaths avoided
2040	Median (5th, 95th)	39,800 (4,900, 49,200)
2060	Median (5th, 95th)	169,000 (38,500, 189,000)
2080	Median (5th, 95th)	297,000 (91,200, 323,200)
2100	Median (5th, 95th)	415,600 (159,700, 444,400)

5. Estimated Mortality Impact of Reduced Smoking-Related Fires, Smoking-Related Perinatal Conditions, and Use of Non-Premium Cigars and Pipe Tobacco as a Result of Implementation of the Proposed Standard

FDA anticipates that the overall public health benefits of this proposed nicotine product standard would be greater than those described above once we account for the impacts of reduced cigarette smoking on smoking-related fires and perinatal conditions, in addition to the impacts of reduced use of other combusted tobacco products. To estimate the potential impact of the proposed standard on mortality, FDA evaluated the existing scientific literature, as well as findings from the population health model—which is described in section VIII.A. of this document. Similar to the approach taken to estimate the mortality benefits of a nicotine product standard for secondhand smoke exposure, estimation of the mortality benefits of a nicotine product standard for smoking-related fires, smoking-related perinatal conditions, and use of non-premium cigars and pipe tobacco used a consistent approach. This approach relied on scaling the estimate of 437,400 deaths annually attributable to direct cigarette smoking from 2005–2009 (Ref. 1), to the number of deaths attributed to each of the following causes: smoking-related fires, smoking-related perinatal conditions, and use of non-premium cigars and pipe tobacco. That ratio was then applied to the model-derived projected changes in avoided cigarette-attributable deaths under the main product standard scenario to project the number of avoided deaths over time from each of these causes (*i.e.*, smoking-related fires, smoking-related perinatal conditions, and use of non-premium cigars and pipe tobacco) (see table 10).

During 2012–2016, an estimated annual average of 18,100 reported home structure fires in the United States were caused by smoking materials, which killed an average of 590 people annually (Ref. 591). Moreover, smoking materials remain a leading cause of fatal home fires in the United States, and people who smoke are not the only victims (Ref. 592). By one estimate, one out of every four fatal victims of smoking-material fires is not the person whose cigarette initiated the fire (Ref. 593). A lower prevalence of cigarette smoking and reduced cigarette consumption is likely to decrease the occurrence of fires caused by smoking materials, including cigarettes and other combusted tobacco products. To estimate the impact of a

nicotine product standard on the number of deaths caused by smoking-related fires, we applied the average of 590 deaths annually from 2012–2016 from home structure fires started by smoking materials (Ref. 591). We calculated the ratio of smoking-related fire deaths to cigarette-attributable deaths to be approximately 0.1 percent and applied that value to the projections of avoided cigarette-attributable deaths, yielding an estimate of approximately cumulative 2,400 deaths due to smoking-related fires avoided by 2060, rising to approximately cumulative 5,900 deaths avoided by the end of the century (table 10).

Cigarette smoking is responsible for approximately 1,000 deaths from perinatal conditions annually, including over 600 deaths from prenatal conditions and 400 deaths from SIDS (Ref. 1). Exposure to secondhand smoke can also cause adverse health effects in infants and children. Currently, approximately half of all U.S. children and adolescents ages 3–18 years are exposed to cigarette smoke regularly at home or other locations that still permit smoking (Ref. 1). Exposure to cigarette smoke among children and adolescents can trigger asthma attacks and lead to more frequent respiratory infections compared to those not exposed to smoke (Ref. 1). Prenatal tobacco exposure and postnatal secondhand smoke exposure increase the risks of fetal deaths, fetal growth restriction/low birth weight, respiratory conditions, and SIDS (Ref. 15, Ref. 1). In addition, thirdhand smoke—the chemical residue from combusted tobacco smoke that can become embedded in the environment (*e.g.*, carpet, dust)—results in exposure to harmful constituents, such as tobacco specific nitrosamines (Ref. 138). Exposure to thirdhand smoke is especially concerning for young children, given their size and behaviors, like crawling on the ground and frequently putting their hands in their mouths.

FDA estimated the impacts of a potential nicotine product standard on perinatal mortality by first calculating the ratio of perinatal deaths (1,013 deaths; (Ref. 1)) to primary smoking-attributable deaths. That value, 0.2 percent, was then applied to the projections of cigarette-attributable deaths avoided yielding an estimate of approximately 4,100 cumulative perinatal deaths avoided by 2060, rising to approximately 10,200 cumulative deaths avoided by the end of the century (table 10). Since decreases in cigarette smoking prevalence under the proposed product standard would have immediate, rather than lagged, impacts

on fetal health and the health of newborn children, we expect avoided smoking-attributable perinatal deaths to accrue more rapidly than the estimates presented here.

The smoke of other combusted tobacco products, particularly those that could be alternatives to cigarettes, such as cigars and pipes, contains many of the same toxic constituents as cigarette smoke, sometimes at even greater concentrations, and consequently carries significant health risks (Refs. 53 and 594). In fact, NNAL concentrations measured in people who smoke cigars daily were found to be as high as those measured in people who smoke cigarettes daily (Ref. 160). Cigar and/or pipe smoking cause cancers of the lung and upper aerodigestive tract, including the oral cavity, oropharynx, hypopharynx, larynx and esophagus (Ref. 158). Additional evidence suggests that cigar and/or pipe smoking is causally associated with cancers of the pancreas, stomach, and bladder (Ref. 165). People who smoke cigars also have increased risks for coronary heart disease and COPD compared with people who have never used tobacco (Ref. 166). In a 2014 publication, researchers estimated that regular cigar smoking was the cause of approximately 9,000 premature deaths in the year 2010, and more than 140,000 years of potential life lost in the United States in 2010 (Ref. 134). The total number of cigar-attributable deaths may be even larger for several reasons. For example, the analysis included only causes of death found to be statistically significantly higher in two cohorts that studied people who smoke cigars, although there may be additional causes of death that are attributable to cigar smoking. In addition, there may be increases in cigar smoking relative risks over time, due to greater variety of cigar products and differences in inhalation patterns (Ref. 134). Therefore, cessation and reduced initiation of combusted tobacco products other than cigarettes as a result of the proposed product standard could yield even greater public health impacts than those presented.

To estimate the impacts of a potential nicotine product standard on avoided deaths attributable to covered cigar products, we used estimates of premature deaths attributable to regular cigar smoking from a prior publication (Ref. 134). Given that the prior analysis included all cigar types in its estimate of 9,246 premature deaths for the year 2010 and that we did not include premium cigars in our current analysis, we estimated the fraction of deaths attributed to cigar products other than premium cigars. We estimate that

among people who ever smoked cigars fairly regularly and now smoke every day or some days in Wave 4 of the PATH Study, 80 percent reported smoking non-premium cigars and 20 percent reported smoking premium cigars, using a classification methodology described previously (Ref. 290) and subsequently updated (Ref. 595). On that basis, 7,397 (*i.e.*, $9,246 \times 0.8$) deaths annually are attributed to using non-premium cigar products. By considering a relatively stable trend in adult cigar use³⁵ and assuming that adult cigar use is the main driver of cigar-attributable deaths in the close future, we assumed that non-premium cigar-attributable mortality would remain constant at 7,397 cigar-attributable deaths per year through 2065 (or roughly the time at which people who use cigars aged 26 and older in 2021 would all have reached age 70 and older). However, as youth and young adult cigar smoking has declined in recent years, we adopt a different trend in baseline cigar-attributable mortality in the further future (after 2065). To obtain baseline non-premium cigar-attributable mortality from 2066 through the end of the modeling period (2100), we assume non-premium cigar-attributable mortality will eventually follow the observed relative decline in cigar use among young adults as they reach older ages. Specifically, we assume that non-premium cigar

smoking-attributable deaths among youth who initiate cigar smoking will decrease on average by 37.5 percent³⁶ over 40 years (from 2078 to 2117).³⁷ That is, the cigar smoking-attributable deaths will decrease on average to 4,600 ($\approx 7,397 \times (1 - 0.375)$) deaths per year over the period from 2078 to 2117. Assuming a linear decrease in cigar smoking-attributable mortality from 2065 to 2117, and an average of approximately 4,600 deaths per year over the period from 2078 to 2117, implies non-premium cigar smoking-attributable mortality will decline linearly from 7,397 in 2065 to approximately 4,390 deaths in 2100. We assume a linear decrease for simplicity and because trends for cigar use considered in this post-processing strategy come from a short interval (PATH Study data, Waves 1 to 5, and Waves 3 to 5). We then calculate the ratio of non-premium cigar to cigarette-attributable deaths for each year in the projection period and apply those values to the projections of avoided cigarette-attributable deaths to estimate non-premium cigar-attributable deaths under the nicotine policy scenario. Using this approach, by 2060, we estimate approximately 54,800 cumulative deaths due to non-premium cigar products would be avoided, rising to approximately 214,700 cumulative deaths avoided by 2100 (see table 10). Similar methods were used to calculate

estimates accounting for the mortality effects of a product standard prohibiting characterizing flavors other than tobacco in cigars. These estimates reduced baseline non-premium cigar-attributable deaths in a phased-in manner reaching a constant reduction of 780 deaths averted per year after 30 years (Ref. 597). These estimates and results are presented in detail in sections VIII.E and VIII.F of this document. To estimate the impacts of a nicotine product standard on avoided deaths attributable to pipe tobacco smoking, we used the estimate of 1,095 premature deaths per year provided by a prior analysis (Ref. 598). We calculated the ratio of pipe tobacco to cigarette-attributable deaths to be 0.3 percent and applied that value to the projections of avoided cigarette-attributable deaths, yielding an estimate of approximately 4,500 cumulative deaths due to pipe tobacco smoking avoided by 2060, rising to approximately 11,000 cumulative deaths avoided by the end of the century (see table 10). Based on these collective findings and estimates, FDA anticipates that the proposed product standard will further improve public health due to the impacts of reduced cigarette smoking on smoking-related fires and perinatal conditions, in addition to the impacts of reduced use of other, non-cigarette combusted tobacco products covered by this proposed rule.

TABLE 10—PROJECTED NUMBER OF TOBACCO-ATTRIBUTABLE DEATHS AVOIDED FOR SMOKING RELATED FIRES, SMOKING RELATED PERINATAL CONDITIONS, NON-PREMIUM CIGAR AND PIPE TOBACCO USE AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027

Year	Scenario	Cumulative smoking-related fire deaths avoided	Cumulative perinatal deaths avoided	Cumulative non-premium cigar-attributable deaths avoided	Cumulative pipe tobacco-attributable deaths avoided
2040	Median (5th, 95th)	600 (100, 700)	1,000 (100, 1,200)	8,900 (1,000, 11,000)	1,100 (130, 1,300)
2060	Median (5th, 95th)	2,400 (600, 2,700)	4,100 (900, 4,600)	54,800 (13,200, 60,500)	4,500 (1,000, 5,000)
2080	Median (5th, 95th)	4,200 (1,300, 4,600)	7,300 (2,200, 7,900)	134,700 (46,000, 144,100)	7,900 (2,400, 8,600)
2100	Median (5th, 95th)	5,900 (2,300, 6,400)	10,200 (3,900, 10,900)	214,700 (91,600, 225,800)	11,000 (4,200, 11,800)

6. Public Health Benefits of the Proposed Standard Not Addressed in FDA’s Population Health Model

While FDA’s population health model’s estimates of the potential impact from a nicotine product standard

³⁵ Adult cigar smoking has historically remained stable. Data from the NHIS over 2000–2015 has shown that prevalence of current cigar smoking has remained generally stable at around 2.3 percent among U.S. adults aged 18 years and older (Ref. 596). Adult (ages 26 or older) cigar use also remained relatively stable in NSDUH data for 2011 and 2019 and did not significantly change (4.2 percent in 2011 to 4.0 percent in 2019 for cigars) (Ref. 286).

³⁶ According to data from the PATH Study, young adult (ages 18–24) past 30-day cigar use declined

suggest a significant public health benefit to the United States resulting from substantial reductions in smoking prevalence, these analyses do not address other additional benefits. The overall public health benefits of this

from 15.7 percent during Wave 1 (2013–2014) to 11 percent during Wave 5 (2018–2019), representing a 30 percent relative decline in prevalence. Additionally, data from the PATH Study Waves 3 (2015–2016) and 5 (2018–2019) indicate that cigar use among 18-year-olds declined from 7.2 percent to 3.9 percent, implying a steeper decline of approximately 45 percent in more recent years within this smaller age cohort. We use these two data points to estimate the decrease in cigar smoking among young people because both provide relevant information from a national survey that is

proposed product standard are likely to be even greater than those quantified, since our analysis does not account for the full range of impacts that smoking has on public health in the United States.

specific to tobacco use and average them to produce an estimate of 37.5 percent (*i.e.*, $(30 + 45)/2$).

³⁷ For youth, we assume that initiation occurs by the age of 18, followed by a cigar smoking-attributable death 52 years later. We then assume cigar use initiation occurs during years 2025 to 2064 (40-year period), and cigar smoking-attributable deaths begin to occur a year after the period from 2077 (*i.e.*, 2025 + 52) through 2116 (*i.e.*, 2064 + 52); that is, over the period from 2078 to 2117.

First, although we estimated the impact of self-reported quality of life, this may not capture the full breadth and depth of smoking-attributable morbidity. Tobacco smoke exposure can cause immediate and long-term adverse health effects (Ref. 1). Cigarette smoking “has been causally linked to diseases of nearly all organs of the body, to diminished health status, and to harm to the fetus” (Ref. 1). Each year, an estimated 480,000 people in the United States die from smoking; the U.S. Surgeon General has reported that for every person that dies from smoking, about 30 individuals will suffer from at least one smoking-related disease (Ref. 1). One study estimated that individuals in the United States have had 14.0 million major smoking-attributable conditions, including more than 7.4 million cases of COPD, nearly 2.3 million heart attacks, 1.8 million cases of diabetes, nearly 1.2 million stroke events, more than 300,000 cases of lung cancer, and nearly 1 million cases of other smoking-attributable cancers (*i.e.*, bladder, cervix, colon/rectum, kidney, larynx, mouth, tongue, lip, throat, pharynx, stomach) (Ref. 564). Cigarette smoking, in addition to causing disease, can diminish overall health status leading to higher risks for surgical complications, including wound healing and respiratory complications, increased absenteeism from work, and greater use of healthcare services (Ref. 1). In terms of a monetary measure of the impact of cigarette smoking on the public health, in 2018, cigarette smoking cost the United States more than \$600 billion, including more than \$240 billion in healthcare spending (Ref. 10), nearly \$185 billion in lost productivity from smoking-related illnesses and health conditions (Ref. 10), nearly \$180 billion in lost productivity from smoking-related premature death (Refs. 1 and 10), and \$7 billion in lost productivity from premature death from secondhand smoke exposure (Refs. 1 and 11). Increased smoking cessation, reduced cigarette consumption, and lower progression to regular use will reduce both mortality from smoking and the enormous burden of cigarette-attributable diseases in the United States.

Second, the estimated impacts to public health do not include the reductions in morbidity associated with reduced exposure to secondhand smoke among infants and children. A report of the U.S. Surgeon General (Ref. 1) found that approximately half of all children and adolescents ages 3–18 in the United States are exposed to cigarette smoke regularly at home or other locations that

still permit smoking. Also, a recent study using NYTS data reported that, in 2019, 25.3 percent and 23.3 percent of students were exposed to home and vehicle secondhand smoke, respectively (Ref. 145). Exposure to cigarette smoke among children and adolescents can trigger asthma attacks and lead to more frequent respiratory infections compared to those not exposed to smoke (Ref. 1).

Third, a lower prevalence of cigarette smoking and reduced cigarette consumption will decrease the occurrence of fire-related injuries and damages caused by smoking materials, including cigarettes and other combusted tobacco products. From 2012 to 2016, an estimated average of 18,100 home structure fires in the United States annually were caused by smoking materials (Ref. 591). Reductions in smoking as a result of the proposed nicotine product standard are likely to lead to not only fewer fatalities (as described previously) but also reductions in the annual average of 1,130 injuries (Ref. 591).

Fourth, these projections did not include the potential health benefits associated with people who smoke cutting down on the number of cigarettes smoked as a result of the proposed nicotine product standard. Quitting cigarette smoking entirely clearly leads to the greatest reductions in disease risk, and duration of smoking has been shown to be a greater driver of disease risk than frequency of use (Ref. 28). Although some studies have not found evidence of lower disease risk after cutting down on cigarettes (Refs. 28, 266, 599 to 601), others have shown that substantial reductions in cigarette consumption can lead to some reductions in disease risk, especially for lung cancer, for those who would have otherwise continued to smoke (Ref. 602). Such studies have found decreased risk of lung cancer deaths (Ref. 603) and decreased risk of lung cancer among people who smoke who reduce cigarette consumption (Refs. 604 and 605). As described above, studies of VLNC cigarettes have shown that their use results in reductions in cigarettes smoked per day and exposure to toxic constituents among individuals who continue to smoke, which may reduce smoking-related disease risks. Consequently, additional public health benefits may be observed among those who continue to smoke cigarettes (but substantially fewer CPD) after a nicotine product standard is in place.

7. Potential Risks to the Population as a Whole of the Proposed Nicotine Product Standard Versus the Potential Benefits of the Proposed Product Standard

There are possible countervailing effects that could occur from the proposed product standard, if finalized, and potential factors that could limit its population health effect. Potential risks to the population, however, would generally only occur among individuals currently smoking cigarettes and other combusted tobacco products covered by the scope of this proposed rule, as FDA concludes there are little to no risks to those who do not use tobacco. These potential risks do not offset the anticipated benefits of the rule. The countervailing or limiting effects on people who currently use tobacco products could include compensatory smoking. As part of this rulemaking, FDA is required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among populations that are disproportionately impacted by tobacco-related morbidity and mortality, such as adolescents who use tobacco and other populations.

With a lower level of nicotine in cigarettes, some people who use cigarettes and certain other combusted tobacco products could alter their smoking behavior in the form of compensatory smoking (*i.e.*, a change in normal smoking behavior that would increase exposure to cigarette smoke to compensate for reduced nicotine intake) when switching from usual brand or NNC cigarettes to VLNC cigarettes. This concern is echoed in qualitative research of people who currently use tobacco who report fears that a potential reduction in nicotine will cause them to engage in compensatory smoking (Refs. 264, 606 to 608). Compensatory smoking—or compensation—occurs when people who smoke seek to obtain the amount of nicotine needed to sustain their addiction by smoking more CPD, taking more and deeper puffs, or puffing with a faster draw rate. In both brief and extended exposure studies with VLNC cigarettes, compensation was measured using CPD, puff topography measures, and biomarkers of CO exposure, such as breath CO or COHb. Some transient compensatory smoking may occur following initial VLNC cigarette exposure. However, after continued use of VLNC cigarettes, people who smoke stop attempting to compensate for the reduced nicotine content, because they are unable to obtain adequate amounts of nicotine through these behaviors. The following

paragraphs discuss data demonstrating this outcome. See also section VII.B of this document discussing compensatory smoking with an immediate nicotine reduction approach versus a gradual reduction approach.

When exposure to VLNC cigarettes is brief (*e.g.*, the first few uses of VLNC cigarettes), transient compensatory smoking may occur. In brief exposure studies, changes in smoking topography (Refs. 393 to 395) and increases in CO (Refs. 393, 411, and 420) have been observed. For example, one study demonstrated the transient nature of compensatory smoking by showing increases in smoking topography and CO exposure during the first and second exposures to VLNC cigarettes, followed by the subsequent dissipation of these effects by the third and fourth exposures (Ref. 394). Similarly, another study found that during a 5-day study where participants checked into a hotel and were restricted to only study-issued cigarettes, mouth-level nicotine exposure indicated that participants initially puffed VLNC cigarettes with greater intensity than NNC cigarettes, although this effect diminished across sessions (Ref. 609). However, results from the majority of studies show no compensatory smoking as a result of switching from usual brand or NNC cigarettes to VLNC cigarettes. Although not all studies examined every measure of compensatory smoking, most studies found no differences between control and VLNC cigarette conditions regarding CPD (Refs. 5, 32, 34, 40, 41, 265, 331, 374, 387, 386, 390, 396, and 415), CO exposure (Refs. 5, 32, 34, 40, 41, 265, 374, 381, 390, 391, 396, 402, 409, 410, 412 to 414, 467, and 610), smoking topography (Refs. 381, 391, 403, 411, 415, and 611), or all three measures (Refs. 329, 382 to 384).

Notably, compensatory smoking has been observed with some reduced nicotine content cigarettes containing intermediate levels of nicotine (*e.g.*, LNC cigarettes). For example, in a study of 165 people who use cigarettes assigned to switch to LNC cigarettes or VLNC cigarettes, researchers found small but statistically significant differences in CPD between the LNC and VLNC cigarette conditions, such that LNC CPD increased over the course of the 6-week intervention, while VLNC CPD decreased (Ref. 32). However, one of the largest studies involving reduced nicotine content cigarettes found no compensatory smoking behavior for cigarettes containing intermediate levels of nicotine (Ref. 29). Therefore, FDA concludes the nicotine level proposed for this standard would result in limited, if any, compensatory smoking

that would likely dissipate over time. These data also support FDA's proposed immediate nicotine reduction approach (see section VII.C of this document).

Studies consistently report that consumers have misperceptions about the harms of nicotine and VLNC cigarettes (see sections IV.F and V.B of this document). A majority of U.S. consumers incorrectly believe that nicotine is the primary cause of cancer and health harms from cigarettes (Refs. 227 to 229, 232, 233, 235 to 245, 264, and 612 to 618), and a proportion of consumers with this misperception also believe that RNC cigarettes are less harmful than NNC cigarettes (Refs. 260 to 262). Additionally, while a majority of consumers understand that nicotine is addictive (Refs. 227 to 229, 232, 233, and 619), they do not necessarily believe that RNC cigarettes would be less addictive than NNC cigarettes (Refs. 260 and 261). There is also evidence from qualitative studies showing that some consumers do not understand the technical feasibility of reducing nicotine in cigarettes to minimally addictive or nonaddictive levels, which may impact consumers' ability to comprehend and accept messages communicating the policy (Refs. 270 and 229). FDA recognizes the importance of addressing consumer misperceptions of the harm and addictiveness of nicotine and VLNC cigarettes to minimize the unintended effects of a proposed product standard that limits the level of nicotine in cigarettes and certain other combusted tobacco products to make those products minimally addictive or nonaddictive. FDA will continue to conduct research on consumer perceptions of tobacco product harms, use communication tools (*e.g.*, consumer outreach, public education initiatives, engagement with interested parties), and consider further regulatory options within our authorities (*e.g.*, potential future labeling and advertising regulations) to ensure that all consumers are informed of the risks of using tobacco products that contain nicotine, including VLNC cigarettes.

Prior work also has explored whether the proposed product standard may have a differential impact on specific populations. Studies that have investigated the effects of VLNC cigarettes in adolescents who smoke cigarettes have done so under conditions of brief exposure (*e.g.*, single exposure to a VLNC cigarette in a laboratory setting). A study comparing VLNC and LNC cigarette smoking topography in adolescents who smoke cigarettes found that participants took statistically significantly more puffs from the VLNC cigarette compared to

the LNC cigarette, and a non-significant trend emerged such that increases in breath CO were higher after smoking the VLNC cigarette compared to the LNC cigarette (Refs. 395 and 416). However, the LNC cigarette was rated as statistically significantly more pleasant than the VLNC cigarette (Ref. 395).

Similar to studies in adults who smoke cigarettes, studies in youth and young adults who smoke cigarettes have shown that positive subjective effects ratings (*e.g.*, "satisfaction," "pleasure," "taste," "strength," and "stimulation") are lower for VLNC cigarettes compared to LNC and NNC cigarettes. A laboratory study of people ages 15–19 who smoke found no effect of nicotine content on withdrawal, negative affect, or CO boost; however, NNC cigarettes were associated with greater reductions in craving and increased smoking satisfaction relative to VLNC cigarettes (Ref. 442). A similar laboratory study in young adults (age 18–25) found no influence of nicotine content on total nicotine withdrawal score, affect, or smoking topography; however, NNC cigarettes were associated with increased subjective effects ratings compared to LNC and VLNC cigarettes (Ref. 620). Notably, a secondary analysis of data from a clinical trial (Ref. 29) found that, at the end of the 6-week trial, there was no influence of age on subjective effects, TNE levels, or puff volume in participants who smoked LNC or VLNC cigarettes (Ref. 621).

Several studies have examined the effects of nicotine content in cigarettes on adolescents and young adults who smoke. One laboratory study that assessed the effects of nicotine content and menthol preference among adolescents (ages 15–19) who smoke found that VLNC cigarettes were rated statistically significantly lower than NNC cigarettes, and menthol preference did not affect subjective effects ratings of VLNC cigarettes (Ref. 408). One study also found that young adults (ages 18–24) who smoke exhibited lower demand for LNC and VLNC cigarettes than adults, but there were no other differences between the two age groups in smoking topography, breath CO, cigarette puffs, craving, withdrawal, or smoking urge measures (Ref. 622). Another study investigating how nicotine exposure contributes to relief of craving and negative affect among young adults (ages 18–25) who smoke found that smoking reduced craving and negative affect regardless of nicotine content, and smoking topography did not vary as a function of nicotine content (Ref. 611). Finally, a study of youth and young adults who smoke found that two-thirds of participants

believed that study cigarettes had lower health risks than usual brand cigarettes, that they were largely concerned with compensatory smoking following a nicotine reduction policy, and that half stated an intention to quit smoking after the policy is put in place while the other half would continue to smoke or switch to another tobacco product (Ref. 606).

One study assessed longer duration effects (*i.e.*, 3 weeks) of VLNC cigarettes in adolescent daily smokers (ages 15–19) not currently intending to quit. Participants assigned to smoke VLNC cigarettes smoked significantly fewer total CPD than those in the NNC cigarette group. VLNC cigarettes were associated with lower levels of craving reduction than NNC cigarettes; however, there were no differences nicotine dependence or TNE levels among VLNC and NNC cigarette groups at the end of the study (Ref. 623). A secondary analysis of this study showed that participants assigned to smoke VLNC cigarettes had significantly lower demand for study cigarettes than those assigned to smoke NNC cigarettes, suggesting that a nicotine reduction policy may reduce the reinforcing value of combusted cigarettes in adolescents (Ref. 624).

In summary, while existing data suggest that adolescents prefer LNC cigarettes over VLNC cigarettes, and that they may display compensatory smoking behaviors in response to VLNC cigarettes, these data are limited. As discussed in section VII.B of this document, compensation typically dissipates after repeated exposure. Thus, in the absence of extended exposure studies, it is difficult to draw conclusions regarding the effects of VLNC cigarette use on compensatory smoking in adolescents and young adults.

Individuals with symptoms of mental health disorders smoke cigarettes in disproportionately large numbers. People with symptoms of mental health disorders who smoke cigarettes have increased nicotine withdrawal symptoms (Refs. 625 and 626) and are more likely to smoke to ameliorate negative mood (Ref. 627). As a result, this population has increased risk of tobacco-related mortality (Ref. 130).

Researchers have investigated the effects of VLNC cigarettes in people who use cigarettes with symptoms of mental health disorders to determine whether VLNC cigarettes are associated with differential effects on craving, withdrawal, smoking topography, or use behavior among this group compared to the general population. In this group, as in the general population, NNC

cigarettes were associated with greater reductions in craving and withdrawal symptoms compared to VLNC cigarettes. In this group, VLNC cigarettes were not associated with increased markers of compensatory smoking (*e.g.*, smoking topography, CO) compared to the general population. Researchers also assessed psychiatric symptomatology as a function of VLNC cigarette use and found that VLNC cigarettes were associated with improvements in mood symptoms, likely due to the anxiety-increasing properties of nicotine.

Several studies investigated the effects of LNC and VLNC cigarettes on mood following mood induction (*i.e.*, an experimental method for inducing a specific mood state) in people who use cigarettes with symptoms of mental health disorders (Refs. 434, 450, and 628). These studies found that, following positive mood induction, LNC cigarettes compared to VLNC cigarettes were associated with an enhancement of positive mood among people who smoke and are prone to depression, but not control participants (Refs. 450 and 628). In addition, LNC cigarettes, but not VLNC cigarettes, were associated with a worsening of negative mood in response to negative mood induction among people who smoke, regardless of baseline mental health status (Ref. 628). Similarly, following an anxiety-eliciting mood induction, participants with post-traumatic stress disorder self-reported greater relief of anxiety after smoking LNC cigarettes compared to VLNC cigarettes; however, LNC cigarettes increased physical autonomic symptoms of anxiety (*e.g.*, skin becomes a better conductor of electricity, heart rate) relative to VLNC cigarettes (Ref. 434).

A secondary analysis of an extended exposure study assessed the effects of cigarettes varying in nicotine content on changes in psychiatric symptomatology among those with and without elevated depression symptoms (Ref. 629). Among participants with elevated depression symptoms, those assigned to smoke LNC or VLNC cigarettes for 6 weeks had lower depressive symptoms at the end of the study compared to those assigned to smoke NNC cigarettes. Another study that assigned participants with serious mental illness to receive either NNC or VLNC cigarettes saw no change in participants' psychiatric symptoms at the end of 6 weeks (Ref. 440).

Several studies assessed the effects of VLNC cigarettes on smoking rates, nicotine craving, dependence, withdrawal, and subjective effects among those with symptoms of mental health disorders (Refs. 391, 409, 434, 467, 468, 629, and 630). While some

studies found no statistically significant differences in craving or withdrawal as a function of nicotine content following brief smoking abstinence in those with symptoms of mental health disorders (Refs. 391, 434, and 467), others showed that use of usual brand cigarettes was associated with larger decreases in craving and withdrawal compared to VLNC cigarettes (Ref. 468). An extended exposure study found that, relative to NNC cigarettes, use of LNC and VLNC cigarettes reduced smoking rates, nicotine dependence, and cigarette craving, and these effects were not moderated by baseline depressive symptoms (Ref. 629). In addition, similar to the general population, people who smoke with poor mental health rate NNC cigarettes as more rewarding (*e.g.*, taste, satisfaction) and reinforcing compared to VLNC cigarettes (Refs. 391, 450, 467, and 628). Additionally, a 33-week study that randomized participants to either NNC cigarettes or a gradual nicotine reduction to VLNC levels found that the gradual reduction group exhibited significantly lower cotinine levels, CPD, and exhaled CO compared to the NNC cigarette group. Mental health effects and adverse events did not significantly differ between the two groups, and significantly more participants in the gradual nicotine reduction group were abstinent at the end of the treatment compared to the NNC cigarette group (Ref. 631).

A study that compared the effects of VLNC, LNC, and NNC cigarettes on smoking behavior in people with opioid use disorder who smoke cigarettes, women of childbearing age with a high school education or less who smoke cigarettes, or individuals with affective disorders who smoke cigarettes found no statistically significant differences in smoking topography or breath CO as a function of nicotine content (Ref. 391). Subsequent analyses of this study also found that cannabis use status, presence of chronic health conditions, and sex did not correlate with differences in smoking topography or the reinforcing effects of nicotine among people who smoke (Refs. 459 and 632). A larger 12-week RCT among these same three populations found statistically significantly lower CPD and nicotine dependence levels across study weeks among those assigned to received VLNC or LNC cigarettes compared to those assigned to receive NNC cigarettes (Ref. 633). A secondary analysis of this study found no statistically significant effects of nicotine dose or population on tests of cognitive performance, suggesting that cognitive performance was not

significantly impaired with prolonged exposure to VLNC cigarettes among vulnerable populations (Ref. 634). A study among participants with schizophrenia found that both people with schizophrenia who smoke and control participants smoked fewer puffs and had lower total puff volumes, shorter inter-puff intervals, longer puff durations, and marginally higher individual puff volumes when smoking VLNC cigarettes compared to usual brand cigarettes (Ref. 467). However, a subsequent analysis using data from this same study showed that these differences were not associated with increases in breath CO boost (Ref. 392).

A 33-week randomized clinical study evaluated the effects of gradually reducing the nicotine content in cigarettes to VLNC cigarette levels on ratings of dependence, biomarkers, and cessation in 245 adults of low socioeconomic status. CPD, plasma cotinine, CO, and NNAL levels were significantly lower for the gradual reduction group compared to the NNC cigarette group; however, there were no significant differences in dependence or withdrawal as a function of group. Those who received VLNC cigarettes were statistically significantly more likely to make a quit attempt during the study compared to those in the NNC cigarette group; however, there was no statistically significant difference in quit rates as a function of group among those who chose to make a quit attempt (Ref. 635). A secondary analysis of this study showed that outcomes did not differ as a function of menthol status, except that those participants who smoked menthol cigarettes had less of a cotinine reduction (Ref. 636).

Several studies used laboratory paradigms to assess the effects of alcohol on specific components of smoking behavior for nicotine versus non-nicotine factors in people who consume alcohol heavily. One study found that alcohol increased smoking urge and subjective ratings of smoking for both NNC and VLNC cigarettes (Ref. 637), while another study found that NNC cigarettes were associated with increases in subjective effects and a greater reduction in cigarette craving than VLNC cigarettes, and these effects were enhanced by ethanol self-administration (Ref. 448). In addition, in a sample of people who smoked who also regularly consumed alcohol, NNC cigarettes reduced craving and increased cognitive performance compared to VLNC cigarettes (Ref. 448). Furthermore, several secondary analyses of clinical studies found no evidence that alcohol or marijuana use moderates the effects of VLNC cigarettes, and VLNC cigarette

use does not increase compensatory alcohol, marijuana, or other illicit drug use (Refs. 386, 632, and 638). However, one secondary analysis found that although 20-weeks of VLNC cigarette use reduced CPD compared to NNC cigarette use, co-users of marijuana and cigarettes showed increased marijuana use when assigned to VLNC cigarettes (Ref. 639).

In summary, research has shown that VLNC cigarettes reduce the number of cigarettes smoked per day among populations that use tobacco at disproportionately high levels, including those of low socioeconomic status, and those with mental or behavioral health conditions. Importantly, there has been little to no evidence that VLNC cigarettes increase risk of adverse effects (*e.g.*, exacerbations of psychiatric symptomatology, drug use) in these populations. The proposed nicotine product standard is not anticipated to be detrimental to these populations; rather, it is anticipated to benefit these groups, as well as the general population as a whole.

FDA recognizes that actors participating in illicit markets are unlikely to conform their products and sales to Federal, State, and local laws. As discussed elsewhere in this document, the available evidence suggests that the health impacts of counterfeit products should be minimal. As the National Research Council (NRC) and the Institute of Medicine (IOM) (NRC/IOM) Report notes, “Research on counterfeit cigarettes to date has shown some differences in levels of tar and selected toxicants in comparison with conventional cigarettes . . . but these elevated levels have not been shown to affect overall toxicity and, based on current evidence, are unlikely to significantly increase the health risk of an already dangerous product” (Ref. 560). Even in studies (Ref. 640) that suggest that counterfeit cigarettes can contain higher levels of harmful substances, the studies cannot make conclusions about the individual or population-wide health risks from such substances, in part because of the variations between them, inconsistent distribution of the products among the population, and inconsistent use among consumers. FDA will continue to monitor the best available science to determine if this changes in the future.

Based on the available evidence, FDA finds that, while there may be potential risks that could diminish the expected population health benefits of the proposed standard, such effects would be significantly outweighed by the potential benefits of the proposed

nicotine product standard. FDA requests additional information concerning the potential risks discussed in this section, as well as any other negative effects that could result from this rule, and how they could be minimized.

E. Approach Concerning Adjustments to Inputs to the Model Accounting for Other Tobacco Product Standards

In 2022, FDA issued proposed tobacco product standards to prohibit menthol as a characterizing flavor in cigarettes and to prohibit all characterizing flavors (other than tobacco) in cigars (87 FR 26454, May 4, 2022). If finalized, these rules are anticipated to reduce overall youth initiation and increase cessation among individuals who smoke cigarettes and cigars. In this adjusted model, we utilized estimates of the likely population health impact of these rules, quantified in peer-reviewed publications and discussed in the rules, to adjust the baseline inputs for initiation of combusted and noncombusted products, as well as cessation of combusted products and likelihood of switching to incorporate the impact of the final rules in this proposed nicotine product standard.

We quantified the potential impact of a menthol cigarette product standard on the U.S. population (87 FR 26454), assuming that the implementation of a rule prohibiting menthol affects baseline model input parameters associated with smoking initiation, smoking cessation, noncombusted initiation, and switching from cigarettes to noncombusted products. To avoid confusion with the main analysis baseline scenario, we called this new scenario a “menthol product standard baseline scenario.” First, we assumed that a menthol product standard is implemented in 2025, 2 years before the implementation of a potential nicotine product standard in 2027. Changes in tobacco use behaviors due to the implementation of a menthol product standard (primarily for people who would initiate future menthol cigarette use and people who currently use menthol cigarettes) were derived from an expert elicitation that was developed to assess the impact of a menthol product standard on smoking initiation and cessation, and on noncombusted use (Ref. 562). Specifically, 11 experts were asked to estimate anticipated behaviors under a menthol product standard, including transitioning to illicit menthol combusted products, switching to non-menthol combusted products, switching to ENDS products or HTPs, or quitting use of all tobacco products. We used the results of the expert elicitation (finalized in September 2020) to

compute factors that can be used to scale smoking initiation and cessation rates, as well as switching and noncombusted initiation, accounting for a potential reduction/increase in rates. People who currently smoke non-menthol cigarettes were assumed to be unaffected by a menthol product standard. We used the average impact scenario from Levy et al. 2023 (Ref. 562) to be consistent with the approach taken in the proposed menthol product standard rule. Details regarding the calculation of scaling factors, considering the expert elicitation data, can be found in Appendix K of FDA's modeling document (Ref. 42).

In the menthol product standard baseline scenario, baseline smoking initiation and noncombusted initiation rates were adjusted starting in 2025 (*i.e.*, year of a potential menthol prohibition implementation) until the end of the simulation period. Also, baseline smoking cessation and complete switching (from cigarettes to noncombusted products) were adjusted only at the first year of such a potential menthol product standard implementation. After the first year, when a sudden increase in smoking cessation and complete switching was incorporated, the remaining people who smoke initiated use of non-menthol or illicit menthol cigarettes, subject to the cessation and complete switching rates for people who smoke non-menthol cigarettes (Ref. 641). We conducted the analysis considering a mean decrease in cigarette smoking initiation (based on estimates from an expert elicitation), a mean increase in noncombusted product initiation, and a mean increase in smoking cessation and switching, as presented in Levy et al. 2023 (Ref. 562). It is important to note that the menthol-adjusted population health model does not directly estimate the public health impacts of a prohibition on menthol as characterizing flavor in cigarettes. In other words, the difference between the unadjusted baseline scenario and menthol-adjusted baseline scenario of the model should not be expected to approximate the impact of a potential menthol product standard. FDA's determination of the estimated public health impact of the menthol product standard is discussed in detail in the preamble to the proposed menthol product standard. In the nicotine population health model, FDA utilizes results from an expert elicitation (Ref. 562) developed to estimate changes in

tobacco use behaviors resulting from a menthol product standard (such as changes in smoking initiation or cessation) to adjust for the effect of a menthol rule over time. One important assumption of the FDA model is that the nicotine product standard would be implemented in 2027, whereas a menthol rule would be implemented in 2025. This is important to keep in mind as public health benefits attributable to a menthol rule (such as mortality and morbidity health impacts) will be accruing for 2 years before implementation of the nicotine product standard (and, therefore, not captured in this model).

A more comprehensive analysis of the public health impact of the menthol cigarette product standard can therefore be found in the proposed menthol product standard. There are also other important differences between the menthol-adjusted FDA model and the Levy et al. modeling approach that can impact comparability, such as input model parameters, modeling frameworks, assumptions, and source data. For these reasons, it is not appropriate to expect that the difference between public health impact estimates of the nicotine product standard with and without the menthol adjustment would directly approximate the potential public health benefits of the menthol product standard as presented in the proposed menthol product standard.

In 2022, FDA also issued a proposed product standard to prohibit characterizing flavors (other than tobacco) in cigars (87 FR 26396, May 4, 2022). It is estimated that such a standard would prevent 780 deaths due to cigar smoking in the United States each year (Ref. 134). A post-processing analysis of cumulative non-premium cigar-attributable deaths avoided was conducted to account for the effects of such a product standard, considering the adjustments due to the menthol cigarette product standard. For this analysis, we assumed both rules—the menthol cigarette and flavored cigar product standards—to be implemented in 2025. Specifically, we assumed that the avoided cigar-attributable deaths expected to result from the flavored cigar rule begin to occur 2 years after the rule's effective date (2027) and would increase in a phased-in manner over a 30-year period. We then assumed a full annual mortality benefit of 780 avoided deaths would continue after 30 years

(from 2026 to 2055), with a constant benefit of 780 deaths avoided until year 2064. We also assumed cigar-attributable deaths will increase from 780 in 2064 to 1,120 in 2100.

Details regarding the calculation of avoided cigar-attributable deaths because of the flavored cigar rule can be found in Appendix L of FDA's modeling document (Ref. 42). The estimated deaths averted by a flavored cigar product standard were subtracted from baseline non-premium cigar deaths in the United States each year to produce yearly estimates for non-premium cigar deaths with a flavored cigar standard. We used these estimates to calculate a ratio of non-premium cigar to cigarette-attributable deaths for each year in the projection period and applied those values to the projections of avoided cigarette-attributable deaths to estimate non-premium cigar-attributable deaths under the nicotine product standard scenario.

F. Benefits and Risks to the Population as a Whole Accounting for Other Tobacco Product Standards

Table 11 presents the impact results of the nicotine product standard using baseline assumptions adjusted for the effect of a menthol cigarette product standard for years 2040, 2060, 2080, and 2100. In general, changes to baseline inputs of initiation and cessation of combusted products as well as switching to noncombusted products as a result of implementation of a menthol cigarette product standard slightly reduced projected smoking prevalence and avoided mortality and morbidity, compared to the main analysis results. Specifically, we estimate that by 2060, the proposed nicotine product standard would avert approximately 1.6 million deaths due to tobacco, rising to approximately 3.4 million by 2100. These estimates are approximately 11 percent and 21 percent less than the corresponding estimates that do not account for the potential impact of a menthol product standard. The reduction in premature deaths as a result of the nicotine product standard, when accounting for a menthol product standard, would result in 17.9 million life years gained by 2060, raising to 60.6 million life years gained by 2100. These estimates represent a 9 percent and 21 percent reduction compared with the corresponding estimates under the main analysis.

TABLE 11—IMPACT OF PROPOSED NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027 ON PROJECTED SMOKING PREVALENCE AND AVOIDED MORTALITY AND MORBIDITY FROM THE MAIN ANALYSIS (UNADJUSTED BASELINE SCENARIO) AND WITH ADJUSTMENT FOR A MENTHOL CIGARETTE PRODUCT STANDARD IMPLEMENTED IN 2025

[Median (5th, 95th percentiles) estimates]

Year/period	Estimates from main analysis	Estimates with adjustment for a menthol cigarette standard
Cigarette Smoking Prevalence (%)		
2040	0.2 (0.07, 4.0)	0.1 (0.06, 2.8)
2060	0.2 (0.07, 2.2)	0.1 (0.05, 1.4)
2080	0.2 (0.06, 2.0)	0.1 (0.05, 1.3)
2100	0.2 (0.06, 1.9)	0.1 (0.05, 1.2)
Cumulative Tobacco-Attributable Deaths Avoided (Millions)		
2040	0.4 (0.1, 0.5)	0.4 (0.1, 0.5)
2060	1.8 (0.4, 2.0)	1.6 (0.4, 1.7)
2080	3.1 (1.0, 3.4)	2.6 (0.7, 2.8)
2100	4.3 (1.6, 4.6)	3.4 (1.1, 3.6)
Cumulative Life Years Gained (Millions)		
2040	2.0 (0.2, 2.7)	2.0 (0.2, 2.6)
2060	19.6 (3.6, 22.7)	17.9 (3.4, 20.4)
2080	47.4 (12.5, 52.5)	40.6 (10.3, 44.5)
2100	76.4 (26.5, 82.5)	60.6 (19.2, 65.3)
Cumulative QALYs Gained from Reduced Smoking Morbidity (Millions)		
2040	9.6 (2.7, 10.0)	7.8 (2.1, 8.1)
2060	24.0 (10.1, 24.7)	17.5 (7.0, 17.9)
2080	38.2 (18.5, 39.2)	26.1 (11.9, 26.6)
2100	53.1 (27.5, 54.4)	34.9 (17.0, 35.7)

Table 12 presents the impact results of the nicotine product standard implemented in 2027, using baseline assumptions adjusted for the effect of a flavored cigar product standard implemented in 2024. We estimate that

by 2060, in the United States, approximately 45,600 deaths due to non-premium cigar use will be averted, rising to approximately 164,000 deaths avoided by 2100 (table 12). In general, these estimates are approximately 17

and 30 percent less than the corresponding estimates without the potential impact of a product standard for flavored cigars.

TABLE 12—PROJECTED NUMBER OF TOBACCO-ATTRIBUTABLE DEATHS FROM NON-PREMIUM CIGAR USE AVOIDED FOR AS A RESULT OF A NICOTINE PRODUCT STANDARD IMPLEMENTED IN 2027 FROM THE MAIN ANALYSIS AND WITH ADJUSTMENT FOR FLAVORED CIGAR AND MENTHOL CIGARETTE PRODUCT STANDARDS IMPLEMENTED IN 2025

Year	Percentiles	Cumulative non-premium cigar-attributable deaths avoided from main analysis	Cumulative non-premium cigar-attributable deaths avoided with flavored cigar and menthol cigarette standards
2040	Median (5th, 95th)	8,900 (1,000, 11,000)	8,000 (1,000, 9,500)
2060	Median (5th, 95th)	54,800 (13,200, 60,500)	45,600 (11,100, 49,700)
2080	Median (5th, 95th)	134,700 (46,000, 144,100)	107,700 (35,000, 114,500)
2100	Median (5th, 95th)	214,700 (91,600, 225,800)	164,000 (65,000, 172,100)

G. Conclusion

FDA has considered scientific evidence related to the likely impact of the proposed rule establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products on people who currently do not use these products, people who currently use these products, and the U.S. population as a whole. The impact of the proposed standard was

considered alone, as well as adjusted for the inclusion of other tobacco product standards: prohibition of menthol as a characterizing flavor in cigarettes and prohibition of all characterizing flavors (other than tobacco) in cigars. Based on these considerations, we find that the proposed tobacco product standard is appropriate for the protection of the public health because it would increase the likelihood that many people who

currently smoke cigarettes and/or certain other combusted tobacco products would stop smoking altogether, yielding significant health benefits from smoking cessation. Additionally, we find that the proposed standard is appropriate for the protection of the public health because it would decrease the likelihood that people who do not smoke cigarettes and/or use certain other combusted

tobacco products—particularly youth and young adults—who experiment with combusted tobacco products will become addicted to these products, thereby decreasing progression to regular use, resulting in reduced tobacco-related morbidity and mortality associated with combusted tobacco product use. The proposed standard would also yield benefits in terms of reduced mortality as a result of reduced secondhand smoke exposure, smoking-related fires, smoking-related perinatal conditions, and use of alternative tobacco products.

Tobacco use is the leading preventable cause of disease and death in the United States. Cigarettes are responsible for 480,000 premature deaths every year from many diseases, put a substantial burden on the U.S. healthcare system, and cause massive economic losses to society (Ref. 1 at p. 659–666). Even modest reductions in the percentage of people initiating and modest increases in the percentage of people quitting smoking would lead to substantial reductions in the annual smoking-attributable deaths and fewer cases of disease attributed to combustible tobacco products in the United States.

In the United States, approximately 362,000 youth (ages 12–17) smoked their first cigarette in 2021 (Ref. 552). Additionally, nearly 90 percent of adults who currently smoke cigarettes daily in the United States report having smoked their first cigarette by the age of 18 (Ref. 1). Nicotine is a highly addictive substance, and multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among those who smoke cigarettes infrequently (Refs. 24, 65, and 93).

Reducing the addictive potential of combusted cigarettes and certain other tobacco products via establishing a maximum level of nicotine in these products would help to decrease the likelihood that people who do not smoke cigarettes and/or use certain other combusted tobacco products—particularly youth and young adults—who experiment with them will develop addiction to nicotine and progress to regular use, thereby greatly reducing the chances of suffering from tobacco-related disease and death. FDA anticipates that the proposed standard would produce substantial health benefits. Even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease in the United States caused by smoking, including reductions in smoking-related morbidity and mortality, diminished exposure to

secondhand smoke among people who do not smoke cigarettes, decreased potential years of life lost, decreased disability, and improved quality of life for current and future generations to come.

While preventing initiation to regular cigarette smoking and combusted tobacco product use by even modest amounts carries the greatest potential from this proposed standard to improve population health in the long term, FDA anticipates that the proposed standard would produce substantial short- and long-term health benefits resulting from decreased consumption and increased cessation among people who currently smoke cigarettes or other combusted tobacco products and wish to decrease use or quit. In the United States, there are currently approximately 39 million people ages 12 and older who smoke combusted tobacco products (Refs. 275 and 281). As previously described, the health benefits of smoking cessation are substantial. FDA's population health model estimates that approximately 1.8 million deaths in the United States due to tobacco would be avoided by the year 2060, rising to 4.3 million by the end of the century. The reduction in premature deaths attributable to the product standard would result in 19.6 million life years gained by 2060 and 76.4 million life years gained by 2100. Beyond averted deaths, societal benefits would include reduced smoking-related morbidity and health disparities, diminished exposure to secondhand smoke among people who do not smoke cigarettes, decreased potential years of life lost, decreased disability, and improved quality of life among people who formerly smoked cigarettes.

FDA's finding that the proposed product standard would be appropriate for the protection of the public health is reasonable and well-supported by scientific evidence. Cigarettes are the most toxic consumer product when used as intended, and nicotine is the primary constituent in cigarettes and other tobacco products that causes and maintains addiction. Given the existing scientific evidence described in sections VIII.B and VIII.C of this document, FDA finds that the proposed product standard is appropriate for the protection of the public health because it would increase the likelihood that many people who currently smoke cigarettes and/or certain other combusted tobacco products who wish to stop smoking altogether, would be able to do so, yielding significant health benefits from smoking cessation. Additionally, we find that the proposed standard is appropriate for the protection of the public health because

it would decrease the likelihood that people who do not smoke cigarettes and/or certain other combusted tobacco products—particularly youth and young adults—who experiment with them and initiate use, develop an addiction to nicotine, and progress to regular use as result of that addiction, thereby greatly reducing the chances of suffering from tobacco-related disease or death. Across the population, these changes in cigarette smoking behavior and combusted tobacco product use would lead to lower disease and death in the United States in both the short-term and in the future, due to diminished exposure to tobacco smoke among both people who smoke cigarettes and people who do not smoke cigarettes.

In addition to the determination that the proposed product is appropriate for the public health, FDA anticipates the proposed product standard also will improve health outcomes among populations that are disproportionately impacted by tobacco use and tobacco-related morbidity and mortality, such as adolescents as well as those with mental health and substance use disorders. As previously described, adolescence is a period of significant vulnerability regarding the onset and progression of tobacco use. Additionally, cigarette smoking is disproportionately prevalent among persons with symptoms of mental health disorders and substance use disorders, resulting in increased risk of tobacco-related morbidity and mortality in these groups. Accordingly, the proposed product standard is anticipated to promote better public health outcomes across these population groups.

IX. Additional Considerations and Requests for Comment

A. Section 907 of the FD&C Act

FDA is required by section 907 of the FD&C Act to consider the following information submitted in connection with a proposed product standard:

- For a proposed product standard to require the reduction or elimination of an additive, constituent (including smoke constituent), or other component of a tobacco product because FDA has found that the additive, constituent (including a smoke constituent), or other component is or may be harmful, scientific evidence submitted by any party objecting to the proposed standard demonstrating that the proposed standard will not reduce or eliminate the risk of illness or injury (section 907(a)(3)(B)(ii) of the FD&C Act).
- Information submitted regarding the technical achievability of compliance with the standard, including with regard

to any differences related to the technical achievability of compliance with such standard for products in the same class containing nicotine not made or derived from tobacco and products containing nicotine made or derived from tobacco (section 907(b)(1) of the FD&C Act).

- All other information submitted, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of chapter IX of the FD&C Act and the significance of such demand (section 907(b)(2) of the FD&C Act).

As required by section 907(c)(2) of the FD&C Act, FDA invites interested persons to submit a draft or proposed tobacco product standard for the Agency's consideration (section 907(c)(2)(B)) and comments on and information regarding structuring the standard so as not to advantage foreign-grown tobacco over domestically grown tobacco (section 907(c)(2)(C)) of the FD&C Act. In addition, FDA invites the Secretary of Agriculture to provide any information or analysis that the Secretary of Agriculture believes is relevant to the proposed tobacco product standard (section 907(c)(2)(D) of the FD&C Act).

With this proposed rule, FDA is requesting all relevant documents and information described in this section. Such documents and information may be submitted in accordance with the "Instructions" included in the preliminary information section of this document.

Section 907(d)(5) of the FD&C Act allows FDA to refer a proposed regulation for the establishment of a tobacco product standard to the Tobacco Products Scientific Advisory Committee (TPSAC) at the Agency's own initiative or in response to a request that demonstrates good cause for a referral and is made before the expiration of the comment period. Sections 917(c)(2) and (c)(3) (21 U.S.C. 387q(c)(2) and (c)(3)) also provide that TPSAC shall provide advice, information, and recommendations on the effects of the alteration of the nicotine yields from tobacco products and regarding whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved, respectively.

B. Pathways to Market

To legally market a new tobacco product³⁸ in the United States, a tobacco product must receive authorization from FDA permitting the marketing of the new tobacco product under one of three premarket review pathways: (1) the applicant obtains an order under section 910(c)(1)(A)(i) of the FD&C Act (order after review of a premarket tobacco product application under section 910(b)); (2) the applicant obtains an order finding the new tobacco product to be substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act under section 910(a)(2)(A)(i) (order after review of a Substantial Equivalence (SE) Report submitted under section 905(j) of the FD&C Act (21 U.S.C. 387e(j))); or (3) the applicant makes a request under 21 CFR 1107.1 and obtains an exemption from the requirements related to SE (section 905(j)(3)(A)), and at least 90 days before commercially marketing the product, submits a report under section 905(j) including the information required in section 905(j)(1)(A)(ii) and (B) of the FD&C Act.

Applicants may be able to use the SE pathway for products seeking to comply with this proposed product standard (if finalized) by making modifications to their products in a manner that FDA finds does not cause the new tobacco product to raise different questions of public health. Applicants may be able to submit a streamlined SE Report containing information sufficient to demonstrate that the changes to the subject of that SE Report do not cause the new tobacco product to raise different questions of public health and to certify that no other changes were made to the new tobacco product as compared with the predicate product and that all other characteristics are identical (see relevant provisions of the SE final rule codified at 21 CFR 1107.18(l)(2)). FDA has received numerous successful applications where the manufacturer described all modification(s) between the new and predicate tobacco product and provided a certification statement that all other characteristics are identical. For example, for products modified to comply with this product standard, the applicant could demonstrate how the modification was made to the tobacco filler, provide test data to show that the

modification reduced the nicotine content to meet the standard and did not cause the new product to raise any different questions of public health, and provide a certification that no other modifications were made to the new tobacco product other than those made to reduce the level of nicotine.

An applicant may also be able to use the SE Exemption pathway under section 905(j)(3)(A) of the FD&C Act to the extent the applicant is modifying a legally marketed tobacco product by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive if such modification would be a minor modification. While the SE Exemption pathway may be a viable option in limited circumstances, FDA notes that the statutory definition of "additive" excludes tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical (section 900(1) of the FD&C Act). Therefore, to the extent modifications to a tobacco product involve changes to the tobacco (*e.g.*, changes to the nicotine content of the tobacco used in a tobacco product), such changes would render section 905(j)(3) of the FD&C Act inapplicable.

If a currently legally marketed tobacco product is already in compliance with this proposed product standard, a premarket authorization application would not be needed.

FDA requests comments regarding changes manufacturers may make to their tobacco products to comply with this proposed product standard and what information and evidence they might provide to satisfy the premarket review requirements of the Tobacco Control Act.

C. Considerations and Request for Comments on Scope of Products

As indicated throughout this document, FDA has determined that the proposed standard, which would apply to cigarettes and certain other combusted finished tobacco products, is appropriate for the protection of the public health. It would cover the products that are responsible for the greatest amount of tobacco-related morbidity and mortality. The proposed scope of this rule—applying to cigarettes (other than noncombusted cigarettes, such as HTPs that meet the definition of a cigarette), cigarette tobacco, RYO tobacco, cigars (other than premium cigars), and pipe tobacco—is appropriate to protect the public health and is justified by existing evidence. We request comments, data, and research regarding the proposed scope of this rule.

³⁸ Products that were commercially marketed in the United States as of February 15, 2007 (referred to as "pre-existing tobacco products," previously referred to as "grandfathered products"), are not considered new tobacco products and do not require prior authorization to be legally marketed (section 910(a) of the FD&C Act).

FDA is not proposing to include noncombusted cigarettes, such as HTPs that meet the definition of a cigarette in section 900(3) of the FD&C Act (proposed § 1160.3 includes a definition of cigarette), within the scope of this proposed product standard. While noncombusted cigarettes (such as HTPs) that meet the definition of cigarette in the FD&C Act must adhere to existing restrictions for cigarettes under FDA regulations, some of these products may deliver fewer or lower levels of some toxicants than combusted cigarettes (Ref. 642). FDA recognizes that tobacco products exist on a continuum of risk, with combusted cigarettes being the deadliest, and that certain specific products meeting the definition of a cigarette (e.g., some that are not combusted) may pose less risk to individuals who use these products or to population health than other products meeting the definition of a cigarette.

In general, as discussed in this document, nicotine is the primary addictive constituent in tobacco products, and it is the nicotine in such products that both creates and sustains addiction, playing a significant role in creating and perpetuating tobacco-related negative health consequences. While these effects raise concerns in the context of any tobacco product—none of which is without risk—FDA recognizes that certain products that meet the definition of cigarette in the FD&C Act may present different considerations with respect to this proposed product standard. Accordingly, FDA requests comments, data, and research regarding the proposal to exclude noncombusted cigarettes (such as HTPs that are cigarettes) from the scope of this proposed rule, including any data that could justify otherwise.

FDA considered including waterpipe tobacco products within the scope of this proposed product standard; however, the Agency has determined that waterpipe tobacco involves profoundly different use behaviors than combusted cigarettes, which makes it an unlikely substitute for cigarettes. We therefore do not propose including waterpipe tobacco products within the scope of this proposed rule.

Data on frequency of use differentiates waterpipe tobacco from cigarettes. For instance, according to the 2024 NYTS, 0.7 percent of middle and high school students (or approximately 190,000 students) reported using waterpipe tobacco within the previous 30 days, compared with estimates for previous 30-day cigarette use (1.4 percent; 380,000 students) and cigar use (1.2 percent; 330,000 students) (Ref. 3).

However, waterpipe tobacco is significantly less likely to be smoked daily. In fact, given the relative infrequency of waterpipe use, it is often reported in terms of monthly versus less than monthly use, rather than daily versus non-daily. Data from Waves 1 (2013–2014) and 2 (2014–2015) of the PATH Study indicated that, among adults who used waterpipes in the past year, 77.1 percent reported less than monthly use at Wave 1; by Wave 2, 44.9 percent of these adults continued using waterpipe less than monthly, while 6.4 percent progressed to monthly or more frequent use (Ref. 643). For comparison, 59.1 percent of adults in the 2018 NHIS who smoke cigarettes report daily use (Ref. 644). Wave 3 (2015–2016) PATH Study data also indicate the infrequency of daily waterpipe use: 0.1 percent of youth, 0.3 percent of young adults, and 0 percent of adults 25 and older reported daily waterpipe use (Ref. 645). Comparatively, analysis from Wave 3 of the PATH study found that 0.6 percent of youth, 11.4 percent of young adults, and 15.3 percent of adults older than 25 reported daily cigarette smoking (Ref. 646).

FDA acknowledges that the health consequences of waterpipe usage are far from innocuous. People who use waterpipes are exposed to many of the same toxicants as people who smoke cigarettes, and due to the extended duration of each waterpipe session (i.e., approximately 1 hour), waterpipe use may lead to higher toxicant exposure per session than toxicant exposure from one cigarette (Refs. 647 and 648). Thus, people who use waterpipes are likely subject to many of the same severe negative health effects as people who smoke cigarettes (Ref. 649).

However, FDA does not anticipate significant migration to waterpipe usage under the proposed product standard. Waterpipes as currently marketed are generally large and require time-consuming preparation, leading to an approximate waterpipe smoking session of 1 hour (Ref. 650). The limited accessibility and mobility of waterpipes as generally currently used contribute to their predominant intermittent usage patterns (Ref. 650). FDA assesses that these aspects of waterpipe design would similarly substantially limit their utility as a substitute for cigarettes and other combusted tobacco products that would be subject to the proposed product standard, especially as compared to the portability and ease of use of many HTP, ENDS, and other noncombusted tobacco products that are currently legally marketed and not subject to the proposed product standard.

FDA requests information and data regarding the proposal to exclude waterpipe tobacco from the scope of this proposed rule.

FDA is not including noncombusted tobacco products, such as ENDS (which include e-cigarettes) and smokeless tobacco products, in the scope of this proposed product standard. FDA's approach in proposing this product standard for cigarettes and certain other combusted tobacco products seeks to protect public health by reducing combusted tobacco product use (and therefore reducing exposure to harmful toxicants created through combustion) while potentially less harmful, noncombusted tobacco products remain available for people who do not quit all tobacco-product use. As such, at this time, FDA is focusing this proposed rule on nicotine levels in cigarettes and certain other combusted products because combusted tobacco products are responsible for the majority of death and disease due to tobacco use. Importantly, this action would also help to prevent people who experiment with cigarettes and cigars (mainly youth) from moving beyond experimentation, developing an addiction to nicotine, and progressing to regular use of combusted tobacco products as a result of that addiction. We request comments, data, and research regarding the proposed scope of this rule.

D. Considerations and Request for Comments on the Potential for Illicit Trade

The implementation of a maximum nicotine level in cigarettes and certain other combusted tobacco products could result in some people seeking NNC combusted tobacco products through illicit trade markets. FDA is also considering whether illicit trade could occur as a result of a nicotine product standard and whether such activity could significantly undermine the public health benefits of the product standard.

Since the enactment of the Tobacco Control Act, FDA has been committed to studying and understanding the potential effects of a product standard on the illicit tobacco market. As part of FDA's consideration of possible regulations, the Agency asked the NRC and IOM of the National Academy of Sciences (now the National Academies) to assess the international illicit tobacco market, including variations by country; the effects of various policy mechanisms on the market; and the applicability of international experiences to the United States (Ref. 560). In 2015, the NRC/IOM issued its final report entitled "Understanding the U.S. Illicit Tobacco

Market: Characteristics, Policy Context, and Lessons from International Experiences,” finding that, although there is insufficient evidence to draw firm conclusions regarding how the U.S. illicit tobacco market would respond to regulations requiring a reduction in the nicotine content of these products, demand for illicit cigarettes would be limited because some people who smoke would quit, and others would use modified products (*e.g.*, VLNC cigarettes) or seek legal alternatives (Ref. 560 2015 at p. 9). In addition, in March 2018, FDA issued a draft concept paper, entitled “Illicit Trade in Tobacco Products after Implementation of a Food and Drug Administration Product Standard,” as an initial step in assessing the possible health effects of a tobacco product standard in the form of demand for contraband or nonconforming tobacco products (83 FR 11754). Among other issues, the draft concept paper examined the factors that might support or hinder the establishment of a persistent illicit trade market related to a product standard (Ref. 44). Additionally, in the Nicotine ANPRM, FDA expressed interest in data regarding possible increases in illicit trade and its effect on the marketplace in the event that a nicotine tobacco product standard is finalized. Comments were submitted by members of the tobacco industry, public health organizations, academic researchers, and the public. Comments varied in their conclusions as to how significant illicit trade might be after implementation of an FDA product standard, but no information was submitted in response to the Nicotine ANPRM that caused FDA to revise its overall assessment about the difficulties in establishing sustained, significant illicit trade markets that are able to evade enforcement authorities.

Establishing and maintaining illicit markets in relevant tobacco products will be challenging, and to the extent that they emerge, it is unlikely they will be significant enough to outweigh the benefits of the product standard. Although some people who smoke may seek to purchase illicit products if available and accessible, the NRC/IOM report stated that this “would require established distribution networks and new sources of product (which would either have to be smuggled from other countries or produced illegally) to create a supply of cigarettes with prohibited features” (Ref. 560 at p. 9). The current illicit cigarette trade in the United States is predominantly based on tax evasion and is facilitated by ease of access to tobacco products close to where the

sales to consumers take place (*e.g.*, across State lines). Enforcement against such illicit trade is outside the scope of FDA’s authority (as FDA does not enforce tax laws) and is complicated by the inability to distinguish tax-paid from tax-evading cigarette packs in most instances. However, due to the reduction of nicotine in combusted tobacco products nationwide, a lack of supply would likely limit illicit trade of NNC cigarettes and certain other combusted tobacco products once a product standard is in place. Illicit manufacturing of NNC cigarettes at a scale large enough to diminish the public health benefits of this proposed product standard would be difficult to disguise from Federal, State, and local enforcement authorities. Moreover, importation across international borders is substantially more difficult than across State borders, particularly for the volume necessary to sustain nicotine addiction in people who smoke. Additionally, while it would remain legal for domestic cigarette manufacturers to produce NNC cigarettes and certain other combusted tobacco products for export (as previously described in section III.C of this document), it is unclear the extent to which there would be diversion of legally manufactured products for export that are subsequently sold illegally domestically. As noted in multiple FDA reports to Congress regarding U.S. tobacco product exports, after the product standard prohibiting characterizing flavors (other than tobacco or menthol) in cigarettes was implemented, the U.S. Census Bureau surveyed the vast majority of domestic manufacturers and found no evidence that any continued to manufacture flavored cigarettes or their components or parts (Ref. 651). Importantly, and relevant to any continued domestic manufacture for export, section 920(d) of the FD&C Act (21 U.S.C. 387t(d)) requires that manufacturers and distributors notify the Attorney General and the Secretary of the Treasury of illicit trade activities (such as import, export, distribution, or diversion), increasing the overall vigilance on the matter. Finally, as the NRC/IOM Report explains, comprehensive interventions by several countries show it is possible to reduce the size of the illicit tobacco market through enforcement mechanisms and collaborations across jurisdictions (Ref. 560).

Research also has shown that the choice between VLNC and NNC cigarettes can be influenced by factors such as cost (see section VI.B of this document for further discussion). It is

well-established that people who smoke are price-sensitive, and there is a direct correlation with the increased price of cigarettes and reductions in consumption (Ref. 652), showing for every ten percent increase in price, there is an overall reduction in consumption of 3–5 percent, and youth smoking decreases by 6–7 percent. This price sensitivity also contributes to the willingness of people who smoke cigarettes to shift consumption toward non-cigarette tobacco products in times of economic or product constraint (Refs. 345, 346, and 349). Additionally, there is an “inconvenience cost” to the purchase of illicit tobacco products that rises and falls depending upon the location of illegal sales, reliability of supply, fear of embarrassment and legal penalties, and more (Ref. 560 at p. 67). Although illicit NNC cigarettes and certain other combusted tobacco products will not be subject to taxes, participants in any illicit market will demand profits sufficient to cover both their costs as well as compensate for the risks of enforcement, limiting how low they can price the illicit tobacco products. As a result, when the cost or effort required to obtain illicit products increases, people who smoke may switch their preference from NNC combusted tobacco products to VLNC versions (Ref. 391), to other legal tobacco products, and/or renew their cessation efforts. Each of these alternatives reduces the number of potential buyers of illicit products, lowering the incentives to try, create, and sustain such markets.

Related to concerns about enforcement against individual consumers for possessing or using nonconforming tobacco products acquired through an illicit market, FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use of nonconforming product acquired through an illicit market, and FDA cannot and will not enforce against individual consumers for possession or use of NNC cigarettes or other combusted tobacco products covered by this proposed product standard. In addition, State and local law enforcement agencies do not enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf. FDA recognizes concern about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and

community safety and seeks comments on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

FDA is not proposing to ban any category of tobacco products with this proposed product standard, and authorized products that are not subject to the proposed product standard will remain legally available. Therefore, this proposed product standard is not expected to lead to a surge in illicit tobacco product use. In reaching this conclusion, FDA has considered several factors that are likely to affect the potential for illicit trade. For example, FDA anticipates that a nationwide standard that prohibits the manufacture (other than for export as previously described in section III.C of this document) and sale of cigarettes and certain other combusted tobacco products that exceed the maximum nicotine level set by this proposed product standard, coupled with FDA's authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, would limit the manufacture and distribution of these products. FDA also expects that a nationwide product standard would eliminate the use of online retailers to purchase illicit tobacco products as well as any incentive to travel within the United States in search of jurisdictions without a nicotine product standard because no such jurisdictions would exist. FDA thus anticipates that the rule would result in much less illicit trade than observed in the case of a State or local requirement and that any such trade would be significantly outweighed by the benefits of the rule. Even if some amount of illicit trade develops (Refs. 42 and 653 discuss projected impacts of various rates of potential illicit trade), it would have to be of significantly greater magnitude than any previously seen illicit markets in order to outweigh the significant public health benefits of this proposed standard, and it would have to continue to exist at those levels despite the various enforcement agencies and tools involved.

FDA requests comments, including supporting data and research, regarding whether and to what extent this proposed rule would result in an increase in illicit trade in NNC cigarettes and certain other combusted tobacco products covered by the proposed nicotine product standard and how any such increase could impact public health. Data or other reliable information that do not rely on estimates of current, interstate tax-evading illicit trade would be particularly relevant. If an illicit market

develops after this proposed product standard is finalized, FDA has the authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, including those imported or purchased online. FDA conducts routine surveillance of sales, distribution, marketing, and advertising related to tobacco products and takes appropriate actions when violations occur. If this product standard is finalized as proposed and goes into effect, it would be illegal to import cigarettes and certain other combusted tobacco products that exceed 0.70 mg nicotine per gram of total tobacco, and such products would be subject to import examination and refusal of admission under the FD&C Act. Similarly, it would be illegal to sell or distribute cigarettes and certain other combusted tobacco products that do not comply with this product standard, including those sold online, and doing so may result in FDA initiating enforcement or regulatory actions. We note that the Prevent All Cigarette Trafficking Act of 2009 establishes restrictions that make cigarettes generally nonmailable through the U.S. Postal Service, subject to certain exceptions (18 U.S.C. 1716E). Outside of these exceptions, the U.S. Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable cigarettes, smokeless tobacco, or ENDS.³⁹

X. Description of Proposed Regulation

This proposed rule would establish a new part 1160 that would set a maximum level of nicotine in finished cigarettes and certain other finished combusted tobacco products. Part 1160 would describe the scope of the proposed regulation, applicable definitions, the establishment of a maximum nicotine level in products covered by this proposed rule, product testing and related requirements, and recordkeeping requirements.

A. General Provisions (Proposed Subpart A)

1. Scope (Proposed § 1160.1)

Proposed § 1160.1(a) would provide that this part sets out a tobacco product standard under the FD&C Act to limit nicotine yield by setting a maximum nicotine content level for certain finished tobacco products. We are proposing that this product standard would cover the following finished tobacco products: cigarettes (other than

noncombusted cigarettes, such as HTPs that meet the definition of a cigarette), cigarette tobacco, RYO tobacco, cigars (other than premium cigars), and pipe tobacco (other than waterpipe tobacco). These products are defined in proposed § 1160.3. As stated throughout this preamble, this proposed product standard focuses on cigarettes and certain other combusted tobacco products given their addictiveness, availability as migration and dual use candidates with cigarettes, and the extent of tobacco-related death and disease associated with such products. As stated in section IX.C of this document, FDA requests comment regarding the scope of products covered by this proposed rule.

Proposed § 1160.1(b) would prohibit the distribution, sale, or offering for distribution or sale within the United States finished tobacco products within the scope of the rule that are not in compliance with the tobacco product standard. For example, FDA would consider such finished tobacco products to be noncompliant if they contain a nicotine level that exceeds the proposed maximum nicotine level set forth in proposed § 1160.10. Additionally, manufacturers and importers would not be allowed to enter or introduce into domestic commerce any finished tobacco product (*i.e.*, cigarettes, cigarette tobacco, RYO tobacco, cigars, and pipe tobacco) that does not comply with the requirements of the final rule, irrespective of the date of manufacture.

Proposed § 1160.1(c) would prohibit the manufacture within the United States of finished tobacco products within the scope of the rule that are not in compliance with the tobacco product standard unless such tobacco products are intended for export and are eligible for export under section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)). A tobacco product intended for export shall not be deemed to be in violation of section 907 of the FD&C Act or this product standard if it meets the criteria enumerated in section 801(e)(1), including not being sold or offered for sale in domestic commerce.

2. Definitions (Proposed § 1160.3)

Proposed § 1160.3 provides the definitions for the terms used in the proposed product standard. Several of these definitions are included in the FD&C Act or have been used in other regulatory documents.

- *Accessory*: Consistent with 21 CFR 1140.3 and the Consolidated Appropriations Act, 2022 (Pub. L. 117–103), FDA proposes to define “accessory” as any product that is intended or reasonably expected to be

³⁹ These restrictions were updated to include similar prohibitions on the shipment of ENDS in 2021 (86 FR 58399, October 21, 2021).

used with or for the human consumption of a tobacco product; does not contain tobacco or nicotine from any source 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 product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Accessories of cigarettes, cigarette tobacco, and RYO tobacco, as three of the originally-regulated products under the FD&C Act, are considered “tobacco products” and, therefore, would be subject to this proposed product standard (if finalized). However, accessories of other tobacco products (e.g., cigars) are not regulated as “tobacco products” pursuant to FDA’s final deeming rule (81 FR 28974 at 29015–29016, May 10, 2016) and, therefore, would not be subject to this proposed product standard. Examples of such accessories would be ashtrays, cigar clips, and pipe pouches, because they do not contain tobacco or nicotine from any source, are not made or derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. However, if such a product was intended or reasonably expected to affect the performance of a tobacco product (e.g., nicotine impregnated ash tray), it would no longer be considered an accessory and would be subject to the proposed product standard.

- **Batch:** FDA proposes to define “batch” as a specific identified amount of a finished 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 have, as part of existing manufacturing processes, defined 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. Currently, there is no definition of “batch” for tobacco products. However, the proposed regulation Requirements for Tobacco

Product Manufacturing Practice (TPMP) (see <https://www.federalregister.gov/documents/2023/03/10/2023-04591/requirements-for-tobacco-product-manufacturing-practice>) includes a proposed definition of “batch,” and this rulemaking’s provision is modeled on the proposed TPMP provision. Pursuant to proposed § 1160.12, manufacturers would be required to conduct batch testing and maintain those records.

- **Cigar:** FDA proposes to define a “cigar” as a tobacco product that: (1) is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This definition was used in the seven consent orders that the FTC entered into with the largest mass marketers of cigars (see, e.g., *In re Swisher International, Inc.*, Docket No. C–3964 (FTC August 18, 2000)) and also is codified at 21 CFR 1143.1. The cigar wrapper would be considered a “component or part” of a cigar (see definition herein) and, therefore, would be covered by this proposed product standard. As discussed elsewhere in this document and in proposed § 1160.1, premium cigars are excluded from the scope of this proposed rule.

- **Cigarette:** As defined in section 900(3) of the FD&C Act, the term “cigarette”: (1) means a product that: (i) is a tobacco product; and (ii) meets the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)); and (2) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as RYO tobacco.

- **Cigarette tobacco:** As defined in section 900(4) of the FD&C Act, the term “cigarette tobacco” means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

- **Commercial distribution:** Consistent with 21 CFR 1107.12, FDA proposes to define “commercial distribution” as any distribution of a finished tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. “Commercial distribution” does not

include the handing or transfer of a tobacco product from one consumer to another for personal consumption.

- **Component or part:** Consistent with 21 CFR 1140.3, FDA proposes 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. The term excludes anything that is an accessory of a tobacco product. Components or parts of cigarettes, cigarette tobacco, and RYO tobacco, as three of the originally regulated products under the FD&C Act, are considered “tobacco products” and, therefore, would be subject to this proposed product standard (if finalized). Examples of cigarette components or parts that would be subject to this proposed product standard include cigarette paper and filters. In addition, components or parts of other tobacco products (e.g., cigars) are regulated as “tobacco products” pursuant to FDA’s final deeming rule (81 FR 28974 at 29015–29016) and, therefore, would be subject to this proposed product standard (if finalized). Some examples of such components or parts include cigar blunt wraps, removable tips, mouthpieces, and filters. These examples generally are intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of a tobacco product. If a liquid nicotine product or other tobacco product is intended or reasonably expected to alter the nicotine content of any tobacco product covered by this proposed rule, such liquid nicotine or other tobacco product would be considered a component or part of a finished tobacco product covered under the rule’s scope and, therefore, would be in violation of the rule if the amount of nicotine in the finished tobacco product exceeds 0.70 mg of nicotine per gram of total tobacco. With respect to these definitions, FDA notes that “component” and “part” are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms “component” and “part” interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between “component” and “part” in the future.

- **Finished tobacco product:** Consistent with 21 CFR 1107.12, FDA proposes to define a “finished tobacco product” to mean a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or

filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers (*e.g.*, tobaccoists selling cigars individually from a box or pipe tobacco filler by weight). Examples of finished tobacco products include a pack of cigarettes or a bag of RYO or pipe tobacco.

- **Manufacturing code:** FDA proposes 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, and concludes with “-NS.” This information would help determine the product’s history (*e.g.*, batch testing records) and assist manufacturers and FDA in the event of a nonconforming tobacco product investigation and any corrective actions that stem from such investigation.

- **Manufacturing date:** FDA proposes to define “manufacturing date” as the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished tobacco product is packaged for distribution. The manufacturing date is included in the manufacturing code, which can be used by the manufacturer and FDA to help determine the product’s history (*e.g.*, batch testing history) in the event of a nonconforming tobacco product investigation. As stated in section X.C of this document, FDA requests comment regarding the manufacturing code requirements in this proposed rule.

- **Nicotine:** FDA proposes to define “nicotine” as the chemical substance named 3–1(1-methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine, derived from any source.

- **Nonconforming tobacco product:** FDA proposes to define “nonconforming tobacco product” as any tobacco product that does not meet the requirements of § 1160.10 (nicotine level specifications) or § 1160.30 (manufacturing code).

- **Package or packaging:** As defined in section 900(13) of the FD&C Act, the term “package” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

- **Person:** As defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), the term “person” includes an individual, partnership, corporation, or association.

- **Pipe tobacco:** FDA proposes to define the term “pipe tobacco” as any tobacco that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco to

be smoked in a pipe. However, this definition specifically excludes tobacco labeled and sold exclusively for use in a waterpipe (*i.e.*, hookah tobacco). As discussed in section IX.C of this document, FDA is not proposing to include waterpipe tobacco within the scope of this product standard.

- **Rework:** FDA proposes to define “rework” as action taken on a nonconforming tobacco product to ensure that the product meets the specifications and other requirements of this part before it is released for commercial distribution.

- **Roll-your-own tobacco:** As modeled after section 900(15) of the FD&C Act, FDA proposes to define the term “roll-your-own tobacco” (or RYO) as any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes or cigars. This product is frequently used interchangeably with cigarette tobacco and pipe tobacco (as defined in this section).

- **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 a requirement established to ensure that the tobacco product meets any applicable product standard under section 907 of the FD&C Act.

- **Tobacco filler:** FDA proposes to define “tobacco filler” as cut, ground, powdered, or leaf tobacco or other nicotine-containing substances in a finished tobacco product. For portioned tobacco products, the material enclosing any tobacco or nicotine-containing substances (*e.g.*, cigarette paper) is not considered tobacco filler.

- **Tobacco product:** As defined in section 201(rr) of the FD&C Act, 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); a device under section 201(h); a combination product described in section 503(g) (21 U.S.C. 353(g)); or a food under section 201(f) of the FD&C Act if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

- **Tobacco product manufacturer:** As defined in section 900(20) of the FD&C Act, the term “tobacco product manufacturer” means any person, including a repacker or relabeler, who: (1) manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States.

- **Total tobacco:** FDA proposes to define the term “total tobacco” as the tobacco filler (defined in proposed § 1160.3) and any other tobacco or tobacco-derived material used as part of a tobacco product. For cigars (*i.e.*, those cigars that are covered by this proposed product standard, as defined in proposed § 1160.3), the tobacco included in the wrapper and binder would be part of the “total tobacco.” The nicotine content in the total tobacco of the finished tobacco product must not exceed the proposed maximum nicotine level.

- **United States:** As defined in section 900(22) of the FD&C Act, the term “United States” means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

B. Product Requirements (Proposed Subpart B)

1. Maximum Nicotine Level (Proposed § 1160.10)

FDA is proposing to regulate nicotine yield by requiring that a finished tobacco product contain no more than 0.70 mg of nicotine per gram of total tobacco. As stated in proposed § 1160.3, the term “total tobacco” means both the tobacco filler and any other tobacco or tobacco-derived material used as part of a tobacco product. This level would be based on the nicotine content of the tobacco product, as the means to regulate nicotine yield in the tobacco smoke or emissions. If a liquid nicotine product or other tobacco product (including a tobacco product containing nicotine from any source) is intended or reasonably expected to alter the nicotine content of any tobacco product covered by this proposed rule, such liquid nicotine or other tobacco product would be considered a component or part of a tobacco product covered under the rule’s scope and, therefore, would be in violation of the rule if the total amount of nicotine in the finished tobacco

product exceeds 0.70 mg of nicotine per gram of total tobacco.

As stated previously, the term “finished tobacco product” refers to those products subject to this regulation, including any components, parts, or accessories that are regulated as tobacco products and sealed in a final package, except for components, parts, or accessories not made or derived from tobacco. For cigarettes, cigarette tobacco, and RYO tobacco, all of which were covered under Congress’s original grant of authority (section 901(b) of the FD&C Act), all components, parts, and accessories of such products would be covered under this proposed product standard and subject to the proposed maximum nicotine level. Accessories of deemed tobacco products (*i.e.*, accessories for cigars, pipe tobacco) would not be covered. FDA intends to use its premarket review authority under sections 905 and 910 of the FD&C Act to ensure that manufacturers do not reengineer their products in a way that would circumvent the proposed maximum nicotine level.

2. Product Testing (Proposed § 1160.12)

Proposed § 1160.12 contains provisions for the testing of finished tobacco products that would be subject to this proposed rule. Specifically, proposed § 1160.12(a) would require that tobacco product manufacturers conduct testing on each batch of finished tobacco products to ensure that the batch conforms with proposed § 1160.10. Under this provision, the manufacturer of the finished tobacco product would be required to use an analytical test method that meets the requirements set forth in proposed § 1160.14. FDA recommends manufacturers use one of three analytical test methods described in section VII.D of this document (*i.e.*, FDA’s Tobacco Products Laboratory method, CRM No. 62, or CRM No. 87). This section also states that samples for such testing would need to be selected in accordance with proposed § 1160.16.

Proposed § 1160.12(b) would require that a full report of the source data and results of all batch testing be maintained by the tobacco product manufacturer in accordance with proposed § 1160.32. These reports would be generated for test samples from each batch and would not be required for each individual finished tobacco product. This report would have to include the following information:

(1) Full identification of the finished tobacco product that is the subject of the report, including, if applicable, the submission tracking number (STN) associated with marketing authorization

(including the static product ID (PD), if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity, and nicotine source;

(2) Nicotine level of each sample tested from the batch and standard deviation;

(3) The batch manufacturing date and location, including facility name and address, for each sample;

(4) The testing date and location, including the facility name and address;

(5) The manufacturing code of each sample tested (in accordance with proposed § 1160.30(c));

(6) The test method and sampling procedure used;

(7) Names and qualifications of the person(s) conducting the testing and any laboratory accreditation;

(8) The manufacturing and testing equipment used (including documentation to show that the equipment is appropriate for its intended purpose and has been calibrated to ensure accurate and reliable results); and

(9) The criteria used to make a decision to accept or reject each batch and the decision made with respect to each batch (*e.g.*, accept, reject) based on the results of the product testing. This information would constitute the documentation of the source data and actual results of the product testing conducted on each batch.

The main purpose of this report would be to verify that products subject to this proposed product standard do not exceed the maximum nicotine level and to document the company’s decision for each batch with respect to acceptance, rejection, and reworking of the products. FDA expects that information collected pursuant to proposed § 1160.16(b) would be integrated into the proposed § 1160.12(b) records (*i.e.*, proposed § 1160.16(b) records would be the basis for documenting background information about the product being tested, including, for example, the product category and subcategory, brand and subbrand, packaging information, nicotine source, manufacturing date, and the manufacturing code). These proposed § 1160.12(b) records also would document the ultimate disposition of the batch based on the testing of the representative samples. Section III.C of this document describes FDA’s rulemaking and inspection authorities related to these records.

While the proposed batch testing and sampling requirements would provide FDA with critical information, the

Agency also recognizes concerns that it could be costly for certain manufacturers to test each batch. Therefore, FDA requests comment, including supporting data, regarding potential alternatives to batch testing and sampling to ensure finished tobacco product compliance with proposed § 1160.10 that would reduce costs for manufacturers.

3. Analytical Test Method (Proposed § 1160.14)

Proposed § 1160.14 would require that tobacco product manufacturers use an analytical test method and demonstrate that the test method was validated in an analytical test laboratory.

Validation means a process of demonstrating or confirming that the analytical test method is suitable and reliable for its intended purpose. Validation of an analytical method applies to a specific laboratory, for a specific product, and equipment performing the analytical test method for an intended use over a reasonable period. Although there are various approaches to demonstrate that an analytical test method is validated (*e.g.*, ICH Guideline Validation of Analytical Procedures: Text and Methodology Q2), FDA intends to use the approach outlined in the draft guidance entitled “Validation and Verification of Analytical Testing Methods Used for Tobacco Products” to determine if a submitted test method is fit-for-purpose. In March 2024, FDA published a final guidance for industry entitled “Q2(R2) Validation of Analytical Procedures” and although it is not specific to tobacco products, FDA’s approach under that guidance to determine if a method is fit-for-purpose is applicable for use under this tobacco product standard.⁴⁰

As described in section VII.D of this document, FDA recommends manufacturers use one of three publicly available analytical test methods—FDA’s Tobacco Products Laboratory method, CRM No. 62, or CRM No. 87—to demonstrate compliance with this proposed product standard. Each of these analytical test methods includes the proposed nicotine level in the range of levels that can be accurately measured.

⁴⁰ FDA has announced the availability of a draft guidance for industry entitled “Validation and Verification of Analytical Testing Methods Used for Tobacco Products” (86 FR 72603, December 22, 2021; see <https://www.fda.gov/media/155033/download>). The draft guidance, when finalized, would represent FDA’s current thinking on method validation for tobacco products. FDA final guidance “Q2(R2) Validation of Analytical Procedures” is available at <https://www.fda.gov/media/161201/download>.

It is reasonable to expect some manufacturers may prefer to use other test methods. If they are developed and validated, such methods may have different advantages in ease of use, upper and lower bounds of detection, equipment, and expertise. Thus, under this proposal we would evaluate analytical test methods and data as part of a manufacturer's premarket submission in accordance with section 910 of the FD&C Act.

4. Sampling Plans and Procedures (Proposed § 1160.16)

Proposed § 1160.16 would require each tobacco product manufacturer to design and implement a sampling plan that covers each finished tobacco product that it manufactures. This sampling plan must be based on a valid statistical rationale to ensure that the finished tobacco product complies with proposed § 1160.10. This sampling plan would be used in conjunction with the analytical test method in proposed § 1160.14 and would provide procedures for the manufacturer to select samples to demonstrate conformance to the proposed maximum nicotine level requirement.

The required procedures are intended to help ensure that tobacco products containing more than the maximum nicotine level are not sold or distributed to consumers. Manufacturers would be required to ensure that all finished tobacco products comply with the requirements of this proposed product standard. Products that do not conform to this standard would be deemed adulterated under section 902(5) of the FD&C Act and subject to enforcement action.

Proposed § 1160.16(a) provides the general requirements for sampling plans. The proposed provision would require manufacturers to design and implement a sampling plan or plans for each finished tobacco product based on a valid scientific rationale to ensure that the product consistently conforms to the requirements set forth in § 1160.10. This provision also explains that the sampling plan must ensure that samples taken are representative of an entire batch (*i.e.*, randomized or systematically selected across the entire batch) and collected from each batch for testing. To account for the variability of nicotine in finished tobacco products, the following factors must be based on adequate statistical criteria: the confidence intervals, the level of necessary precision, and the number of finished products sampled. The sampling plan must take into account the manufacturing quality history of the manufacturer (*e.g.*, batch testing records,

nonconforming tobacco product investigations). For example, a manufacturer that has a high number of nonconforming tobacco product investigations or a high number of batch rejections may decide to create a more robust sampling plan because of its history of producing nonconforming tobacco products.

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. 654 to 656). 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. FDA requests comment, including supporting data, regarding whether a final rule should provide a more detailed definition of or criteria for what constitutes "valid scientific rationale" (such as representative sampling) with regard to an adequate sampling plan.

Proposed § 1160.16(a) also would require that the sampling plan describe the sampling methodology (including scientific rationale), incorporate all sources of variability (including variability of the analytic method and nicotine levels), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling plan to achieve the sampling objective. The sampling plan must also describe the criteria the manufacturer would use to make a decision to accept or reject each batch. 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 machine or hand-rolled cigars.

With regard to the variability of the tobacco product, confidence intervals, level of necessary precision, and number of finished tobacco products sampled must be based on adequate statistical criteria. This provides manufacturers 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 the support for the scientific technique or methods used to establish the representative samples used and to show that the sampling size is representative of the material being sampled. The manufacturer must maintain a nicotine content level no greater than 0.70 mg nicotine per gram of total tobacco for any products within the batch.

Proposed § 1160.16(b) would require that test samples from each batch be collected and examined in accordance with certain procedures. These procedures are consistent with ISO 8243, an international standard that specifies two methods of providing representative samples of a population of cigarettes manufactured for sale.

Under proposed § 1160.16(b)(1), test samples would have to consist of the finished tobacco product as it is intended to be sold or distributed to consumers and not of a separate production sample.

Proposed § 1160.16(b)(2) would require that all test samples be stored according to the intended storage conditions for the finished tobacco product. In addition, the manufacturer would have to include all of its factories, stock rooms, warehouses, and other locations containing finished tobacco products among the population to be sampled. Because a batch may include product that is in the warehouse and product that is in the factory, or in a place between the warehouse and factory, this requirement would ensure that the sample is representative of the entire population (batch) of finished tobacco products packaged for consumer use. This practice is consistent with the ISO 8243 standard (for sampling nicotine) and ensures that the samples are representative of the population of finished tobacco products packaged for consumer use.

Under proposed § 1160.16(b)(3), the manufacturer would have to take test samples from each batch within 30 calendar days of the date the product is manufactured. Based on FDA's experience, any protracted time between manufacturing and testing will add uncertainty in the accuracy of reported results. Thus, we are proposing a 30 calendar day timeframe from the

manufacture date for the manufacturer to take test samples from each batch. The amount of material acquired during sampling must be sufficient to complete all testing required by proposed § 1160.14, including any repeat testing that may be necessary. The sample materials would have to be selected from each batch in accordance with the applicable sampling plan. This would ensure that there has not been any degradation or change in part of the samples.

Proposed § 1160.16(b)(4) would require that sampling be performed by persons who have sufficient education, training, and experience to accomplish their assigned functions.

Under proposed § 1160.16(b)(5), each test sample would need to be identified so that the following information can be determined:

- Full identification of the finished tobacco product sampled, including, if applicable, the STN associated with marketing authorization (including the PD, if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity, and nicotine source;
- The manufacturing code;
- The date on which the sample was taken;
- The sampling location (including the address of the facility and specific location within the facility where the sample was taken);
- The name of the person(s) who collected the sample; and
- The location where the sample will be tested (including the facility name and address).

This information would be generated at the time the samples are pulled for testing and for each sample pulled, rather than reflecting aggregate information for all the samples in a particular batch. The purpose of this information is to fully identify each sample, including what the product is, when and where it was taken, and the batch from which it was taken. These records would serve dual purposes. First, they could be used to verify that a company is following its sampling plan and the required procedures in the codified including number of samples pulled, when they are pulled, and locations from where they are pulled. Second, these records would be used to generate some of the information for the records required under proposed § 1160.16(b)(8). They also would document the start of the chain of custody for the samples.

Proposed § 1160.16(b)(6) provides packaging requirements for when samples are sent for testing. Test samples would have to be packed securely with adequate protection against damage that might occur, including mechanical damage or adverse changes in humidity or temperature. The manufacturer also would have to send, under separate cover, a list of the samples included in each shipment to the testing facility. These samples should be identified by the relevant information required by proposed § 1160.16(b)(5).

Proposed § 1160.16(b)(7) would require that all samples from a single batch be tested at the same testing facility. This requirement is designed to ensure consistency in the procedures used and to protect against sample degradation.

Proposed § 1160.16(b)(8) provides sampling requirements for the testing facility. If samples will be transported to a different facility from the manufacturing facility for testing, once test samples arrive at the testing facility, samples must be inspected, accounted for, and properly stored under the finished tobacco product's intended storage conditions. The facility also would be responsible for generating a report for the batch test, maintained by the manufacturer in accordance with § 1160.32, which includes the information in proposed § 1160.16(b)(8)(i) through (vi):

- Full identification of the finished tobacco product sampled, including, if applicable, the STN associated with marketing authorization (including the PD, if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity; and nicotine source;
- The manufacturing code;
- The date on which the samples were taken, if available;
- The sampling location (including the address and specific locations within any facilities where the samples were taken);
- The number of test samples drawn from the batch; and
- Complete records of the samples received and tested, including the date of receipt, the identifier of all persons who tested the samples, and the test results.

This information would be generated once the test samples arrive at the testing facility. Unlike the information required under proposed § 1160.16(b)(5), this report would be an aggregate report for all the samples

taken from a batch. The primary purpose of this information, along with the information required by proposed § 1160.16(b)(5), would be to establish the chain of custody for the samples from the time they were taken through their transfer to the testing facility where they will be tested. FDA expects that this information would be integrated into the records required by proposed § 1160.12(b) to provide information across the batch.

Proposed § 1160.16(b)(9) explains that each batch must be withheld from commercial distribution until it has been sampled and tested, and a decision has been made by the tobacco product manufacturer that the batch conforms to the requirements of this part and may be released for commercial distribution. As discussed in proposed § 1160.18, the manufacturer would be required to reject any nonconforming tobacco products unless a disposition decision and justification to release the batch is made after an investigation determines that the batch meets the requirements of this part.

As noted in the discussion of proposed §§ 1160.12 and 1160.16, the reporting requirements in proposed §§ 1160.12(b), 1160.16(b)(5), and 1160.16(b)(8) are interrelated but intended for different purposes.

Because this tobacco product standard defines the amount of nicotine relative to the amount of total tobacco, manufacturers may be able to base sampling plans on batch sizes based on the tobacco filler. For example, cigarettes of two different lengths made from the same tobacco filler blend may be able to be considered a single batch for the purposes of calculating the sampling plan under proposed § 1160.16. Testing for nonconforming tobacco product under proposed § 1160.16 would require the manufacturer to adequately sample from the entire batch in proportion to production. For example, if two-thirds of the batch is produced as cigarette length A and one-third as cigarette length B, then two-thirds of the samples for testing for conformance would have to be sampled from cigarette length A and one-third from cigarette length B.

Manufacturers that purchase bulk tobacco filler can utilize results of filler testing by the seller in designing and implementing their sampling plan. Reliance on the seller's filler testing would not relieve the manufacturer of the finished tobacco product from its responsibility to test finished tobacco products or from responsibility for complying with this proposed product standard.

5. Nonconforming Tobacco Product (Proposed § 1160.18)

Proposed § 1160.18 would require finished tobacco product manufacturers to establish procedures for the control and disposition of nonconforming tobacco products. A “nonconforming tobacco product” is proposed to be defined as any tobacco product that does not meet the requirements of § 1160.10 (nicotine level specifications) or § 1160.30 (manufacturing code). These procedures are necessary to help prevent the distribution of nonconforming tobacco products by ensuring that all potential nonconforming products are identified, investigated, and segregated, and that appropriate disposition and followup are 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.

Proposed § 1160.18 would require tobacco product manufacturers to establish and maintain procedures to identify, investigate, segregate, and make disposition decisions (*i.e.*, acceptance, rejection, rework) about nonconforming tobacco products to prevent their release for commercial distribution. “Establish and maintain” for purposes of proposed § 1160.18 means define, document (in writing or electronically), implement, follow, and, when necessary, update. This section allows manufacturers the flexibility to determine how they would perform these activities.

Proposed § 1160.18(a) would require tobacco product manufacturers to identify and segregate potential nonconforming tobacco product to prevent the commercial distribution of such products prior to investigation and disposition. 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; 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 products.

Proposed § 1160.18(a) also would require potential nonconforming tobacco 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 1160, “segregation” means setting the identified potential nonconforming product apart from other product (*i.e.*, placing it away from conforming finished product). 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. The requirements to identify and segregate would be triggered upon discovery of a potential nonconforming product. For example, if a tobacco product manufacturer tests samples of finished tobacco product and determines that the representative samples from that batch do not conform to the requirement set forth in proposed § 1160.10, the manufacturer would determine that the batch and related products must be identified and segregated as they may be nonconforming products.

Proposed § 1160.18(b) would require tobacco product manufacturers to investigate all potential nonconforming tobacco products. This may include, for example if:

- The nicotine level of a test sample from any batch of finished tobacco products is determined to be out of conformance with the requirements of proposed § 1160.10;
- FDA notifies the manufacturer that a finished tobacco product in commercial distribution does not conform to the requirements of part 1160; or
- The manufacturer has come to know through any other means that a product is nonconforming.

In this context, a test sample would consist of a number of individual test units that are drawn based on a valid scientific rationale (such as representative sampling) and intended to ensure that the sample accurately reflects the material being sampled. The purpose of a nonconforming product investigation would be to determine the extent and the cause, if possible, of the nonconformity so that additional nonconforming products are not produced or released for commercial distribution. In addition, it would help to prevent recurrence of the nonconformity.

Under proposed § 1160.18(b), the manufacturer would be required to conduct an investigation to determine the extent of the nonconformity upon identification of a nonconforming

product and, as applicable, the locations where the nonconforming products have been distributed. We expect the manufacturer would be able to determine the locations of initial consignees (*e.g.*, wholesalers, distributors, retailers) where the affected products were shipped in the event a corrective action needs to be taken. The investigation would have to include an examination of all relevant processes and controls, laboratory testing, complaints, and any other relevant records and sources of information concerning the nonconforming product. For example, a manufacturer could determine the extent of the nonconformity by examining records and in-process control records for any batches, or portions of batches, that have been rejected during either in-process or finished inspection for failing to meet any or all of the product's specifications. Furthermore, in the event that a similar nonconforming product is identified in a different batch, a manufacturer's investigation could include any applicable information and records from the previous nonconforming product investigation that are relevant to determining the extent of the nonconformity of the affected batch.

Proposed § 1160.18(b) would also require that, for products determined to be nonconforming, the investigation must also determine the scope and cause of 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 a manufacturer's sampling plan and subsequent repeat testing under proposed § 1160.18 determines that a batch of finished cigarettes fail to meet the established nicotine level specification and acceptance criteria, the manufacturer will have to investigate the scope and cause of the nonconformance under this proposed section. If the investigation determines that the cause of the nonconformance is attributed to cut filler received from its supplier that contain nicotine levels that exceed the maximum nicotine level established by the proposed product standard, the manufacturer must also determine the scope of the nonconformance, such as all batches of finished cigarettes that used the affected cut filler.

The manufacturer would have to document any investigation, including any material review, name of the person(s) making the disposition decisions, justification for the

disposition decisions, results of retesting, decisions with respect to reworking, and followup results from the investigation (*e.g.*, corrective actions). FDA may inspect these records to verify that the manufacturer has performed an adequate investigation.

For example, if a manufacturer uses a laboratory to perform product testing under proposed § 1160.12, and there is an out-of-specification (OOS) laboratory test result, the manufacturer would need to investigate the OOS test result under proposed § 1160.18(b) to determine whether the product is nonconforming or the OOS result is due to another cause, such as laboratory error. Under proposed § 1160.18(b), the investigation would be required to include an examination of relevant processes, operations, and any other relevant 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, deviation from an established laboratory test method) and that the potential nonconforming tobacco 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, for example, the manufacturing process. If the manufacturer's nonconforming product investigation determines that the OOS result is due to a legitimate reason such as a testing aberration, *e.g.*, instrument malfunction, and the re-test or rework establishes that the finished tobacco product conforms to the nicotine level of the product standard, such product could be released for commercial distribution.

Proposed § 1160.18(c) would require tobacco product manufacturers to reject a batch of a finished tobacco product if the nicotine level of the test sample does not meet the requirements of § 1160.10, unless a disposition decision and justification to release the batch is made after an investigation shows the batch meets the requirements of part 1160. This might occur in the event of a laboratory or sampling error. Manufacturers would not be able to simply resample a batch until the batch conforms with the proposed maximum nicotine level in § 1160.10 if previous test samples did not meet the requirements of part 1160. If the initial test samples of the batch were not in conformance, the manufacturer must conduct a nonconforming tobacco product investigation. If the manufacturer, for instance, determines

that the nicotine levels were erroneously high due to a malfunction of the testing equipment, the manufacturer could determine that the batch is acceptable for release for commercial distribution.

Proposed § 1160.18(d) would require manufacturers to determine the disposition of all nonconforming tobacco products and any necessary followup. Under proposed § 1160.18(d), nonconforming product cannot be released for distribution without rework or an adequate justification (developed and maintained in accordance with § 1160.32). Thus, nonconforming product could be reworked, distributed with an adequate justification, or discarded. Additionally, nonconforming product could be exported if it meets the requirements of section 801(e)(1) of the FD&C Act. Proposed § 1160.18(d) also would require the manufacturer to develop an adequate written justification before releasing such product for commercial distribution. An adequate written justification would be required to address how the nonconforming product meets all requirements under this part. Nonconforming product cannot be released for commercial distribution without rework or an adequate written justification supporting its release. An example of reworking a nonconforming product would be a manufacturer rebinding the cut filler and retesting to ensure that it conforms to the established product standard.

Proposed § 1160.18(e) would require each tobacco product manufacturer to maintain records of all activities required under § 1160.18. 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.

C. Manufacturing Code and Recordkeeping Requirements (Proposed Subpart C)

1. Manufacturing Code Requirements (Proposed § 1160.30)

Proposed § 1160.30 would require that the packaging of all finished tobacco products include a manufacturing code. The manufacturing code would allow manufacturers and FDA to identify the production batch of a particular finished 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 tobacco product investigation and any corrective actions to be taken by a manufacturer as a result of the investigation. The “-NS” designation will enable retailers to readily identify that a finished tobacco product conforms with this standard. Finished tobacco products that do not have this designation do not conform to this standard. The manufacturing code information also would aid FDA in ensuring compliance with this proposed product standard by clearly identifying those products that conform to the standard and linking those products to records that substantiate their conformance.

As stated in proposed § 1160.30(a), the manufacturing code would be required to be permanently affixed to the packaging or label of all finished tobacco products. The manufacturing code must be affixed in a manner that ensures it will remain on the packaging or label through the expected duration of use of the product by the consumer. In addition, proposed § 1160.30(b) would require that the manufacturing code be permanently affixed, legible, conspicuous, prominent, and appear in the English language.

As stated in proposed § 1160.30(c), the manufacturing code must contain the following information listed in the following order:

- The manufacturing date in 2-digit numerical values in the month-day-year format (MMDDYY);
- The finished tobacco product batch number; and
- The designation “-NS” at the end ⁴¹ (to signify that the product was manufactured in accordance with this nicotine product standard).

FDA requests comment on the manufacturing code requirements in this proposed rule.

2. Recordkeeping Requirements (Proposed § 1160.32)

Proposed § 1160.32 contains recordkeeping requirements. This information is necessary for FDA to ascertain and confirm that finished tobacco products are in compliance with the proposed product standard.

First, proposed § 1160.32(a) would require that each facility that manufactures tobacco products subject to this part (*i.e.*, cigarettes and certain other finished tobacco products) establish and maintain records related to compliance with this part, including the following:

⁴¹ The “-NS” designation will enable retailers to readily identify that a finished tobacco product conforms with this standard. Finished tobacco products that do not have this designation do not conform to this standard.

(1) The source data and results of analyses conducted to determine conformance with § 1160.10, including all information identified in § 1160.12(b);

(2) All source data used to validate an analytical test method;

(3) All sampling plans and sampling reports under § 1160.16;

(4) Documentation that the persons performing sampling under § 1160.16 have sufficient education, training, and experience to accomplish the assigned functions; and

(5) All nonconforming tobacco product identification, segregation, investigation, rework, and disposition decision procedures, including justifications under § 1160.18.

This information is necessary for FDA to ascertain and confirm that the products are in compliance with the proposed product standard.

Second, proposed § 1160.32(b) provides certain specifications for these records. All records required under this part, regardless of storage medium, would need to be attributable (*i.e.*, traceable to its source), legible (*i.e.*, in a readable format), contemporaneously recorded (*i.e.*, recorded at the time of performance), original (*i.e.*, first capture of the data), and accurate (*i.e.*, correct, truthful, complete, valid, and reliable). In addition, these records would be required to be written in English; alternatively, an accurate English translation must be made available upon request. Documents that have been translated from a foreign language into English would have to be accompanied by the foreign language version of the document and a certification by the manufacturer's authorized representative (which could be a U.S. agent for the manufacturer) that the English language translation is complete and accurate, and a brief statement of the qualifications of the person who made the translation (*e.g.*, education, experience). These records would need to be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the manufacturer and to FDA. These records, including those not stored at the establishment, would need to be readily accessible to FDA during the retention period (as discussed in § 1160.32(c)) for inspection and photocopying or other means of reproduction. Original or true copies of these records that can be immediately retrieved from another location, including by computer or other electronic means, would satisfy the requirements of this section.

FDA expects that requested records that are maintained offsite would be

made available within 24 hours or, if that is not feasible, as soon as possible before the close of the inspection. While the Agency expects that most records can be made available to FDA within 24 hours, FDA recognizes that, in some cases, additional time may be needed to retrieve records from a third party or archival storage. Records that can be immediately retrieved from another location, including by computer or other electronic means, would meet the requirement that the records be readily available.

Proposed § 1160.32(c) would require that the records kept under this part be retained for at least 4 years from the date of commercial distribution of the finished tobacco product that is the subject of the record. FDA has selected 4 years to help ensure that the records would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act.

FDA believes that detailed recordkeeping requirements are necessary to confirm that finished tobacco products are in compliance with the proposed product standard. For example, requiring manufacturers to document their test results would enable FDA to confirm that the manufacturer's analytical test method is adequate to meet the requirements of part 1160. In addition, requiring nonconforming tobacco product records would help the manufacturer and FDA determine the extent of the nonconformity with the product standard and, as applicable, the locations where the nonconforming products have been distributed, for example, in the event of a recall.

XI. Proposed Effective Date

In accordance with section 907(d)(2) of the FD&C Act,⁴² FDA proposes that any final rule that may issue based on this proposal become effective 2 years after the date of publication of the final rule. Therefore, after the effective date, no manufacturer or importer would be allowed to distribute, sell, or offer for distribution or sale within the United States any finished tobacco product that does not comply with proposed part 1160. After the effective date of the final rule, manufacturers and importers would not be allowed to enter or introduce into domestic commerce any finished tobacco product (*i.e.*, cigarettes,

cigarette tobacco, RYO tobacco, cigars, and pipe tobacco) that does not comply with the requirements of the final rule, irrespective of the date of manufacture. Prior to the effective date of any final rule that may issue based on this proposed rule, wholesalers, retailers, and related entities would be able to sell available stock of finished tobacco products that are not in compliance with part 1160 while transitioning inventory in anticipation of the effective date of the final rule; however, they would not be permitted to sell off such stock after the effective date. FDA notes that keeping products subject to this proposed rule with higher nicotine levels on the market for an extended period of time is not in the interest of public health.

The Nicotine ANPRM requested comment on a proposed effective date for a nicotine tobacco product standard. Several comments recommended that FDA establish a 1-year timeframe for implementation. Other comments urged FDA to set a 2-year timeframe for implementation, which they stated would be the minimum required by section 907 of the FD&C Act due to the impact on farmers. A few comments argued that an implementation period should be required for all manufacturers, regardless of the number of employees and/or annual revenues, because the long time to develop the regulation plus the implementation period would be sufficient warning for all companies. However, many comments argued that the implementation period should be significantly longer than a 1- or 2-year period to allow farmers, tobacco intermediaries, and manufacturers to develop and implement the methods of reduction.

The comments differed as to whether FDA should allow manufacturers any time to sell off nonconforming tobacco product. Several comments urged FDA to allow manufacturer sell-off of existing nonconforming inventory, with some stating that a 6-month or 12-month selloff period should be sufficient for nonconforming product to move through the supply chain. Nevertheless, several comments opposed provisions that would allow sell-off of existing inventory, arguing that the extensive period of the development of the standard combined with a 2-year phase-in period would give the companies more than enough time to sell-off or recall existing inventory. Some comments stated that a 60-day selloff period would be a sufficient selloff period while still maintaining the public health goals of the standard. FDA requests comments, including

⁴² Section 907(d)(2) of the FD&C Act states that a regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

supportive data and research, regarding a selloff period (e.g., 60 days after the effective date of the final rule) for retailers to sell through their current inventory of nonconforming product.

FDA considered many factors in determining an appropriate proposed effective date. Pursuant to section 907(d)(2) of the FD&C Act, FDA considered the technical achievability of compliance with the proposed product standard and the existence of patents that would make it impossible to comply in the proposed 2-year timeframe. For example, for manufacturers that may not want to use chemical extraction, FDA considered how long it would likely take for a tobacco product manufacturer to acquire sufficient VLNC tobacco to meet the proposed product standard. Industry documents indicate that the timing of availability of leaf once commercial seed is provided is one growing season (Ref. 657). Seed production and germination testing can be conducted in multiple seasons within a single year with small-scale trial to commercial availability taking place over the course of 1 year (Ref. 658). For example, industry documents indicate that a request for purchase of low alkaloid nicotine in March 1990 would be expected to result in leaf delivery during August and September (Ref. 657).

Once purchased, FDA considered how long tobacco must be stored prior to use in cigarettes and other combusted tobacco products. Industry documents suggest a minimum storage age (particularly for burley and flue-cured tobaccos) of around 12 months (Refs. 659 to 663). Other tobacco manufacturers suggest that tobaccos should be stored for 22 months, although other studies suggest that aging beyond 12 months has minimal effects (Refs. 662 and 664). Industry documents also indicate that processed tobaccos do not appear to require long-term inventory or aging in the same manner as whole-leaf tobaccos (Ref. 659). FDA requests comments, including supportive data and research, on the technical achievability of compliance with the proposed product standard and the existence of patents that would make it impossible to comply in the proposed 2-year timeframe.

FDA also finds that a 2-year effective date will “minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade” pursuant to section 907(d)(2) of the FD&C Act. As discussed extensively throughout this document, tobacco use is the leading cause of preventable disease and death

in the United States, and nearly all of the adverse health effects are ultimately the result of addiction to the nicotine in cigarettes and certain other combusted tobacco products, which leads to repeated exposure to toxicants from these products. Given the tremendous public health risks presented—particularly to youth who experiment with these products, develop an addiction to nicotine, and progress to regular use—by combusted tobacco products, FDA finds that any balancing of impacts to domestic and international trade is far outweighed by the significant public health benefits of this proposed product standard for all age groups. FDA also believes that a 2-year effective date would allow adequate time for implementing any necessary changes in technology to achieve the proposed nicotine level, for making any changes to tobacco purchasing choices and curing methods, and for preparation or changes needed in facilities, which can be accomplished simultaneously. In addition, this timeframe should provide adequate time for manufacturers to seek and obtain marketing authorization from FDA for their new tobacco products. FDA believes that this 2-year period would provide sufficient time for a tobacco product manufacturer to submit, and FDA to review, applications for new tobacco products that comply with this provision. This is particularly true given our expectation that most manufacturers that reduce the nicotine levels of their products to comply with the proposed standard would be submitting SE Reports, which may decrease the amount of data required for authorization. See section IX.B of this document regarding pathways to market tobacco products that have been modified to meet the proposed standard. FDA requests comments, including supportive data and research, on the timeframe for manufacturers to prepare applications and obtain marketing authorization from FDA for their new tobacco products.

FDA finds this proposed effective date to be appropriate for the protection of the public health, given that current nicotine levels in the finished tobacco products cause addiction and repeated exposure to toxicants, which ultimately result in the majority of tobacco-related disease and death in the United States. Additional delay, past 2 years, would only increase the number of youth and young adults who transition to regular use of cigarettes and certain other combusted tobacco products and would delay switching to potentially less harmful tobacco products or cessation

by people who currently smoke cigarettes.

Pursuant to section 907(d)(2), FDA requests comments by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with this proposed product standard, including information concerning the existence of patents that make it impossible to comply in the proposed 2-year timeframe. FDA also requests comment on the timeframe for manufacturers to prepare applications and obtain marketing authorization from FDA for their new tobacco products. Further, FDA requests comments and data regarding whether 2 years is sufficient to comply with this standard or whether this effective date should be later to provide additional time for manufacturers to develop any necessary changes in technology, facilities, farming methods, or other factors or business practices affecting compliance. FDA also requests comments and supporting data as to whether a shorter effective date would be necessary for the protection of the public health.

XII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are “significant” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they “have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” OIRA has determined that this proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because businesses, including small businesses, would incur costs to comply with the proposed product standard, we find that the proposed 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 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 2023 threshold after adjustment for inflation is \$183 million, using the 2023 Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least 1 year that meets or exceeds this amount.

B. Summary of Costs and Benefits

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 (Ref. 653) and at <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>. The summary of costs, benefits, and transfers is presented in table 13. Benefits occur because the proposed rule would discourage people who do not use tobacco products from initiating combusted tobacco products and progressing to regular use and increase cessation or switching to potentially lower risk tobacco products among people who currently use covered combusted tobacco products and wish to quit. Lower prevalence of combusted tobacco product use would lead to reduced health consequences for people who formerly used combusted tobacco products and those who were previously exposed to secondhand smoke. The main quantified benefits come from averted mortality and morbidity as a result of reduced prevalence for people who currently use combusted tobacco products, and reduced mortality from reduced exposure to secondhand smoke among people. As described in section VIII.A above, to assess the potential public health impacts of a nicotine product standard, FDA developed a population health model using inputs derived from available empirical evidence and expert

opinion to estimate the impact of changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States. We use output from this population health model to estimate averted mortality and preliminarily apply the value of a statistical life while requesting feedback about how to follow HHS guidance (see PRIA Section II.M.6). The morbidity estimates come from population health model output that evaluates the health difference for being in the state of smoking versus not smoking. Unquantified benefits include medical cost savings, productivity loss savings, reduced exposure to thirdhand smoke, and environmental impacts. We estimate that the present value of the quantified benefits over a 40-year time horizon ranges between \$7.6 trillion and \$33.2 trillion with a primary estimate of \$30.6 trillion at a 2 percent discount rate. The primary annualized quantifiable benefits equal \$1.1 trillion at a 2 percent discount rate.

As most of the benefits from avoided initiation among youth and young adults due to this proposed product standard are expected to fall outside of the 40-year time horizon of the main analysis, we present an extended analysis over a period beyond the 40-year time horizon to capture the impact on youth and young adults. The present value of quantified benefits, mostly attributable to youth and young adults, over this extended period range between \$8.4 trillion and \$19.7 trillion with a primary estimate of \$19.1 trillion at a 2 percent discount rate. Additionally, we present the incidence of benefits for specific populations in the Distributional Effects section.

We expect this proposed rule, if finalized, to impose costs on industry to follow the product standard, on the broader economy to repurpose land, labor, and capital, on consumers impacted by the product standard, and on FDA to enforce this product standard. The tobacco market faces a one-time primary cost with a present value of \$374 million at a 2 percent discount rate (low-impact scenario estimate of \$112 million to a high-impact scenario estimate of \$700 million) to read and understand the rule.⁴³ We also use population health

model output on prevalence to estimate the baseline and policy market size. These estimates feed into cost estimates, such as lost producer surplus. Producers of combusted tobacco products incur a primary annualized producer surplus loss of \$1.7 billion (low-impact scenario of \$0.2 billion and a high-impact scenario of \$2 billion) at a 2 percent discount rate. We expect that some manufacturers would reformulate their products to comply with this standard. We estimate a one-time reformulation cost with present value of \$0.6 billion (low-impact scenario estimate of \$8.8 billion to a high-impact scenario estimate of \$0.04 billion). Manufacturers that reformulate would collectively incur a one-time cost to submit their new tobacco product for FDA review, estimated at a present value \$1 million at a 2 percent discount rate (low-impact scenario estimate of \$15 million to a high-impact scenario estimate of \$0.1 million). In addition, these manufacturers would also incur recurring costs to test the nicotine level of their products with a primary annualized estimate of \$0.3 million (low-impact scenario estimate of \$1.9 million to a high-impact scenario estimate of \$0.1 million) at a 2 percent discount rate. We estimate a one-time cost for FDA to review submissions for new tobacco products at a present value of \$1.0 million at a 2 percent discount rate (low-impact scenario estimate of \$15.3 million to a high-impact scenario estimate of \$0.1 million). The economy faces a one-time economic transition cost with a present value of \$7.2 billion at a 2 percent discount rate (low-impact scenario estimate of \$4.3 billion to a high-impact scenario estimate of \$9.1 billion) to reallocate productive resources (such as labor and capital) currently devoted to the manufacture of NNC covered combusted tobacco products to other tobacco products or to non-tobacco products. We estimate transition cost based on average industry capital expenditures and literature on the cost of labor transition. Consumers of NNC covered combusted tobacco products would face a one-time search cost with a present value of \$1.4 billion at a 2 percent discount rate (low-impact scenario estimate of \$0.46 billion to a high-impact scenario estimate of \$2.8 billion) to find other tobacco products or NRT as a replacement for the prohibited NNC products. We estimate one-time withdrawal costs for

⁴³ For the purposes of our analysis, we use the population health model described in section VIII.A of this document to estimate impacts for a range of averted mortality and tobacco prevalence. The “high impact scenario”, generally referred to as the upper bound, corresponds to the scenario where the policy has 95th percentile averted mortality projected by the population health model, which also corresponds with the lowest (5th percentile)

post-policy combusted tobacco prevalence. For some costs (product reformulation, premarket submission, and review, and testing costs), the “upper bound” corresponds to the scenario with the fewest products and, thus, would reflect the lowest estimate of costs.

consumers who quit tobacco products, with a primary estimate of \$1.4 billion at a 2 percent discount rate (low-impact scenario estimate of \$0.02 billion to a high-impact scenario estimate of \$8.99 billion), at a 2 percent discount rate. We estimate additional costs associated with FDA enforcement of the product standard to range from an annualized value of \$3.3 million to \$7 million at a 2 percent discount rate. Unquantified costs may include changes in consumer surplus for some people who smoke NNC products, including potential utility changes for consumers who switch from NNC to VLNC combusted tobacco products. The present value of the costs over a 40-year time horizon has a primary estimate of \$58 billion (low-impact scenario estimate of \$19.3

billion to a high-impact scenario of \$76.2 billion) at a 2 percent discount rate. The primary estimates for the annualized costs are \$2.1 billion at a 2 percent discount rate.

In addition to benefits and costs, this rule would cause transfers from the Federal Government, State governments, and firms to consumers, who in turn would spend this money in other sectors of the economy (including savings), in the form of reduced revenue and tax revenue. We also estimate transfers between or within firms to cover shifts in user fee obligation. The primary estimate for the annualized transfers from the Federal Government, in the form of reduced excise tax, ranges from \$1.4 billion to \$4.3 billion, with a primary estimate of \$4.1 billion at a 2

percent discount rate. The primary estimate for the annualized transfers from State governments, in the form of reduced excise tax, ranges from \$2.8 billion to \$8.9 billion, with a primary estimate of \$8.4 billion at a 2 percent discount rate. The primary estimate for the annualized transfers from the firms, in the form of reduced revenue, is \$20.0 billion at a 2 percent discount rate (low-impact scenario of \$6.2 billion; high-impact scenario of \$17.6 billion). The primary estimate for the annualized user fee obligation shifted from combusted tobacco products to noncombusted tobacco products has a range from \$26.3 million to \$461.1 million with a primary estimate of \$332.6 million at a 2 percent discount rate. Transfers are summarized in table 13.

TABLE 13—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[Millions of 2023 dollars over a 40-year time horizon]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes
Benefits							
Annualized monetized benefits	\$1,097,053	\$273,521	\$1,190,582	2023	2	2025–2064 (40 years)	See footnote. ⁴⁴
Annualized quantified, but non-monetized, benefits.							
Unquantified benefits	Medical cost savings, productivity loss savings, reductions in smoking-related fires (excluding mortality), reduced litter, and other associated harms to the environment						
Costs							
Annualized monetized costs	2,077	690	2,729	2023	2	2025–2064 (40 years).	
Annualized quantified, but non-monetized, costs.							
Unquantified costs	Changes in consumer surplus for some people who smoke normal nicotine content combusted tobacco products, including potential utility changes for consumers who switch from NNC to VLNC combusted tobacco products.						
Transfers							
Annualized monetized Federal budgetary transfers.	4,092	1,386	4,313	2023	2	2025–2064 (40 years).	
Bearers of transfer gain and loss?	Transfers of Excise Tax Revenues from Federal Governments to Consumers						
Annualized monetized State budgetary transfers.	8,414	2,848	8,877	2023	2	2025–2064 (40 years).	
Bearers of transfer gain and loss?	Transfers of Excise Tax Revenues from State Governments to Consumers						
Other annualized monetized transfers	19,964	6,235	17,603	2023	2	2025–2064 (40 years).	
Bearers of transfer gain and loss?	Transfers of Revenues from Tobacco Firms to Consumers						
Other annualized monetized transfers	333	26	461	2023	2	2025–2064 (40 years).	
Bearers of transfer gain and loss?	Transfers from User Fees Owed by Combusted Tobacco Firms to s Owed by Noncombusted Tobacco Firms						
Net benefits							
Annualized monetized net benefits	1,094,976	272,831	1,187,853	2023	2	2025–2064 (40 years).	
Category	Effects						Notes
Effects on State, local, or Tribal govern- ments.	Significant transfer of tax revenues for State governments. Potential transfer of tax revenue for local and Tribal governments.						
Effects on small businesses	Significant revenue reductions and compliance costs for small, combusted tobacco product manufacturers. We expect most small, combusted manufacturers would shut down or switch industries.						
Effects on wages	No significant wage impacts.						

TABLE 13—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued
[Millions of 2023 dollars over a 40-year time horizon]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes
Category	Effects						Notes
Effects on growth	Anticipated growth in the noncombusted tobacco sector.						

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

XIII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding is available in the docket for this proposed rule (Refs. 665 and 666) and may be seen in Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an environmental assessment under 21 CFR 25.20.

XIV. Paperwork Reduction Act of 1995

This proposed 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). A description of these provisions is given in the *Description* section of this document

⁴⁴ FDA notes that these results hinge on an expert elicitation in which the experts were provided peer reviewed literature on VLNC and NNC cigarette use in experiments. The expert elicitation and much of the literature specifically referenced the nicotine level of 0.4 mg nicotine per gram total tobacco. However, in 22nd Century Group, Inc.'s modified risk tobacco product applications, the company reported that after 9 years of sampling by the company, the average nicotine content of its genetically engineered VLNC tobacco is 0.6 mg nicotine per gram of total tobacco, with a range of 0.4 to 0.7 mg nicotine per gram of total tobacco. It is likely that the Quest and SPECTRUM Nicotine Research Cigarettes, used throughout the scientific literature, also contained between 0.4 to 0.7 mg nicotine per gram of total tobacco (Ref. 257). This suggests the literature the experts reviewed studied cigarettes in the range of 0.4–0.7 mg nicotine per gram total tobacco as opposed to only 0.4 mg nicotine per gram total tobacco. Therefore, the results of the expert elicitation are still applicable to a nicotine level of 0.7 mg nicotine per gram total tobacco. For reference, nicotine content in the top 100 cigarette brands (2017) is 17.2 mg nicotine per gram total tobacco (Ref. 9).

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. If finalized, this proposed rule will seek approval of a new information collection.

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; (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; and (5) the standard and customary business practices of tobacco manufacturers as it relates to capital, operating, and maintenance costs associated with this collection of information.

Title: Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (0910–NEW).

Description: The FD&C Act authorizes FDA to adopt tobacco product standards, including product standards that include provisions for nicotine yields and for the reduction or elimination of other constituents (including smoke constituents) or harmful components (section 907(a)(3)(A) and (4) of the FD&C Act). FDA is proposing to limit nicotine yield by setting a maximum nicotine content level for finished cigarettes and certain other finished combusted tobacco products not to exceed 0.70 mg of nicotine per gram of total tobacco.

Subpart A contains the general provisions of this proposed product standard including scope, prohibited activities, and definitions.

Subpart B contains the proposed product standard requirements pertaining to finished tobacco products that cover product testing (§ 1160.12), sampling plans (§ 1160.16), analytical test methods (§ 1160.14), nonconforming tobacco products (§ 1160.18), package label requirements (§ 1160.30) and recordkeeping requirements (§ 1160.32).

Subpart C contains manufacturing code (§ 1160.14) and recordkeeping (§ 1160.32) requirements.

Proposed § 1160.12 contains provisions for the testing of finished tobacco products that would be subject to this proposed rule. Specifically, proposed § 1160.12(a) would require that tobacco product manufacturers conduct testing on each batch of finished tobacco products.

Proposed § 1160.12(b) would require that a full report of the source data and results of all batch testing be maintained by the tobacco product manufacturer. Based on FDA subject matter expertise and experience from tobacco inspections, we expect that manufacturers would discuss in these reports how their product is batched. These reports would be generated for test samples from each batch and would not be required for each individual finished tobacco product. This report would have to include the following information:

(1) Full identification of the finished tobacco product that is the subject of the report, including the product category, subcategory, product name (brand and subbrand), package type, package quantity, and nicotine source;

(2) Nicotine level of each sample tested from the batch and standard deviation;

(3) The batch manufacturing date and location, including facility name and address, for each sample;

(4) The testing date and location, including the facility name and address;

(5) The manufacturing code of each sample tested (in accordance with proposed § 1160.30(c));

(6) The test method and sampling procedure used;

(7) Names and qualifications of the person(s) conducting the testing and any laboratory accreditation;

(8) The equipment used (including documentation to show that the equipment is appropriate for its intended purpose and has been calibrated to ensure accurate and reliable results); and

(9) The criteria used to make a decision to accept or reject each batch and the decision made with respect to each batch (e.g., accept, reject) based on the results of the product testing. This information would constitute the documentation of the source data and actual results of the product testing conducted on each batch.

The main purpose of this report would be to verify that products subject to this proposed product standard do not exceed the maximum nicotine level and to document the company's decision for each batch with respect to acceptance, rejection, and reworking of the products. FDA expects that information collected pursuant to proposed § 1160.12(b) would be integrated with the proposed § 1160.18(b) records (*i.e.*, proposed § 1160.12(b) records regarding the product being tested, including, for example, the product category and subcategory, brand and subbrand, packaging information, nicotine source, manufacturing date, and the manufacturing code would inform the § 1160.18(b) investigation). These proposed § 1160.12(b) records also would document the ultimate disposition of the batch based on the testing of the representative samples.

Proposed § 1160.14 would require that manufacturers analyze the nicotine levels of cigarettes and certain other finished combusted tobacco products covered by the rule using a validated analytical test method. Manufacturers would be required to demonstrate that the test method used was validated in an analytical test laboratory. Proposed § 1160.16 would require each tobacco product manufacturer to design and implement a sampling plan that covers each finished tobacco product that it manufactures. This sampling plan would provide procedures for the manufacturer to select samples to demonstrate conformance to the proposed maximum nicotine level requirement. The required procedures would help ensure that products that exceed the maximum level of nicotine are not sold or distributed to consumers. This provision also explains that the sampling plan must ensure samples taken are representative of an entire batch and are randomly selected and collected from each batch for testing.

This section would also require test samples from each batch be collected and examined in accordance with

certain procedures (proposed § 1160.16(b)). Each test sample would need to be identified so that the following information can be determined:

- Full identification of the finished tobacco product sampled, including product category, subcategory, product name (brand and subbrand), package type, package quantity, and nicotine source;
- The manufacturing code;
- The date on which the sample was taken;
- The sampling location (including the address of the facility and specific location within the facility where the sample was taken);
- The name of the person(s) who collected the sample; and
- The location where the sample will be tested (including the facility name and address).

Proposed § 1160.18 would require finished tobacco product manufacturers to establish procedures for the control and disposition of nonconforming tobacco products. The proposed procedures would require tobacco product manufacturers to establish and maintain procedures to identify, investigate, segregate, and make disposition decisions (*i.e.*, acceptance, rejection, rework) about nonconforming finished tobacco products to prevent their release for commercial distribution. FDA interprets “establish and maintain” for purposes of proposed § 1160.18 to mean define, document (in writing or electronically), implement, follow, and, when necessary, update.

Identification of potential nonconforming product (*i.e.*, a tobacco product that does not conform to the proposed maximum nicotine level requirement) can be accomplished in many ways (e.g., applying a label with the relevant information directly to the product container; if an electronic system is utilized, associating the nonconforming product information with the relevant barcode). 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 1160, “segregation” means setting the identified potential nonconforming product apart from other product (*i.e.*, placing it away from conforming finished product). This segregation could be accomplished by placing it in a quarantined or specifically marked-off area.

The manufacturer would be required to conduct an investigation to determine the extent of the nonconformity upon identification of a nonconforming

product and, as applicable, the locations where the nonconforming products have been distributed. We expect the manufacturer would be able to determine the locations of initial consignees (e.g., wholesalers, distributors, retailers) where the affected products were shipped in the event a corrective action needs to be taken. The investigation would have to include an examination of all relevant processes and controls, laboratory testing, complaints, and any other relevant records and sources of information concerning the nonconforming product. Tobacco product manufacturers would be required to reject a batch of a finished tobacco product if the nicotine level of the test sample does not meet the requirements unless a disposition decision and justification to release the batch is made after an investigation shows the batch meets the requirements.

Tobacco product manufacturers would be required to determine the disposition of all nonconforming tobacco products and any necessary followup. Nonconforming product cannot be released for commercial distribution without rework or an adequate justification (developed and maintained in accordance with § 1160.32). Thus, nonconforming product could be reworked, distributed with an adequate justification, or discarded. An adequate written justification would be required to address how the nonconforming product meets all requirements under this part.

Proposed § 1160.18(e) would require each tobacco product manufacturer to maintain records of all activities required under § 1160.18. 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.

FDA expects that information collected pursuant to proposed § 1160.12(b) would be integrated with the proposed § 1160.18(b) records (*i.e.*, proposed § 1160.12(b) records regarding the product being tested, including, for example, the product category and subcategory, brand and subbrand, packaging information, nicotine source, manufacturing date, and the manufacturing code would inform the § 1160.18(b) investigation). These proposed § 1160.12(b) records also would document the ultimate disposition of the batch based on the testing of the representative samples.

Proposed § 1160.30 would require the use of a manufacturing code to serve as

a common identifier for production and distribution records. The purpose of the manufacturing code is to allow manufacturers and FDA to identify the production batch of a particular finished 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.

The manufacturing code would be required to be permanently affixed to the packaging or labeling of all finished tobacco products. The manufacturing code must be affixed in a manner that ensures it will remain on the packaging or label through the expected duration of use of the product by the consumer. In addition, proposed § 1160.30(b) would require that the manufacturing code be permanently affixed, legible, conspicuous, prominent, and appear in the English language.

As stated in proposed § 1160.30(c), the manufacturing code must contain the following information listed in the following order:

- The manufacturing date in 2-digit numerical values in the month-day-year format (MMDDYY);
- The finished tobacco product batch number; and
- The designation “-NS” at the end.

The manufacturing code would allow manufacturers and FDA to identify the production batch of a particular finished 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.

Proposed § 1160.32 contains recordkeeping requirements that are necessary for FDA to ascertain and confirm that finished tobacco products are in compliance with the proposed product standard. The proposed product standard would require that manufacturers establish and maintain records regarding the results of testing conducted on each batch to determine conformance with the proposed standard. In addition, this proposed product standard would require that manufacturers maintain records of batch testing, source data for analytical test method validation, sampling plans and sampling procedures, and nonconforming tobacco products.

First, proposed § 1160.32(a) would require that each facility that

manufactures tobacco products subject to this part (i.e., finished tobacco products) establish and maintain records related to compliance with this part, including the following:

- (1) The source data and results of analyses conducted to determine conformance with § 1160.10, including all information identified in § 1160.12(b);
- (2) All source data used for analytical test method validation;
- (3) All sampling plans and sampling reports under § 1160.16;
- (4) Documentation that the persons performing sampling under § 1160.16 have sufficient education, training, and experience to accomplish the assigned functions; and
- (5) All nonconforming tobacco product identification, segregation, investigation, rework, and disposition decision procedures, including justifications, under § 1160.18. This information is necessary for FDA to ascertain and confirm that the products are in compliance with the proposed product standard.

Second, proposed § 1160.32(b) provides certain specifications for these records. All records required under this part, regardless of storage medium, would need to be attributable, legible, contemporaneously recorded, original, and accurate. In addition, these records would be required to be written in English; alternatively, an accurate English translation must be made available upon request. Documents that have been translated from a foreign language into English would have to be accompanied by the foreign language version of the document and a certification by the manufacturer's authorized representative (which could be a U.S. agent for the manufacturer) that the English language translation is complete and accurate, and a brief statement of the qualifications of the person who made the translation (e.g., education, experience). These records would need to be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the manufacturer and to FDA.

Proposed § 1160.32(c) would require that the records kept under this part be retained for at least 4 years from the date of commercial distribution of the finished tobacco product that is the subject of the record. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act.

FDA believes that detailed recordkeeping requirements are

necessary to confirm that finished tobacco products are in compliance with the proposed product standard. For example, requiring manufacturers to document their test results would enable FDA to confirm the manufacturer's test method is adequate to meet the requirements of part 1160. In addition, requiring nonconforming product records would help the manufacturer and FDA determine the extent of the nonconformity with the product standard and, as applicable, the locations where the nonconforming products have been distributed; for example, in the event of a recall.

Description of Respondents: The information collection requirements in the proposed standard would apply to tobacco product manufacturers, which means any person, including a repacker or relabeler, who (1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States. Specifically, the information collection would apply to manufacturers of cigarettes (other than noncombusted cigarettes, such as heated tobacco products that meet the definition of a cigarette), cigarette tobacco, roll-your-own (RYO) tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding “premium cigars”), and pipe tobacco (other than waterpipe tobacco). FDA recognizes that many of the proposed provisions of the proposed rule are in accordance with the quality control and manufacturing practices that manufacturers have already adopted on a voluntary basis.

Application requirements are set by the final Substantial Equivalence (0910–0673) and Premarket Tobacco Product Application (0910–0879) rules. For products covered by this proposed standard, we expect most manufacturers will seek authorization using the substantial equivalence premarket pathway, which may decrease the amount of data required for authorization. See section IX.B of this document regarding pathways to market tobacco products that have been modified to meet the proposed standard. Based on FDA's subject matter expertise and industry data, we recognize that between 85 and 90 percent of all cigarette production is conducted by large manufacturers. We also find that the other tobacco product categories, such as non-premium cigars, pipe, and RYO tobacco, have similar levels of market concentration. We assume that large tobacco product manufacturers represent the bulk of tobacco product

production capacity and so represent the majority of recordkeeping burden.

The proposed provision § 1160.12 (batch testing), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Batch testing is conducted either by the manufacturer in-house or by a 3rd-party accredited laboratory. If sent to a 3rd-party laboratory, we do not expect any capital, operating, or maintenance costs associated with batch testing to be incurred by the manufacturer. We expect a manufacturer would only test their products in-house if they already possess an in-house laboratory accredited to conduct scientific tests. We would not anticipate capital, operating, or maintenance costs for these in-house laboratories as capital and maintenance are components of maintaining accreditation. We do not expect any manufacturers currently without an in-house laboratory to newly establish an in-house accredited laboratory as a result of this product standard.

The proposed provision § 1160.14 (analytical test method), is also part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of

information. Manufacturers are already required to submit test results of analytical testing for nicotine and other relevant harmful and potentially harmful constituents (HPHCs) as part of premarket submissions. As the establishment and use of analytical testing is already generally required for premarket submissions, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.16 (sampling plans), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Manufacturers already routinely conduct analytical testing to check for consistency in their finished products. To conduct such testing, manufacturers would have needed to establish a sampling plan to generate a representative sample of their product for testing. As such, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.18 (nonconforming tobacco products), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Based on FDA subject matter expertise and inspections, we find that almost all manufacturers

already check for consistency and conformance of their products and rework product as necessary to supply information for internal quality checks and distribution purposes, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.30 (manufacturing code labeling), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Based on FDA subject matter expertise and industry information, we find that almost all manufacturers already apply a manufacturing code to their products. Because a manufacturing code also supplies information that the manufacturer needs for internal quality and distribution purposes (standard and customary practices), we do not anticipate additional capital, operating, or maintenance cost from these provisions.

FDA specifically invites comments on our discussion of the standard and customary business practices of tobacco manufacturers as it relates to capital, operating, and maintenance costs associated with this collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 14—ESTIMATED ANNUAL RECORDKEEPING BURDEN ⁴⁵

21 CFR section or activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 1160.12 Product Testing	143	50.84	7,270	9	65,430
§ 1160.14 Analytical Test Method	143	4	572	1	572
§ 1160.16 Sampling Plan	143	4	572	1	572
§ 1160.18 Procedures for Nonconforming Tobacco Products and Related Investigations; Procedures for Control and Disposition of Nonconforming Tobacco Products	143	1	143	14	2,002
§ 1160.30 Package Label Requirements (Manufacturing Code)	143	4	572	7	4,004
§ 1160.32 Recordkeeping Requirements (Batch Testing Records)	143	50.84	7,270	6	43,620
Total Annual Burden					116,200

Table 14 displays the recordkeeping burden associated with this proposed rule. Included in this estimate is the recordkeeping burden for establishing and maintaining records regarding the results of testing conducted on each batch to determine conformance with the proposed standard, sampling plans

⁴⁵ There are no capital costs or operating and maintenance costs associated with this collection of information.

and sampling procedures, and records related to manufacturing controls. FDA’s burden estimates are based on CTP’s Tobacco Registration and Listing Module Next Generation (TRLM NG) data and Dun & Bradstreet firm data (D&B). The requirements in the Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products proposed rule would apply to both domestic and foreign

manufacturers of finished tobacco products that are distributed or sold in the United States. We estimate the number of affected entities, by tobacco product category and size of operation group. We estimate that there are a total of 143 entities potentially affected by the proposed rule (domestic manufacturers and importers of impacted tobacco products, including 133 manufacturers and importers of

cigarettes, cigars, pipe tobacco, and RYO tobacco and 10 dual operation facilities that manufacture both combusted and noncombusted products). For purposes of the PRA estimates, FDA used the entities affected and a weighted average of the median hours to calculate the respondents and total burden hours.

We estimate a total of 7,270 batches per year are required to be tested under § 1160.12 (product testing). Based on information from inspections and other FDA subject matter expertise, including typical batch sizes and projected combusted tobacco production by year, FDA estimates that there will be 50.84 records per recordkeeper with 9 hours of average burden per recordkeeping. FDA assumes respondents will establish a total of 7,270 annual records for a total of annual 65,430 hours.

Based on information from inspections and other FDA subject matter expertise, we expect that core blends are the products that manufacturers will choose to reformulate to meet the product standard. Manufacturers would incur a burden to establish an analytical test method and sampling plan for each reformulated core blend. FDA experts assume that each manufacturer, on average, utilizes four different core blends per tobacco category that they manufacture. Under § 1160.14 (analytical test method), respondents

would determine an analytical test method to use for complying with the product standard. During validation of the analytical test method within the laboratory to be used, the respondent would record and collect the data generated and maintain these records. FDA estimates there will be 4 records per recordkeeper with 1 hour of average burden per recordkeeping and respondents will establish a total of 572 annual records for a total of annual 572 hours. Under § 1160.16 (sampling plan), FDA estimates there will be 4 records per recordkeeper with 1 hour of average burden per recordkeeping. FDA assumes respondents will establish a total of 572 annual records for a total of annual 572 hours.

Under § 1160.18 (procedures for nonconforming products), FDA assumes there will be 1 record per recordkeeper with 14 hours of average burden per recordkeeping for a total of 143 annual records and a total of annual 2,002 hours. This estimate is based on information from tobacco inspections and FDA experience in developing good manufacturing practices in non-tobacco industries. Further, as stated above, based on FDA subject matter expertise and inspections, we find that almost all manufacturers already check for consistency and conformance of their products and rework product as necessary to supply information for

internal quality checks and distribution purposes.

Proposed § 1160.30 would require manufacturers to apply a manufacturing code to the packaging and label of tobacco products. Based on FDA subject matter expertise and market tracking information, we find that almost all manufacturers already apply a manufacturing code to their products. FDA assumes 4 records per recordkeeper with 7 hours of average burden per recordkeeping, and a total of 572 annual records for a total of annual 4,004 hours.

Under § 1160.32 (batch testing records), FDA assumes 50.84 records per recordkeeper with 6 hours of average burden per recordkeeping. This estimate is based on establishing the format and maintaining batch test records for detailed recordkeeping requirements, including English translation and accessibility, that are necessary to confirm that finished tobacco products are in compliance with the proposed product standard. FDA assumes that respondents will maintain a total of 7,270 annual records for a total of annual 43,620 hours.

FDA expects the additional one-time (*i.e.*, occurring only in the first year) reporting burden for the information collection that will result from this rule, to be as follows:

TABLE 15—ESTIMATED ONE-TIME REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Review and familiarization with the rule	1,465	1	1,465	10	14,650
Total One-Time Burden					14,650

Based on FDA subject matter expertise, we assume that all entities affected by this proposed rule would spend time to read and understand the rule, resulting in a one-time reporting burden. FDA estimates that there will be 293 entities and 5 individuals at each entity that will read the final rule. It is estimated that each respondent will spend up to 10 hours reading and understanding the rule for a total of 14,650 one-time burden hours. Per the requirements of this proposed rule, FDA estimates the total burden will be 130,850 hours (116,200 + 14,650).

FDA invites comments on the estimates in this section and specifically any burden specific to small manufacturers to whom this proposed standard would apply. To ensure that comments on information collection are

received, OMB recommends that written comments be submitted through [reginfo.gov](https://www.reginfo.gov) (see **ADDRESSES**). All comments should be identified with the title of the information collection.

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**.

XV. Federalism

We have analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13132. Section 4(a) of the Executive order 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.” We have determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the rule does not contain policies that have

federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

This rule is being issued under section 907 of the FD&C Act, which enables FDA to prescribe regulations relating to tobacco product standards, and the sale and distribution restriction in this rule is also being issued under section 906(d) of the FD&C Act, which enables FDA to prescribe regulations restricting the sale and distribution of a tobacco product. If this proposed rule is made final, the final rule would create requirements whose preemptive effect would be governed by section 916 of the FD&C Act (21 U.S.C. 387p) entitled “Preservation of State and local authority.”

Section 916 of the FD&C Act broadly preserves the authority of States and localities to protect the public against the harms of tobacco use. Specifically, section 916(a)(1) of the FD&C Act establishes a general presumption that FDA requirements do not preempt or otherwise limit the authority of States, localities, or tribes to, among other things, enact and enforce laws regarding tobacco products that relate to certain activities (e.g., sale, distribution) and that are in addition to or more stringent than requirements established under chapter IX of the FD&C Act.

Section 916(a)(2)(A) of the FD&C Act is an express preemption provision that establishes an exception to the preservation of State and local governmental authority over tobacco products established in section 916(a)(1). Specifically, section 916(a)(2)(A) of the FD&C Act provides that “[n]o 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 tobacco product standards”

However, section 916(a)(2)(B) limits the applicability of section 916(a)(2)(A) of the FD&C Act, narrowing the scope of State and local requirements that are subject to express preemption. Paragraph (a)(2)(B) provides that preemption under paragraph (a)(2)(A) does not apply to State or local “requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.”

If this proposed rule is finalized as proposed, the final rule would create requirements that fall within the scope

of section 916(a)(2)(A) of the FD&C Act because they are “requirements under the provisions of the chapter relating to tobacco product standards.”

Accordingly, the preemptive effect of those requirements on any State or local requirement would be determined by the nature of the State or local requirement at issue—specifically, whether the State or local requirement is preserved under section 916(a)(1) of the FD&C Act, and/or excepted under section 916(a)(2)(B) of the FD&C Act (such as if it relates to the “sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products”). State and local prohibitions on the sale and distribution of tobacco products would not be preempted by this rule, if finalized, because such prohibitions would be preserved by section 916(a)(1) of the FD&C Act or, as applicable, excepted from express preemption by section 916(a)(2)(B) of the FD&C Act. FDA invites comments on how State or local laws may be implicated if this proposed rule is finalized.

XVI. Severability

In accordance with section 5 of the Tobacco Control Act, which provides for the severability of, *inter alia*, all “regulations promulgated under” the authorities provided by that Act, FDA would consider the various requirements and prohibitions established by this rule, if finalized, to be severable. It is FDA’s interpretation and position that the invalidity of any provision of a final rule would not affect the validity of any other part of the rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of a final rule, FDA intends for the remaining parts to continue to be valid. Additionally, as further stated in section 5 of the Tobacco Control Act, if certain applications of a final rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced to the fullest extent possible. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

XVII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13175. We have tentatively determined that the rule contains policies that may 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. We expect some tribal governments to be impacted given that some are manufacturers and retailers of cigarettes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XVIII. References

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

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List of Subjects in 21 CFR Part 1160

Administrative practice and procedure, Labeling, Smoke, Smoking, Tobacco, Tobacco products.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1160 to subchapter K to read as follows:

PART 1160—TOBACCO PRODUCT STANDARD FOR NICOTINE YIELD OF CIGARETTES AND CERTAIN OTHER COMBUSTED TOBACCO PRODUCTS

Subpart A—General Provisions

Sec.

1160.1 Scope.

1160.3 Definitions.

Subpart B—Product Requirements

1160.10 Nicotine level.

1160.12 Product testing.

1160.14 Analytical test method.

1160.16 Sampling plans and procedures.

1160.18 Nonconforming tobacco product.

Subpart C—Manufacturing Code and Recordkeeping Requirements

1160.30 Manufacturing code requirements.

1160.32 Recordkeeping requirements.

Authority: 21 U.S.C. 331, 371(a), 374, 381(e), 381(p)(2), 387b, 387c, 387f(d), 387f(e), 387g, 387i, 387j.

Subpart A—General Provisions

§ 1160.1 Scope.

(a) This part sets forth the product standard to limit nicotine yield by setting a maximum nicotine content level for certain finished tobacco products. The provisions of this part are applicable to cigarettes (other than noncombusted cigarettes, such as heated tobacco products that meet the definition of a cigarette), cigarette tobacco, roll-your-own tobacco, cigars (other than premium cigars), and pipe tobacco (other than waterpipe tobacco).

(b) No person may distribute, sell, or offer for sale or distribution within the United States finished tobacco products, as described in paragraph (a) of this section, that are not in compliance with this part.

(c) No person may manufacture within the United States finished tobacco products, as described in paragraph (a) of this section, that are not in compliance with this part, unless such tobacco products are intended for export and are eligible for export under section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.

§ 1160.3 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 or nicotine from any source 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.

Batch means a specific identified amount of a finished tobacco product produced in a unit of time or quantity and that is intended to have the same specifications.

Cigar means a tobacco product that:

(1) Is not a cigarette; and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Cigarette, as used in this part:

(1) Means a product that:
(i) Is a tobacco product; and
(ii) Meets the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

Cigarette tobacco means any tobacco product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Commercial distribution means any distribution of a finished tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for personal consumption or resale. “Commercial distribution” does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption.

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. The term excludes anything that is an accessory of a tobacco product.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

Manufacturing code means any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date, followed by the batch number, and concludes with “-NS.”

Manufacturing date means the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished tobacco product is packaged for distribution.

Nicotine means the chemical substance named 3-(1-methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or

complex of nicotine, derived from any source.

Nonconforming tobacco product means any tobacco product that does not meet the requirements of § 1160.10 or § 1160.30.

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 tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Person includes an individual, partnership, corporation, or association.

Pipe tobacco means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe.

Rework means action taken on a nonconforming tobacco product to ensure the product meets the specifications and other requirements of this part before it is released for commercial distribution.

Roll-your-own tobacco means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes or cigars.

Specification means any requirement with which a product, process, service, or other activity must conform.

Tobacco filler means cut, ground, powdered, or leaf tobacco or other nicotine-containing substances in a finished tobacco product.

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 under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Total tobacco means tobacco filler and any other tobacco or tobacco-derived material used as part of a tobacco product.

United States means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

Subpart B—Product Requirements

§ 1160.10 Nicotine level.

A finished tobacco product must not exceed a nicotine content of 0.70 milligrams of nicotine per gram of total tobacco.

§ 1160.12 Product testing.

(a) *Batch testing.* Tobacco product manufacturers must conduct testing on finished tobacco products to ensure that the batch conforms with § 1160.10. The manufacturer must use an analytical test method that meets the requirements set forth in § 1160.14. Samples for testing each batch to determine if it conforms with § 1160.10 must be selected in accordance with the requirements set forth in § 1160.16.

(b) *Documentation of test results.* A full report of the source data and results of all batch testing must be maintained by the tobacco product manufacturer in accordance with § 1160.32, including the following:

(1) Full identification of the finished tobacco product that is the subject of the report, including, if applicable, the submission tracking number (STN) associated with marketing authorization (including the static product ID (PD), if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity, and nicotine source;

(2) Nicotine level of each sample tested and standard deviation;

(3) The batch manufacturing date and location, including facility name and address, for each sample;

(4) The testing date and location, including the facility name and address;

(5) The manufacturing code of each sample tested;

(6) The test method and sampling procedure used;

(7) The names and qualifications of the person(s) conducting the testing and any laboratory accreditation;

(8) The equipment used (including documentation to show that the

equipment is appropriate for its intended purpose and has been calibrated to ensure accurate and reliable results); and

(9) The criteria used to make a decision to accept or reject each batch and the decision made with respect to each batch (e.g., accept, reject) based on the results of the product testing.

§ 1160.14 Analytical test method.

Tobacco product manufacturers must use an analytical test method and must demonstrate that the test method used was validated in an analytical test laboratory.

§ 1160.16 Sampling plans and procedures.

(a) *Sampling plans.* Each tobacco product manufacturer must design and implement a sampling plan or plans that cover each finished tobacco product based on a valid scientific rationale to ensure that the product consistently conforms to the requirement set forth in § 1160.10. The sampling plan must ensure that samples taken are representative of an entire batch (i.e., randomized or systematically selected across the entire batch) and collected from each batch for testing. To account for the variability of nicotine in finished tobacco products, the following factors must be based on adequate statistical criteria: the confidence intervals, the level of necessary precision, and the number of finished products sampled. The sampling plan must take into account the manufacturing quality history of the manufacturer (e.g., batch testing records, nonconforming tobacco product investigations). Each sampling plan must describe the sampling methodology, with scientific rationale, incorporate all sources of variability (including variability of the analytic method and nicotine levels), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling plan to achieve the sampling objective. The sampling plan must also describe the criteria the tobacco product manufacturer will use to make a decision to accept or reject each batch.

(b) *Sampling procedures.* Test samples must be collected from each batch and examined in accordance with the following procedures:

(1) Test samples are to consist of the finished tobacco product as it is intended to be sold or distributed to consumers and not of a separate production sample.

(2) All test samples must be stored according to the intended storage conditions for the finished tobacco product. A tobacco product

manufacturer must include all of its factories, stock rooms, warehouses, and other locations containing finished tobacco products in the population to be sampled.

(3) Test samples must be taken from each batch and tested within 30 calendar days of the manufacturing date. The amount of material acquired during sampling must be sufficient for all testing required by § 1160.14, including any repeat testing that may be necessary. Samples must be selected from each batch in accordance with the applicable sampling plan.

(4) Sampling must be performed by persons who have sufficient education, training, and experience to accomplish the assigned functions.

(5) Each test sample must be identified so that the following information can be determined:

(i) Full identification of the finished tobacco product sampled, including, if applicable, the STN associated with marketing authorization (including the PD, if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity, and nicotine source;

(ii) The manufacturing code;

(iii) The date on which the sample was taken;

(iv) The sampling location (including the address of the facility and specific location within the facility where the sample was taken);

(v) The name of the person(s) who collected the sample; and

(vi) The location where the sample will be tested (including the facility name and address).

(6) Samples sent for testing must be packed securely with adequate protection against damage (e.g., mechanical damage, adverse changes in humidity or temperature). A list of the samples in each shipment must be sent to the testing facility under separate cover.

(7) All samples for a batch test must be tested at the same facility.

(8) If samples will be transported to a different facility from the manufacturing facility for testing, once test samples arrive at the testing facility, they must be inspected, accounted for, and properly stored under the finished tobacco product's intended storage conditions, and a report that includes the following information must be generated for the batch test and be maintained by the tobacco product manufacturer in accordance with § 1160.32:

(i) Full identification of the finished tobacco product sampled, including, if applicable, the STN associated with marketing authorization (including the PD, if applicable), product name(s) (including brand and subbrand and the original name described in the premarket application, if different), product category, subcategory, package type, package quantity, and nicotine source;

(ii) The manufacturing code;

(iii) The date on which samples were taken, if available;

(iv) The sampling location (including the address and specific locations within any facilities where samples were taken);

(v) The number of test samples drawn; and

(vi) Complete records of the samples received and tested, including the date of receipt, the identifier of all persons who tested the samples, and the test results.

(9) Each batch must be withheld from commercial distribution until it has been sampled and tested and a decision has been made by the tobacco product manufacturer that it conforms to the requirements of this part and may be released for commercial distribution.

§ 1160.18 Nonconforming tobacco product.

Each 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 tobacco product manufacturer must identify and segregate potential nonconforming product in a manner that prevents commercial distribution of potential nonconforming product prior to investigation and disposition.

(b) *Investigation.* Each tobacco product manufacturer must investigate all potential nonconforming tobacco products 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. For products determined to be nonconforming, the investigation must also determine the scope and cause of nonconformance.

(c) *Rejection of nonconforming product.* Tobacco product manufacturers must reject a batch of a finished tobacco product if the nicotine level of a test sample from the batch does not conform to the requirements of this part unless a disposition decision and justification to release the batch is

made after an investigation determines that the batch meets the requirements of this part.

(d) *Disposition and followup.* Each tobacco product manufacturer must determine the disposition of all nonconforming tobacco products and 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 developed and maintained in accordance with § 1160.32. An adequate written justification must address why releasing the nonconforming product would not result in the tobacco product being adulterated or misbranded. Nonconforming product cannot be released for distribution without rework or an adequate justification.

(e) *Records.* Each 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 that the requirement was met, and any data or calculations necessary to reconstruct the results.

Subpart C—Manufacturing Code and Recordkeeping Requirements

§ 1160.30 Manufacturing code requirements.

(a) Each tobacco product manufacturer must permanently affix a manufacturing code to the packaging or labeling of all finished tobacco products. For a finished tobacco product, the manufacturing code must be affixed in a manner that assures it

will remain on the packaging or labeling through the expected duration of use of the tobacco product by the consumer.

(b) The manufacturing code for each finished tobacco product must be permanently affixed, legible, conspicuous, prominent, and appear in the English language.

(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);

(2) The finished tobacco product batch number; and

(3) The designation “–NS” at the end.

§ 1160.32 Recordkeeping requirements.

(a) Each facility that manufactures tobacco products subject to this part must establish and maintain records related to compliance with this part, including the following:

(1) The source data and results of batch testing conducted to determine conformance with § 1160.10, including all information specified in § 1160.12(b);

(2) All source data for analytical test method validation;

(3) All sampling plans and reports under § 1160.16;

(4) Documentation that the persons performing sampling under § 1160.16 have sufficient education, training, and experience to accomplish the assigned functions; and

(5) All nonconforming tobacco product identification, segregation, investigation, rework, and disposition decision procedures, including justifications, under § 1160.18.

(b) All records required under this part, regardless of storage medium, must

be attributable, legible, contemporaneously recorded, original, and accurate. These records must be written in English, or an accurate English translation must be made available upon request. Documents that have been translated from another language into English must be accompanied by the original language version of the document, a signed statement by the authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation. These 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 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 these records that can be immediately retrieved from another location, including by computer or other electronic means, meet the requirements of this paragraph.

(c) All records required under this part must be retained for a period of at least 4 years from the date of commercial distribution of the finished tobacco product that is the subject of the record.

Dated: January 6, 2025.

Robert M. Califf,

Commissioner of Food and Drugs.

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Part VI

Department of Agriculture

Agricultural Marketing Service

9 CFR Part 201

Poultry Grower Payment Systems and Capital Improvement Systems; Final Rule

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****9 CFR Part 201**

[Doc. No. AMS–FTPP–22–0046]

RIN 0581–AE18

Poultry Grower Payment Systems and Capital Improvement Systems**AGENCY:** Agricultural Marketing Service, U.S. Department of Agriculture.**ACTION:** Final rule.

SUMMARY: This final rule by the United States Department of Agriculture's (USDA or the Department) Agricultural Marketing Service (AMS or the Agency) amends the Agency's regulations under the Packers and Stockyards Act, 1921 (P&S Act or Act). The Act protects fair trade, financial integrity, and competitive markets for poultry. The final rule prohibits certain payment practices under poultry grower ranking systems (commonly known as tournaments) in contract poultry production for broiler chickens, requires live poultry dealers (LPDs) to adopt policies and procedures for operating a fair ranking system for broiler growers, and requires LPDs to provide certain information to broiler growers when the LPD requests or requires the grower to make additional capital investments. These regulations will increase transparency and address deception and unfairness in broiler grower payments, tournament operations, and capital improvement systems.

DATES: This rule is effective July 1, 2026.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, USDA AMS Fair Trade Practices Program, 1400 Independence Ave. SW, Washington, DC 20250; phone: (202) 690–4355; or email: s.brett.offutt@usda.gov.

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I. Executive Summary

The current broiler chicken industry is highly susceptible to both unfairness and deception. Within the last 40 years, the poultry industry has become highly integrated, with most LPDs operating as

“integrators” who frequently own or control all segments of the production process except growout. The growout stage of the production process consists of growers raising young poultry to harvest size under poultry growing arrangements (contracts). To pay the grower, most LPDs, which will also be referred to as “integrators” throughout this rule, use a relative performance or poultry grower ranking system, commonly known as a tournament. Under the tournament system, poultry growers compete against one another to determine payment for their services. As discussed throughout this rule, growers cannot reasonably avoid certain practices that cause them harm. Additionally, growers lack access to certain information, which inhibits their ability to meaningfully understand, negotiate, and enforce poultry growing contracts with LPDs, including in relation to capital investments that LPDs request.

The Packers and Stockyards Act, 1921, as amended (P&S Act or the Act) (7 U.S.C. 181 *et seq.*), authorizes USDA to issue regulations and orders to prohibit unfair and deceptive practices by LPDs.

In a June 8, 2022, advance notice of proposed rulemaking (ANPR), AMS sought comments and information to inform policy development and future rulemaking regarding the use of poultry grower ranking systems (87 FR 34814, June 8, 2022)). Commenters expressed both support and concern about the use of tournaments in poultry production, with the majority expressing support. Other commenters, especially advocacy associations, objected to the current tournament payment system, stating that tournament systems do not fulfill the integrators' claimed purposes and that the tournament payment systems exemplify the manipulative and unjust practices that Congress designed the Act to prevent. These commenters cited integrators' arbitrary, unjust, or punitive distribution of inputs and production variables, potentially punitive manipulation of the group composition, and penalties for small deviations below average performance. Some of these ANPR commenters also stated that the rulemaking could help address bargaining power imbalances for growers by providing proper enforcement, minimum base pay, and other provisions.

Trade organizations commented on the ways input variability affects pay and that LPDs lack incentives to take action to reduce unpredictability in grower inputs and pay outcomes. AMS has observed that monitoring and intervention to remedy unpredictability

requires an LPD to expend effort and incur cost, and that the LPD does not directly benefit from the increased fairness to growers. Without an explicit prohibition on unfair variability, LPDs lack compelling incentives to operate their tournament system contracts fairly. Comments in response to the ANPR, other available data and information, and AMS's Packers and Stockyards Division's (PSD) expertise provided the basis for a proposed rulemaking.

On June 10, 2024, AMS published the proposed rule, Poultry Grower Payment Systems and Capital Improvement Systems, in the **Federal Register** (89 FR 49002). In response to the proposed rule, AMS posted 755 comments, some with multiple signatories, over a 60-day comment period. Comments were submitted by a variety of stakeholders, including farmers' coalitions, government entities, advocacy organizations, industry trade organizations, processors, producers, and other individual interested parties. Stakeholders commented on the proposed rule, as well as several specific questions containing alternate proposals. The proposed rule covered, among other things, rate of compensation for growers, transition and implementation costs, the proposed duty of fair comparison, and reasonable recoupment for required additional capital investments. Farmers' coalitions, advocacy associations, government entities, and unaffiliated individual commenters broadly supported the proposed rule, while the regulated trade organizations and LPDs opposed the proposed rule. Live poultry growers both supported and opposed the proposed rule. Many growers who support the rule raised concerns of unfairness within the tournament system, including that pay rates are influenced by factors outside growers' control, that growers are forced to make new capital investments that have poor to nonexistent return while putting growers in more debt, and that growers must compete against fellow growers in an unfair manner. Those growers who opposed the proposed rule felt that the tournament system does a good job of rewarding effort, and that the rule would upset this system by shifting money away from high-performing growers and by reducing overall bird quality. However, several growers that opposed the rule expressed concern that LPDs force growers to make additional capital investments that do not produce an economic return for the grower.

Section 407(a) of the P&S Act (7 U.S.C. 228(a)) authorizes the Secretary of Agriculture (the Secretary) to make rules and regulations as necessary to

carry out the provisions of the Act (7 U.S.C. 181 *et seq.*), and the Secretary has delegated the responsibility for administering the Act to AMS. See 7 CFR 2.22(a)(3)(iii) (delegating authority to administer the Act from the Secretary to the Under Secretary for Marketing and Regulatory Programs); 7 CFR 2.79(a)(17) (in turn, delegating authority to administer the Act from the Under Secretary to the Administrator, Agriculture Marketing Service). Under this authority, AMS issues this rule to carry out the provisions of section 407 of the Act, as well as provisions of sections 202(a) (7 U.S.C. 192(a)) (which prohibits “any unfair, unjustly discriminatory, or deceptive practice or device”), 401 (7 U.S.C. 221) (which requires an LPD to “keep such accounts, records, and memoranda as fully and correctly disclose all transactions involved in his business”), and 410 (7 U.S.C. 228b) (which bans the failure to pay “the full amount due [to the] poultry grower on account of such poultry”).

In this final rule, AMS amends 9 CFR part 201, subpart N, by adding several new provisions, including: § 201.106 regarding LPD responsibilities for the design of broiler grower compensation arrangements; § 201.110 regarding the fair operation of broiler grower ranking systems; § 201.112 regarding disclosure requirements for LPDs when requesting additional capital investments from broiler growers; and § 201.290 regarding severability. In particular, the Agency is:

- Prohibiting LPDs from discounting or reducing a grower’s rate of compensation as disclosed in the broiler growing arrangement based on the grower’s grouping, ranking, or comparison to others (§ 201.106(a)).

- Establishing that it is a presumptive violation of the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers exceeds 25 percent of total gross payments to growers in a complex on an annual-calendar year basis (§ 201.106(b)).

- For each of the three calendar years following the publication date of the above-referenced provisions, requiring LPDs to submit certain documentation to the Secretary when any contract modification or renewal subject to the prohibition on discounts results in a decrease in the prior annual-calendar year’s complex-wide average gross payment to the grower (§ 201.106(c)).

- Establishing a duty of fair comparison that requires LPDs to design and operate their broiler grower ranking system to provide a fair comparison among growers, with particular attention to certain factors in the

methods of comparison, including the distribution of inputs and flock production practices, the time period of the comparison, the conditions and circumstances for the comparison, the reasonableness of efforts to resolve disputes, and how the LPD will compensate growers when the LPD cannot conduct a fair comparison (§ 201.110(a)).

- Requiring LPDs to establish and maintain written documentation of their processes for the design and operation of a broiler grower ranking system that is consistent with the duty of fair comparison and to retain all relevant written records for five years (§ 201.110(b)).

- Requiring LPDs to provide growers with a Capital Improvement Disclosure Document when an LPD requests that a grower make an additional capital investment and requiring that LPDs make reasonable efforts to assist the grower in translating the document, as well as ensure that the grower is aware of their right to request translation assistance (§ 201.112).

- Introducing a severability clause that specifies that it is USDA’s intent that the provisions in subpart N remain in effect even if any provision or component of any provision is deemed unenforceable (§ 201.290).

II. Background

A. Vertical Integration and Market Power

Today, the broiler chicken industry is highly vertically integrated. That is, a single entity owns or controls nearly all the steps of production and distribution, with the only partial exception being the growout stage, during which broiler growers raise chicks on their farms to slaughter weight. The USDA National Agricultural Statistics Service’s (NASS) Census of Agriculture (Agricultural Census) reported that 96.2 percent of broilers were raised and delivered under production contracts between LPDs and independent farmers, or broiler growers.¹ Under a production contract, the LPD provides the grower chicks, feed, and veterinary treatment services, which the grower uses to grow out the flock. The LPD maintains ownership of the chickens throughout the production process. The grower provides the poultry growing facility, flock management, labor, and utilities

required during flock growout.² At the end of growout, the LPD collects and weighs the mature poultry and pays the broiler grower for their services.

To grow broiler chickens on a commercial scale, a grower must make a substantial initial investment in housing. Over time, LPDs may request or require that growers make additional capital investments to upgrade housing and equipment, which are intended to improve efficiency or respond to customer preferences (e.g., relating to the use of antibiotics or other animal-raising concerns) during the contracting relationship. Growers generally finance these long-term assets against much shorter-term production contracts.³ This exposes growers to financial risk and uncertainty around debt repayment and the recoupment of their investments. For example, compared to other commodity producers, broiler growers registered among the highest share of farms in extreme financial stress, measured as carrying a term debt coverage ratio less than one and a debt-to-asset ratio greater than 55 percent.⁴ Growers are thus dependent on LPDs—who control most aspects of a grower’s production—to recoup their substantial initial and continuing investments.⁵ Growers also currently receive little to no information about the purpose, process, and outcomes expected around such investments.

Currently, most LPDs operate with the benefit of substantial market power and bargaining power in local markets to purchase grower services. Broiler grower operations must be close (usually less than 50 miles) to an LPD’s

² Growout period is defined as the period of time between placement of poultry at a grower’s facility and the harvest or delivery of such animals for slaughter, during which the feeding and care of such poultry are under the control of the grower.

³ MacDonald, James M. “Financial Risks and Incomes in Contract Broiler Production.” *Amber Waves* August 04, 2014. <https://www.ers.usda.gov/amber-waves/2014/august/financial-risks-and-incomes-in-contract-broiler-production/> (last accessed 12/13/2023).

⁴ Nigel Key, Christopher Burns, and Greg Lyons, “Financial Conditions in the U.S. Agricultural Sector: Historical Comparisons,” EIB-211, U.S. Department of Agriculture, Economic Research Service (2019), <https://www.ers.usda.gov/webdocs/publications/95238/eib-211.pdf?v=4876.5> (In 2017, compared to other commodity categories considered, poultry farms showed the greatest share of farms in extreme financial stress—around four times that of larger-scale general livestock and specialty crop, fruit, nut, and vegetable producers and twice that of large-scale grain and oilseed producers. Moreover, the percentage of poultry farmers in extreme financial stress has been increasing since 2006).

⁵ For a discussion the difficulty in adapting of broiler grow houses for other purposes see Tom Vukina and Poramet Leegomochai. “Oligopsony Power, Asset Specificity, and Hold-Up: Evidence from the Broiler Industry.” *American Journal of Agricultural Economics* 88 (2006).

¹ USDA, NASS, *2022 Census of Agriculture: United States Summary and State Data*, volume1, part 51, issued February 2024 pp. 51 and 411. https://www.nass.usda.gov/Publications/AgCensus/2022/Full_Report/Volume_1_Chapter_1_US/usv1.pdf.

feed mills, hatcheries, and processing plants due to the costs of transporting feed to the grower's farm and the costs (including death loss) associated with transporting finished chickens from the grower's farm to the processing plant. This results in poultry production that is often localized and regionally concentrated. Most growers have few LPDs in their area with whom they can contract. Even where multiple LPDs are present, there can be significant costs associated with switching to a different LPD, including adjustments for differences in technical specifications that LPDs may require. To switch LPDs, a grower may need to invest in new equipment and learn to apply different operational techniques for different breeds, target weights, and growout programs. Facility-specific investments may inhibit the ability of growers to switch to a competing LPD where different facility specifications are required. Growers have recently complained of at least one LPD penalizing growers that are trying to switch to an LPD's competition. AMS referred the complaint to the Department of Justice for enforcement under the Packers and Stockyards Act. The Department secured a consent decree that stopped the conduct, prohibited its recurrence, and compensated the harmed growers.⁶

Owing to the vertical integration in the system, LPDs exercise substantial control over growers' operations through the provision of inputs, control over production practices, their tournament settlement and comparison practices, and their level of performance in relation to communication and dispute resolution. In this rule, AMS uses the term "inputs" to mean resources supplied by LPDs, such as chicks or feed. Inputs often vary among growers, which impacts the growers' flock performance, thereby unfairly skewing relative performance measures. Likewise, LPDs determine production practices on growers' farms, and those production practices affect growers' pay. AMS uses the term "production practices" to refer to features of the on-farm production process that are determined by the LPD, such as density of bird placement (number of chicks delivered or placed with a grower per

square foot of broiler housing), age at harvest, and weight at harvest. These practices greatly impact grower compensation. If LPDs fail to apply production practices evenly across grower participants in tournaments, that unevenness also unfairly skews relative performance measures.

Additionally, information asymmetry in poultry contracting arrangements contributes to market inefficiencies and unfair and deceptive practices. Asymmetric information occurs when one party to a contract has more critical information than the other party. Information asymmetry leads to market failure in the broiler production industry as growers lack the information needed to make informed business decisions, whereas LPDs know what each grower makes. This increases LPDs' to set contractual terms in ways that benefit themselves, while the grower lacks the information needed to effectively negotiate compensation for the provision of growout services or to make a comparison and switch to a competitor that offers more competitive terms. Another feature of this information asymmetry is that while LPDs know the amounts they have fixed for grower compensation, growers do not know this amount, which can span a wide range. Similarly, LPDs know the distribution of inputs as well as which growers may be grouped together for settlement in the complex, while growers cannot easily track that information. Exploiting this information asymmetry, LPDs can adjust down compensation in ways that are difficult for growers to know or competitively discipline the LPD, *e.g.*, by switching out. As highlighted by grower comments and based on AMS's experience in evaluating grower concerns in this area, without an accurate projection of purposes, processes, and outcomes related to capital improvement programs, growers cannot accurately and effectively evaluate their allocation of resources to cover necessary expenses⁷ or engage in rational decision-making around whether to pursue (or resist) additional capital investments to improve and protect their own financial interests. Additionally, having widely variable income prevents growers from knowing which elements under their control they

can adjust, and how to adjust them, to correspondingly increase compensation. This can cause growers to futilely expend extraneous resources that do not yield proportionate increases in performance and compensation.⁸ Information asymmetry also facilitates abusive practices, whereas the provision of information would help growers and AMS identify and halt those practices sooner. Disclosure is not an absolute defense. Acts or practices can be unfair or deceptive and violate section 202(a) of the Act even if they have been disclosed.

LPDs often use incomplete contracts in broiler production. When a contract is incomplete, the LPD interprets material terms in their favor as the grower lacks the ability to require a fairer interpretation. Contracts are incomplete when key terms basic to its functioning are vague or missing. Incomplete contracts magnify risks with respect to the performance of the other contractual party, leading to other potential inefficiencies. For example, broiler production contracts regularly disclaim LPD responsibility for input quality or usability. Nor do they provide enforceable detail around LPD management of tournament operations, including tournament groupings or dispute resolution expectations. Moreover, the complexity of such pay systems makes it difficult for growers to fully understand the potential range of payments they are likely to receive or the ways in which LPD performance or nonperformance may affect that pay, preventing them from properly

⁸Numerous commenters described how they would make all of the upgrades recommended by the LPD technician and inexplicably place last compared to other growers: "Six months of down time spent installing several more thousands of dollars of equipment. We've grown two flocks since then and have failed to make enough money to even pay the bank each time. We've had to take out a loan to even survive our day-to-day life and are behind on all farm bills. We do everything the company tells us, but when we finish in the negative, were given all kinds of reasons for why our birds weren't good enough. When speaking with other farmers and techs from other companies, we're told that our weight and feed conversions are good, but a couple of farms seem to continuously have unexplained successful numbers. Basically, were losing money that goes to pay the ones at the top. On one flock, 12 farms were pitted against each other. Two farms performed at a level so high that isn't believable, and three farms performed below the bottom level we can be paid at. The integrator took the bottom three farms out of the tournament calculation and compared the remaining farms without them. How fair is it that they drop the bottom farms, but not the top ones? This resulted in the farms that were close to average being pushed down and making less money because the average was raised considerably with the highfliers included and the bottom places excluded. The company tells us that this helps us, but it doesn't. We've made the decision to sell because we can't continue to put our children through this").

⁶Final Judgment, *United States v. Koch Foods, Inc.*, No. 23-cv-15813, Dkt. No. 23 (N.D. Ill. Feb. 12, 2024). See also, Zimmerman, Sarah, "Department of Justice, 'Justice Department Files Lawsuit and Proposed Consent Decree to Prohibit Koch Foods from Imposing Unfair and Anticompetitive Termination Penalties in Contracts with Chicken Growers,'" <https://www.justice.gov/opa/pr/justice-department-files-lawsuit-and-proposed-consent-decree-prohibit-koch-foods-imposing>.

⁷For example, a grower without an accurate projection of future income may forgo making an expenditure that costs less long-term, *e.g.*, making a bundled purchase for two pieces of equipment at a reduced per-unit price. Instead, if they don't know if they can afford a future purchase, they purchase the minimum amount—one piece of equipment at a time at a higher unit price—to sustain operations short-term.

evaluating the fairness of the contract before signing. Preventing LPDs from injuring producers using these contracts is among the purposes of the Act.⁹ Contracts may be viewed as complete, with no material gaps, if the contract terms include the substantive legal, practical, and economic promises, obligations, and contingencies needed to operate in a poultry growing arrangement. These terms should be verifiable and legally enforceable.

Finally, contracts that require investments in contract-specific assets give rise to the hold-up problem. The economic concept of hold-up refers to a situation in which one or both parties to a transaction must make investments in such contract-specific assets, and the two parties may be unable to cooperate efficiently due to incomplete or asymmetric information and the inability to write, enforce, or commit to contracts. Once a party becomes locked into a transaction by making a transaction-specific investment, they lose bargaining leverage and become vulnerable to exploitation by the other party. Hold-ups occur in broiler production due to market failures associated with incomplete grower information, contract-specific investments, market power, relative capital leverage, as well as insufficient enforcement of law intended to maintain market integrity and prevent market abuses—including unfair breaches of contract. Growers are commonly unable to exercise contract rights to remedy LPD performance failures owing to the risk of hold-up and to the necessity of timely remedies when dealing with living birds. Examples from grower complaints include failure to correct improper or insufficient feed delivery, the delivery of successive inputs that are lower performing, or tournament groupings that are suspect.

B. Tournament Practices

Since the 1990s, the broiler industry overwhelmingly uses the tournament system to compensate growers. As

discussed above, under a tournament system the contract between the broiler grower and the LPD provides for payment to the grower based on a grouping, ranking, or comparison of broiler growers delivering broilers to the same company during a specified period (usually one week). AMS will refer to this as a settlement group. Under a typical tournament system, the broiler grower receives a fixed payment per pound of broilers produced, that LPDs often call a “base pay rate,” plus a calculation adjustment that is supposed to be based on how efficiently, compared to other growers, the grower used the resources provided by the LPD to produce each pound of broilers (informally referred to as a performance adjustment).¹⁰ LPDs typically calculate the performance adjustment primarily by comparing the feed conversion ratio (*i.e.*, the quantity of feed consumed by the flock divided by the weight of the flock delivered) to the average ratio of all growers in the tournament settlement group. Broiler growers whose feed conversion ratio is less than the average ratio for that tournament settlement group receive a bonus above the base pay rate, while those whose costs are above the average incur a discount from the base pay rate.

LPDs benefit from the tournament system in several ways. The tournament system provides LPDs control and certainty over total grower compensation as a group. For each tournament, the LPD knows and sets the total compensation that will be paid per pound of broilers produced by the group. In other words, the LPD is never concerned about paying an excess bonus for an individual flock because the LPD allocates the pool of payments among growers through performance adjustments for growers relative to the floating average performance (*i.e.*, in today’s system, amounts above, or deductions from, the base pay rate). LPDs (and growers, as discussed below) also get the benefit of utilizing a floating average (relative to external shocks, such as weather, as noted below) to incentivize performance. However, the tournament system comes at a cost to growers: that of seeing payment for the services they provide reduced for reasons outside of their control yet within the control of the LPD. This outcome is magnified by the fact that growers cannot easily switch over to a

competitor LPD—even if the competitor LPD offers more attractive compensation—due to the high barriers to switching imposed partly by LPDs.¹¹

LPDs have long claimed that tournaments systems reward growers financially for their experience, skill, effort, and investments in up-to-date and efficient housing and equipment.¹² The extent to which the tournament actually incentivizes additional grower effort and expenditure of resources, and whether those efforts and expenditures were necessary and fair to growers, depends on a range of factors, including the magnitude of the tournament but, in some circumstances, also the design of the housing specification (*e.g.*, the use of automation and other technology), the type of bird being raised (*e.g.*, some require special efforts), the availability of other payment incentives, and the absence of arbitrary distortions in the allocation of payments, among other factors. In theory, provided that all growers in a tournament grouping were treated materially the same and the variables within the tournament grouping were within the control of the growers, a tournament system could insulate growers to some degree against external shocks that affect all growers in the grouping. This is because, in this scenario, performance is based on an average that floats and adjusts to the particular external circumstances that all growers in the pool experienced during the period.¹³ In reality, the

¹¹ See, *e.g.*, “Settlement Administrator Angeion Group Announces Proposed Settlement in Broiler Grow-Out Services Class Action,” PR Newswire (2024), <https://www.prnewswire.com/news-releases/settlement-administrator-angeion-group-announces-proposed-settlement-in-broiler-grow-out-services-class-action-302252706.html> (In 2024, some of the largest LPDs agreed to settle grower claims that the LPDs conspired with rivals to suppress pay by agreeing not to hire growers from each other. Multiple commenters also described the difficulty in switching.); United States Department of Justice, United States Department of Agriculture, (May 2010), Public Workshops Exploring Competition in Agriculture, <https://www.justice.gov/archives/atr/events/public-workshops-agriculture-and-antitrust-enforcement-issues-our-21st-century-economy-10>.

¹² See, *e.g.*, “How the Tournament System Works,” National Chicken Council (informing farmers that: “1 All farmers are provided the same quality of chicks, the same feed, and access to veterinary care. 2 Farmers who invest in more advanced facilities, as well as use the best management practices will likely produce higher quality chickens more efficiently. 3 Farmers receive a base pay (per their contract) and potentially a bonus, based on the health and quantity of the flock (tournament system).”); available at <https://www.chickencheck.in/fq/tournament-system/> (last accessed May 22, 2024).

¹³ Knoeber and Thurman show that tournaments shift most of the risks of broiler production from broiler growers to LPDs relative to a fixed payment system. See Knoeber, C.R. and W.N. Thurman, “Don’t Count Your Chickens . . .”: Risk and Risk

Continued

⁹ See, *e.g.*, Luke Herrine, “Cutthroat Business,” U. of Alabama Legal Studies Research Paper Forthcoming, Aug. 2024, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4936628; Michael Kades, “Protecting livestock producers and chicken growers,” Washington Center for Equitable Growth (May 2022); Peter C. Carstensen, “The Packers and Stockyards Act: A History of Failure to Date,” *The CPI Antitrust Journal* (2) (2010), available at <https://www.competitionpolicyinternational.com/assets/Uploads/CarstensenAPR-2.pdf>; Herbert Hovenkamp, “Does the Packers and Stockyards Act Require Antitrust Harm?” (Philadelphia: Faculty Scholarship at Penn Law, 2011), available at https://scholarship.law.upenn.edu/faculty_scholarship/1862.

¹⁰ There is some inconsistency in the use of payment terms across broiler contracts at different companies or complexes. Most grower contracts define the term base pay rate as it is described in this paragraph. However, some contracts instead use the term base pay when referring to a fixed amount plus the performance adjustment.

tournament system does not sufficiently protect from external shock. A range of shocks and factors external to the growers—some of which are within the control of the LPD—still adversely affect the overall weight of the broilers in a tournament and thereby reduce the compensation for all participating growers.

AMS has concluded that several widely adopted aspects of LPDs' operations are unfair, deceptive, or both. First, without a clearly stated base pay rate, LPDs deceive growers regarding their actual minimum pay. The complexity and unpredictability of LPDs' current operation of tournaments makes it difficult for growers to clearly understand before entering into a contract the minimum amount they could actually receive under the contract.¹⁴ For example, base pay can be, but is not commonly, a guaranteed minimum pay.¹⁵ Second, if performance pay—particularly performance pay that is based on comparisons with other growers—is substantial relative to total compensation, the arbitrary lottery-like aspects in a tournament system operation will, in most circumstances, undermine its effectiveness as a compensation scheme because compensation outcomes will not reflect the effort or performance of growers, and is unfair and deceptive. Third, arbitrary or unjustly discriminatory distribution of inputs, production practices, tournament groupings, or communications and dispute resolution—as key aspects of LPD performance under the contract—also can create a system in which compensation does not reflect the effort or performance of growers, deprives growers of the full amount due for their performance, and is unfair. These provisions are meant to be complementary and mutually

reinforcing. AMS explains each of these concerns in greater detail below, under section IV., “Provisions of the Final Rule.”

As noted above, many broiler growers operate in regions with just one to two LPDs.¹⁶ The local competitive conditions result in higher-risk, lower-paying grower contracts that commonly subject the grower to arbitrary and unfair payment; in particular, these contracts do not guarantee growers an adequate minimum base pay rate, flock placements and stocking densities, or length of contract in relation to the loan obligations commonly necessary to engage in broiler growing. Because LPDs control the distribution of inputs and assignment of production practices, growers repeatedly tell AMS that they experience unfair and deceptive operation of the contract. The typical tournament contract introduces levels of complexity and uncertainty for growers in the calculation of their compensation and in evaluating growers' return on investments so as to render the payment system unfair and deceptive. Furthermore, under that payment system, growers are commonly unable to discover unscrupulous conduct by LPDs, compare offers from competing LPDs, and plan and manage their businesses effectively. LPDs also say growers will operate “independently”—*i.e.*, their individual effort will produce commensurate higher compensation—though in practice their comparison-based compensation pay is heavily dependent on the LPD's inputs and comparison method, close supervision, responsiveness, and the performance of others in their LPD-determined settlement group.

AMS concludes that the “incentive system” in its current form does not excuse the unfair and deceptive operation of tournament systems because factors outside of the grower's

control impact performance. Without adequate regulation under the current system, LPDs fail to provide fair compensation for the grower's effort and deceive the grower regarding tournament operation and pay.

C. Debt and Financial Vulnerabilities

Requests by LPDs for growers to make additional capital investments are a pervasive part of the broiler growing industry such that Congress required that LPDs disclose the possibility of such requests to growers in their contracts (7 U.S.C. 197a(b)). These additional capital investment requests occur against a backdrop of significant financial vulnerability for growers, which implicates issues of potential unfairness and deception. Under this system of capital improvement, the LPD requests—and indeed, in practice, largely requires—growers to invest in housing improvements with little to no information regarding the purposes, processes, outcomes, or likely return to be achieved by the investment. These omissions of material information critical to growers' decision-making is unfair and deceptive. These additional capital investments are highly particularized, which leaves the growers investing in projects and investments that may be used only for growing broilers with a particular LPD. Growers have long complained to AMS that they face a perpetual cycle of debt owing to successive requests by LPDs for additional capital investments, suppressing their returns and leaving them even more vulnerable to the range of abuses outlined above.

Indeed, the Figures below show a declining rate of return on assets and higher debt to asset ratios carried by poultry operations compared to cattle, dairy, and hog operations.

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Shifting in the Broiler Industry,” *American Journal of Agricultural Economics* 77 (August 1995) p. 486–496.

¹⁴ *United States v. Cargill Meat Solutions Corp.*, 1:22-cv-01821-ELH (D. Md. July 25, 2022) (Wayne-Sanderson), pars. 153–56, available at <https://www.justice.gov/media/1238931/dl?inline>; AMS–FTPP–22–0046–0913 (“As a third-generation contract poultry farmer, this is one of the most unstable times I have witnessed or heard about with the growers in the majority. For many years we have been paid based on the tournament system, and for several years I viewed it to be fair, but no longer. Currently, we as growers compete against each other on a weekly basis to see who has the best cost. The list used to be really tight on what cost of top versus bottom grower, but in our complex alone, that is no longer the case. The top grower is making a healthy check, while those below average are not making enough to cover the cost of production and overhead. It is no longer the ones

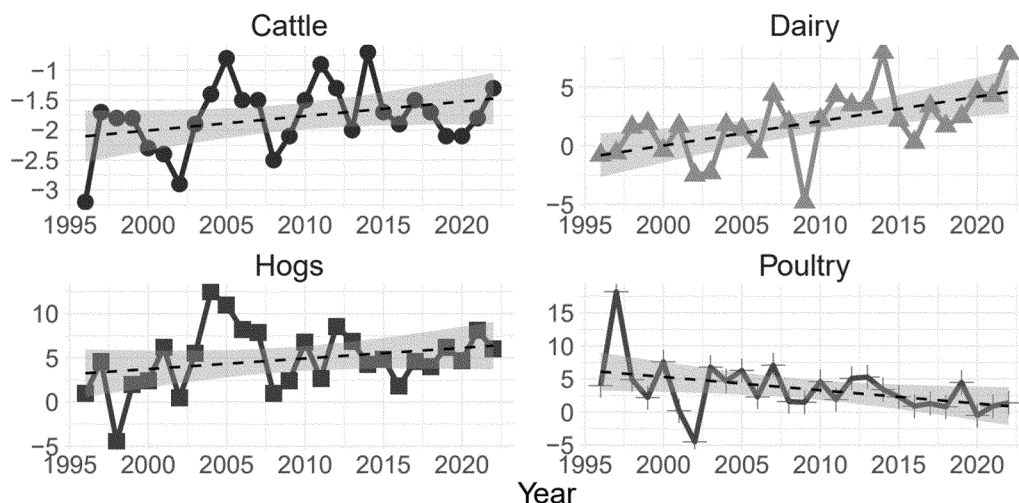
that put in the effort of hard work that are successful in this business”); Transcript, United States Department of Justice, United States Department of Agriculture, Public Workshops Exploring Competition in Agriculture: Poultry Workshop May 21, 2010, Normal, Alabama. Lee Schrader and John Wilson, “Broiler Grower Survey Report,” in Farmers' Legal Action Group, *Assessing the Impact of LPD Practices on Contract Poultry Growers*, ed. Farmers' Legal Action Group (FLAG Survey) (September 2001), <http://www.flaginc.org/publication/assessing-the-impact-of-LPD-practices-on-contract-poultry-growers/> (In 1999, Lee Schrader of Purdue University and John Wilson of Duke University surveyed over a thousand broiler growers in ten of the largest broiler-growing states (Alabama, Arkansas, Delaware, Georgia, Maryland, Mississippi, North Carolina, South Carolina, Texas, and Virginia). Based on AMS' experience, the survey results still provide a relevant reflection of

the views of growers today, including companies' representations about compensation to growers).

¹⁵ See “A Bird's Eye View of How Chicken Farmers Are Paid,” National Chicken Council (informing farmers that: “All farmers are guaranteed a base pay from the chicken company per their contract.”; “No matter what, farmers get paid.”; and “Bonuses are given to farmers who raise healthy flocks and invest in their farm. This is referred to as the tournament system.”); available at <https://www.chickencheck.in/faq/tournament-system/> (last accessed May 22, 2024).

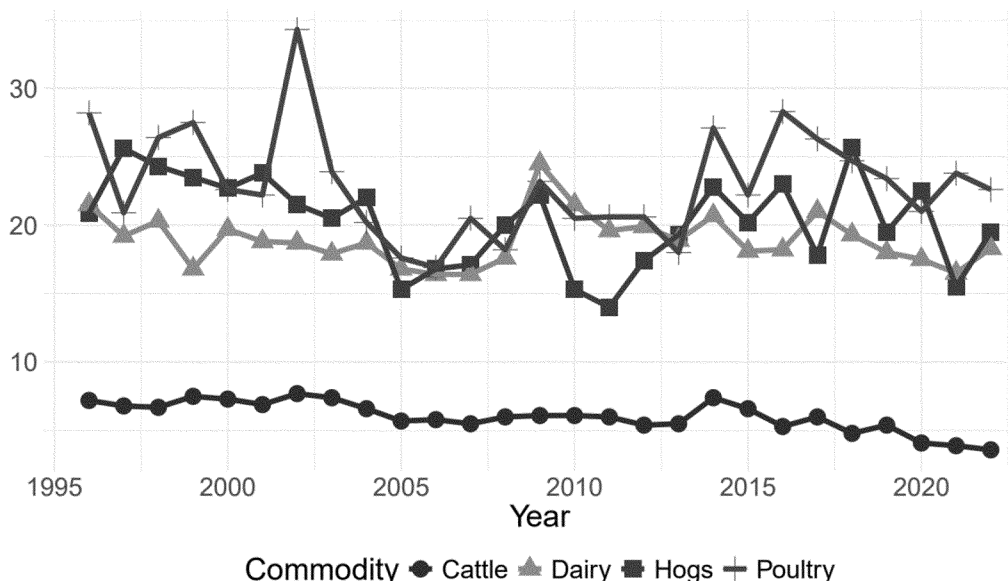
¹⁶ MacDonald, James M. 2014, Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB–126, USDA Economic Research Service, https://www.ers.usda.gov/webdocs/publications/43869/48159_eib126.pdf?v=1829.6 (Half of respondents with two integrators in their area and over a third of those with three integrators asserted that they could not shift to another integrator).

Figure 1: Rate of return on equity for poultry growers has been declining for growers from around 5 percent in 1995 to 2.5 percent in 2022, compared to upward-trending returns for cattle, dairy, and hog producers (with values scaled freely to show the trend in each panel)*



* U.S. Department of Agriculture, Economic Research Service. ARMS Farm Financial and Crop Production Practices (1996 – 2022) (Analysts retrieved information through the ARMS API. Poultry farms showed declining net farm income; livestock income (*e.g.*, receipts from broiler contract fees); lower working capital to expense ratio, which reached negative values in 2016 and 2018; and declining return on farm equity. For conciseness, analysts only present figures showing return on farm equity and debt to asset ratios.)

Figure 2: Debt to asset ratio for poultry growers exceeds that for cattle, dairy, and hog producers*



*U.S. Department of Agriculture, Economic Research Service. ARMS Farm Financial and Crop Production Practices (1996 – 2022) (Analysts retrieved information through the ARMS API. Poultry farms showed declining net farm income; livestock income (*e.g.*, receipts from broiler contract fees); lower working capital to expense ratio, which reached negative values in 2016 and 2018; and declining return on farm equity. For conciseness, analysts only present figures showing return on farm equity and debt to asset ratios.)

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The higher debt to asset ratios carried by poultry operations are driven, in part, by LPD requests for additional capital investments and are also facilitated, partially, by loan guarantees authorized under Federal law. Additionally, the gains from upgrades commonly flow to LPDs, and so growers' higher debt levels are not always supported by efficiency gains that would result from the additional capital investments. Under those circumstances and because of the willingness of lenders to loan due to guarantees, when growers are asked by LPDs to make additional capital investments without critical information about their purposes, processes, or outcomes, they are deprived of key information relating to those decisions. This practice is both deceptive and unfair because it deprives growers of their ability to identify fundamentally coercive or otherwise unfair capital improvement programs at an early enough time to seek AMS enforcement assistance in halting them, if appropriate.

Accordingly, AMS adopts this final rule prohibiting practices that, in AMS's view, violate the Act. The overall tournament system is highly problematic for poultry growers, and it is crucial to implement some guardrails for the industry to prevent unfair and deceptive contracting practices.

III. Summary of the Proposed Rule and Changes in the Final Rule

In the June 2024 proposed rule, AMS proposed amending 9 CFR 201, subpart N, by adding several new provisions: § 201.106 regarding LPD responsibilities for the design of broiler grower compensation arrangements; § 201.110 regarding the fair operation of broiler grower ranking systems; § 201.112 regarding disclosure requirements for LPDs when requesting additional capital investments from broiler growers; and § 201.290 regarding severability.

AMS proposed adding § 201.106, titled "Broiler Grower Compensation Design," to prohibit the reduction, or discounting, of any compensation rate under the broiler growing arrangement based on a grower's performance relative to other growers. The proposed provision would have required broiler grower arrangements to clearly state the grower's rate of compensation and not reduce that rate based on the grower's performance relative to other growers. The arrangement could provide for the rate of compensation to be increased based on that comparison.

AMS proposed adding § 201.110, titled "Operation of Broiler Grower

Ranking Systems," to prevent unfair and deceptive practices in LPDs' operation of ranking systems for broiler growers. Proposed paragraph (a)(1) would have required LPDs to design and operate their poultry grower ranking system to provide a fair comparison among growers, and under proposed paragraph (a)(2), the Secretary would evaluate specific factors to determine if the poultry grower ranking system is reasonably designed to deliver a fair comparison among growers. Proposed § 201.110(a)(3) also included a requirement that, when LPDs could not conduct a fair comparison, they must compensate growers through a non-comparison method. Proposed paragraph (b)(1) would have required documentation regarding the processes (policies and procedures) the LPDs must establish and maintain for the design and operation of poultry grower ranking systems for broiler growers that is consistent with the duty of fair comparison. Under proposed paragraph (b)(2), LPDs would have been required to review their compliance with these processes, and under proposed paragraph (b)(3) they would have been required to retain all written records relevant to their compliance for no less than 5 years from the date of record creation.

AMS proposed adding § 201.112, titled "Broiler Grower Capital Improvement Disclosure Document," detailing in proposed paragraph (a) that an LPD would be required to provide the grower with a Capital Improvement Disclosure Document (Disclosure Document) upon requesting that the grower make an additional capital investment. Paragraph (b) of the proposed regulation described the disclosures that the LPD would be required to include in the Disclosure Document. These disclosures included a justification of the request, financial incentives for the grower, specifications for construction, and a thorough analysis of the grower's projected returns.

Lastly, AMS proposed adding § 201.290, titled "Severability," to ensure that if any provision of subpart N or component of any provision is declared invalid, or if the applicability of any of these provisions to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected. Such a provision is typical in AMS regulations that cover several different topics and was proposed here as a matter of housekeeping.

Upon consideration of public comments on the proposed rule, AMS

has modified the proposed provisions as follows:

- Revised proposed § 201.106 by designating the proposed text as paragraph (a) and adding the paragraph heading "Rate transparency."
- Added a new § 201.106(b), "Excessive variability," that establishes a presumptive violation of the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers exceeds 25 percent of total gross payments to growers in a complex on an annual-calendar year basis.
- Added a new § 201.106(c), "Transition," that requires that LPDs, for each of the three calendar years commencing with and including the rule's effective date, submit to AMS a copy of the prior and modified contract and any LPD Disclosure Document prepared under § 201.102 for any modified or renewed contracts under specified conditions.
- Simplified proposed § 201.110(b)(1)(i) and (ii) (concerning LPDs' processes for determining inputs and production practices) by removing the subparagraphs that itemized each component of the required processes.
- Simplified proposed § 201.110(b)(1)(iii) (concerning LPDs' processes for grower comparison flexibility) by removing subparagraphs (A) through (C) and placing those requirements into three simple paragraphs: (b)(1)(iii), "League composition;" (b)(1)(iv), "Evaluation period;" and (b)(1)(v), "Non-comparison." Accordingly, AMS also redesignated proposed § 201.110(b)(1)(iv), "Communication and cooperation," as paragraph (b)(1)(vi).
- Removed proposed § 201.110(b)(2), "Compliance review" and redesignated proposed § 201.110(b)(3), "Record retention," as paragraph (b)(2).
- Revised proposed § 201.112(a) and (b) to include the paragraph headings "Disclosure requirement" and "Disclosure contents," respectively.
- Revised proposed § 201.112(b)(1) through (3) to remove the term "relevant" as a technical change, along with conforming grammatical edits.
- Revised proposed § 201.112(b)(5) to clarify that, in addition to disclosing any required or approved manufacturers or vendors, the Capital Improvement Disclosure Document must disclose all financial benefits, if any, that the LPD or other affiliated persons receives from the use of the required or approved manufacturer or vendor.
- Revised proposed § 201.112(b)(6) as a technical stylistic change.

- Added a new § 201.112(c) to require the LPDs to make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Capital Improvement Disclosure Document.

Section IV. below explains in detail AMS's reasons for making these changes.

IV. Provisions of the Final Rule

Throughout this final rule, AMS's analysis of unfair and deceptive trade practices in poultry contracts is informed by prior P&S Act case law, States' unfair and deceptive practice laws, and, in particular, the Federal Trade Commission (FTC)'s encapsulation of principles governing unfairness, unfair methods of competition, and deception.¹⁷ AMS looks to the FTC's policy statements owing to the FTC's extensive experience enforcing prohibitions against unfair practices, unfair methods of competition, and deception arising under the FTC Act, which are similar to provisions prohibiting unfair and deceptive practices under section 202(a) of the P&S Act. Like section 202(a) of the Act, section 5 of the Federal Trade Commission (FTC) Act also prohibits unfair and deceptive practices and unfair methods of competition. In 1980, 1983, and 2022, the FTC adopted the aforementioned policy statements summarizing its longstanding approaches to these matters under its cases. While recognizing that the P&S Act is broader than the FTC Act, AMS references these policy statements because they offer useful guidance owing to the similarity of the statutory provisions and case law histories.¹⁸ In addition, AMS recognizes the benefits to

the practical application of this final rule by grounding it on the well-understood principles of unfairness, unfair methods of competition, and deception as identified in the FTC policy statements. It is for these reasons that the FTC Act has, in part, informed this final rule.

A. Broiler Grower Compensation Design (§ 201.106)

AMS is finalizing new § 201.106, "Broiler grower compensation design," with two notable changes from the proposed rule. In the final rule, AMS is retaining § 201.106 as proposed and designating it as paragraph (a), "Rate transparency." AMS is adding paragraph (b), "Excessive variability," and paragraph (c), "Transition." Paragraph (b) adds a presumption against excessive variability in performance compensation to growers competing in a tournament. Paragraph (c) provides for grower protections during the transition from the existing payment systems to systems compliant with this final rule. Each paragraph will be discussed further below.

Most large LPDs today include a tournament component as part of their grower compensation arrangements. Under this type of arrangement, if a grower's feed conversion ratio (*i.e.*, the quantity of feed consumed by the flock divided by the weight of the flock delivered) is above the average of other growers in the tournament, the grower receives a bonus; if the grower is below average, the LPD reduces the grower's compensation. Under the tournament system, the contract between the grower and LPD provides for payment to the grower based on a grouping, ranking, or comparison of growers delivering broilers to the same company during a specified period. These pay rates are generally expressed in cents per pound. Applying these adjustments, whether positive or negative, significantly affects growers' effective rates of compensation and net income.

In its current form, the tournament system operates unfairly and deceptively. Without clearly stated base rates of compensation, the complexity of the tournament makes it difficult for growers to clearly understand the minimum amount they could be paid. Moreover, compensation based on relative performance when LPDs control the operation of the tournament (such as the distribution of inputs and assignment of production practices) creates the potential for growers' performance to be determined by factors outside their control, thereby making the tournament system an ineffective incentive system that is arbitrary and

unfair to growers. The tournament system also introduces considerable complexity and uncertainty for growers in calculating their anticipated total compensation and evaluating the potential return on their investments. Furthermore, if the comparison-compensation factor (*i.e.*, the bonus or deduction) is a large percentage of total compensation, that variance in total grower compensation is no longer a legitimate business but simply shifts economic risk from processors onto poultry growers without a demonstrable countervailing benefit. Without additional guardrails, the current tournament system creates significant risk of deception or unfairness for growers under the Act.

AMS has not found any evidence that poultry tournament systems that include deductions from the base pay rate or excessive variability in grower compensation provide a benefit to growers or competition in the market for grower services that outweighs the harm to growers. Deductions in other livestock contracts commonly reflect performance attributes of the animal itself, which is owned by the producer. Here, the producer provides a service with no ownership interest in or role in the selection of the animal. These deceptive and unfair payment practices create an unfair competitive advantage for LPDs at the expense of growers. Therefore, the widespread adoption of these types of contracts has frustrated fair competition, instead of enhancing it. Such discounting and pay variability also reflect the market power and bargaining power of the LPD in dictating contract terms.

Section 201.106 will provide growers with greater clarity and protection regarding the minimum payments they can expect under broiler growing arrangements. This rule prohibits a range of unlawful behavior by establishing a threshold presumption against excessive pay variability, establishing a transition period to preserve existing pay, and making minimum pay clear for growers. This rule will better enable growers to compare contract terms, evaluate revenue generation, and assess the value of additional capital investments.

i. Section 201.106(a)—Rate Transparency

AMS is finalizing new § 201.106(a), which prohibits the reduction of any rate of compensation under the broiler growing arrangement on account of the grower's grouping, ranking, or comparison to other growers. This provision is identical to that which was proposed, except that the provision is

¹⁷ Federal Trade Commission, Policy Statement on Unfairness, 1980, <https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness> (last accessed Oct. 2024); Federal Trade Commission, Policy Statement on Deception, 1983 available at https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf (last accessed Oct. 2024); Federal Trade Commission: Policy Statement on the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, Nov. 2022, available at <https://www.ftc.gov/legal-library/browse/policy-statement-regarding-scope-unfair-methods-competition-under-section-5-federal-trade-commission> (last accessed Oct. 2024).

Spencer Livestock Comm'n Co. v. USDA, 841 F.2d 1451, 1455 (9th Cir. 1988); *Armour & Co. v. United States*, 402 F.2d 712 (7th Cir. 1968) ("Section 202(a) should be read liberally enough to take care of the types of anti-competitive practices properly deemed 'unfair' by the Federal Trade Commission (15 U.S.C. 45) and also to reach any of the special mischiefs and injuries inherent in livestock and poultry traffic").

¹⁸ Michael Kades, "Protecting livestock producers and chicken growers," Washington Center for Equitable Growth (May 2022).

now designated paragraph (a), with the paragraph heading “Rate transparency.” Under this provision, the broiler growing arrangement must clearly state the compensation rate. The arrangement may not provide for mechanisms or calculations that would reduce the compensation rate based on the grower’s performance relative to other growers, but it can provide for the rate to be increased based on the grower’s performance relative to others. The broiler growing arrangement could provide for the compensation rate to be increased based on the broiler grower’s performance relative to others, but in no event could the rate be decreased or discounted by that comparison.

“Rate of compensation” refers to any payment amount that the LPD utilizes to compensate the grower under a broiler growing arrangement, which could include “base pay,” “minimum pay,” or any other rate defined in the contract. That rate would have to be prominently and clearly defined as the guaranteed level of pay a grower will receive if the grower performs to the minimum specifications of the relevant provisions of the contract. To the extent that a broiler growing arrangement had more than one rate of compensation, none of the rates could be reduced or discounted by a comparison. Under existing AMS regulations, a broiler growing arrangement must include all payment terms in the contract (9 CFR 201.100(c)(2)).

Under section 202 of the P&S Act, AMS concludes that the practice of discounting disclosed “base” pay rates in broiler contracts is an unfair and deceptive practice. This practice forces growers to estimate potential earnings using contractually stated “base” pay rates that, under the tournament system, only half of the settlement group can achieve. This unfair and deceptive practice obscures the value of the contract, thereby frustrating comparisons with competing LPD contracts in markets where growers are fortunate enough to have more than one or two LPDs to contract with.

AMS expects that, under this regulation, LPDs will still be able to elicit a competitive level of performance using a broiler compensation design that conforms to the requirements of this final rule. The LPD could reward performance for feed efficiency relative to the growers in the settlement with a minimum base pay rate per pound and an upward adjustment to the payment formula. Depending upon the facts and circumstances, mere compliance with this regulation does not absolve an LPD of its other legal obligations. A compensation structure without a

penalty or reduction from a true guaranteed minimum pay rate may still—if the facts demonstrate it—result in other violations of the Act.

ii. Section 201.106(b)—Excessive Variability

In the final rule, AMS is adding new paragraph (b), “Excessive variability,” which establishes a presumption that an LPD has violated section 202 of the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers exceed 25 percent of total gross payments to growers in a complex on an annual-calendar year basis. AMS is adopting this approach because excessive variance in total grower compensation arising from comparison-based compensation would, generally, create excessive variability that is deceptive because growers cannot reasonably assess the risk they are undertaking or forecast, predict, or budget their business operations. Further, excessive pay variance makes compensation dependent on arbitrary criteria, random factors, or other criteria that the grower cannot control or affect. When the comparison performance pay too substantially affects compensation, it is unfair.

When growers perform reasonably under the terms of the production agreement, excessive variability in performance pay arises at least in part due to LPD-controlled factors or unavoidable inherent natural variability. These factors are outside of the grower’s control and cannot be completely offset by grower effort or skill. LPDs design ranking systems to allocate grower payments based upon grower effort and skill. When factors other than grower effort and skill are comingled with the metrics used to allocate pay, the practice is ripe for potential abuse and unfairness because excessive variability in performance payments unfairly reduces compensation to growers. This unfairness to growers is particularly pronounced owing to high indebtedness among growers, which leaves them more financially vulnerable to harms from excessive income variability that does not reasonably reflect their own efforts.¹⁹ That pay variability also frustrates growers’ ability to accurately assess, or reasonably control, their rates of compensation and the overall financial risk they undertake under a broiler growing arrangement, which is particularly problematic given the risk

¹⁹ In contrast to contributions by the grower, LPDs contribute much more significantly to overall performance by furnishing the inputs, *e.g.*, genetics, feed, nutrition, sex of chicks, and close supervision of the grower’s managing production.

they bear. The injury is not offset by attendant benefits, since the practice tends toward distorting the market’s true pay amount and reducing growers’ ability to accurately assess, or reasonably control, their finances and make informed business decisions.

Though § 201.106(a) addresses the problem of reductions to rates of compensation that arise owing to groupings, rankings, or comparisons of growers, it does not alleviate all potentially unfair aspects of the tournament system or of the integrated model of broiler production. The proposed rule indicated that AMS intended to engage in case-by-case enforcement to remedy other aspects of tournament system unfairness, including issues arising from excessive variability in payments. In addition to a prohibition on discounting rates of compensation, the proposed rule particularly highlighted the potential importance of a 25 percent presumption on total compensation based on a grouping, ranking, or a comparison (the tournament) to total of base pay rate plus performance compensation. As AMS indicated in the proposed rule, this approach could alleviate extreme variability as an aspect of existing tournament system unfairness.

In the proposed rule, AMS included questions containing additional proposals. One such proposal solicited comment on whether it is presumptively unfair for comparison-based compensation to equal or exceed 25 percent of total (base pay rate plus comparison-based) compensation for any grower and asked a range of questions around the appropriateness of the specific threshold, how to calculate it, and how it would affect the industry.²⁰ These questions included highlighting the role of the 25 percent presumption as a potentially binding constraint, and how LPDs might respond to the prohibition introduced in § 201.106(a) by modifying the compensation structures in grower contracts. AMS’s questions indicated that it could raise base pay and/or limit performance payments—thus reducing the difference between top and bottom performing growers—without increasing total grower compensation expenditures. It also left open the possibility that LPDs could potentially adjust their compensation structures in other ways, such as by providing non-comparison-based incentives to growers they might seek to reward (such as per pound or per square foot compensation for housing known to provide efficiencies to the LPD) or deploy other

²⁰ 89 FR 49002, 49011–49012 (June 10, 2024).

incentives (such as fixed performance bonuses).

In response to the proposed rule, growers and advocate commenters overwhelmingly supported the need for additional limitations on excessive variability in payment arising from rates of compensation, with a particularly strong endorsement of the 25 percent limitation on performance. Commenters underscored the importance of this limitation for some of the reasons that AMS indicated in the proposed rule: that it is necessary to protect growers from unfair reductions in payments.

To incentivize grower effort, LPDs allocate grower pay using relative performance metrics; however, grower effort alone is an insufficient determinant of grower performance. Growers' performance depends on many factors, some of which are under the control of growers while others are not. Some known factors, including a grower's skill and effort, are within a grower's control. Other factors are outside a grower's control, such as feed quality, chick quality, and the skill or other efforts of other growers in the comparison group. Even if all these known factors are accounted for, there is still some unavoidable inherent natural variation in performance that would explain growers' performance volatility, flock to flock, even if all the known factors remain constant. The nature of this variability creates harm to growers in reduced performance payments.

The use of flock performance metrics, specifically feed conversion, as a proxy to grower effort is imperfect. Feed conversion itself is affected by variables beyond grower effort. AMS is not aware of existing technological innovations that could serve to better isolate grower effort, which is exclusively under grower control. That is not to say flock performance metrics serve no purpose in assessment of grower effort and allocation of grower payments. AMS's experience in analyzing performance payments suggest that ranking systems can be a useful and reasonably equitable mechanism for pay allocation with proper regulation and in proper magnitude. Within a reasonably contained range—*i.e.*, presumptively 25 percent of total compensation—the tournament may offer a reasonable benefit to growers by enabling LPDs to efficiently measure grower performance and guard against natural forms of variability that would arise were compensation fixed rather than floating (*i.e.*, the comparison-based average of growers). Yet at too high a level, the potential harms of comparison-based compensation (performance pay

dominating grower pay allocation without rewarding commensurate differences in effort) outweigh the potential benefits. That is unfair under section 202(a) of the Act because compensation under the tournament becomes correlated to input distribution (and other circumstances under the control of the LPD, such as flock production practices or responsiveness to complaints), which is commonly arbitrary—or, in some cases when not arbitrary, can be punitive. Some growers who comply with the contract and are unfairly penalized for factors beyond their control suffer unavoidable harm; they are denied the full amount due for their growout services. While growers can benefit from participation in the tournament, excessive pay variability can cancel out those benefits as they are outweighed by the harms.

Based on previous analysis of grower compensation data for a small sample of broiler complexes, AMS is not aware of any complex with performance payments that are as much as 26 percent of total payments. Additionally, in *United States v. Cargill Meat Solutions Corp.*, commonly referred to as “Wayne-Sanderson,” the final judgment also contains a 25 percent limitation on performance payments.²¹ The Wayne-Sanderson settlement is significant because it was agreed to by one of the largest market participants and has not caused any demonstrable harm to the company or to the market, nor is there any evidence that it disincentivized grower effort or lowered performance. While Wayne-Sanderson had agreed to a 25 percent limitation on performance payments, this final rule establishes that performance payments above 25 percent are *presumed* to be unfair. This is because performance pay variability causes injury to growers when the magnitude of performance pay is so excessive. That is, the performance pay significantly affects whether the grower is successful, yet the amount depends on unavoidable variance and does not reflect grower performance. In those circumstances, compensation no longer correlates to factors within grower control, such as their effort and expertise. This deprives growers of the value, both real and expected, of their services. The vast majority of commenters who addressed the topic of comparison-based compensation endorsed the idea of 25 percent as an appropriate level for a presumption of this type.

We note that this presumption will provide guardrails in helping LPDs set

and maintain performance pay standards that achieve appropriate goals, such as rewarding effort and skill against a floating average that adjusts for common circumstances, like weather, without unduly denying growers the expected value of their growout services. This clarity will guide LPDs that need to modify existing contracts to comply with this final rule, such as with § 201.106(a). For example, absent the existence of § 201.106(b), LPDs could comply with § 201.106(a) by decreasing base pay and excessively increasing the proportion of pay that is dependent on performance compensation. Such contract modifications would supercharge pay variance in the tournament while penalizing growers under the guise of complying with reforms designed to improve transparency and fairness. The presumption under § 201.106(b) helps ensure continuity in compensation at an aggregate level because it guards against excessive variability of performance pay relative to total pay. To stay within the presumptive boundary set by § 201.106(b), an LPD must set a reasonable compensation rate for any new base payment under the contract. AMS underscores that nothing in the rule prevents LPDs from providing other forms of incentive compensation to growers for reasons other than relative performance, such as payments for improved facilities or utility subsidies. Overall, the 25 percent presumption against excessive variability is useful to provide clarity and consistency around when AMS may seek to investigate for case-by-case compliance and enhances the fairness and transparency of compensation rates in broiler growing arrangements. As such, it reflects a logical outgrowth of the proposed rule.

Separately, AMS notes that it also expects to examine for excessive variability other forms of performance payments that are based on how efficiently a grower uses inputs supplied by the LPD: such payments could emerge as a method for evading this provision's purpose. Examples of such performance payment systems include what are commonly called fixed metric performance payments, which predate the current tournament, whereby growers' performance payments are tied to their individual achievement of certain fixed metrics around efficient use of inputs. AMS expects to examine these types of performance systems for excessive variability for similar risks of unfairness, including because the LPD provides the inputs and production

²¹ *United States v. Cargill Meat Solutions Corp.*, 1:22-cv-01821-ELH (D. Md. July 25, 2022).

practices and in those circumstances would be setting the fixed metrics.

In review of the presumption, AMS will consider other complex-specific incentives as requested by the LPD that would otherwise not be appropriate to consider as part of the rates that make up base payment. For example, energy incentives may be considered differently because they vary significantly based on geographic location, and so would result in somewhat different application of the provision for growers at different complexes. Where a relatively high degree of variability in performance pay exists, even within the 25 percent, due in part to energy incentive payments, AMS may examine whether the tournament is unfair.

To rebut the presumption of unfairness triggered when comparison compensation payments exceed 25 percent of total compensation, the LPD may affirmatively demonstrate (i) that a given tournament's compensation system allows all growers to be economically successful without the need to receive any payments based upon a grouping, ranking, or comparison of growers that exceed the amount covered by the presumption; (ii) that payments to all growers that exceed the amount covered by the presumption are sufficient to reflect the increased risk of variability to all growers under that system; and (iii) that the system is not otherwise unfair or deceptive. The Agency would examine any rebuttal on a case-by-case basis to comport with the purposes of the presumption to prevent LPDs from engaging in unfair or deceptive practices or devices that harm poultry growers.

AMS adopted this provision after considering the case-by-case presumption set forth in the proposed rule and public comments that urged AMS to instead establish a greater limitation on excessive variability of payments arising from performance, especially comparison-based, compensation. Public comment regarding this provision, and AMS's response to those comments, are discussed in greater detail below in section V., "Comment Analysis."

iii. Section 201.106(c)—Transition

In the final rule, AMS is also adding new § 201.106(c), which requires that, for any contract modification or renewal subject to § 201.106(a) that results in a grower receiving less than the prior year's complex-wide average gross payment, the LPD must submit a copy of the prior contract and the modified contract, as well as any LPD Disclosure Document prepared under § 201.102

with respect to the prior and the modified contract, to the Secretary.

AMS will monitor contracts to identify signs of the unfair exercise of LPD bargaining power during this transition period. These could include, for example, a predatory method of competition whereby an LPD seeks to lower pay across the entire complex or discriminatory or retaliatory conduct that seeks to lower the pay of some subset of growers. Unfair conduct by the LPD could potentially arise where the LPD seeks to undermine contractually agreed-upon earnings from the previous contract irrespective of the tournament. One way for AMS to identify such conduct could be through LPD Disclosure Documents (currently required under existing 9 CFR 201.102), which would be required if LPDs modify or replace contracts in seeking compliance with this rule. The record-keeping and reporting requirements in this final rule will further help identify any potential illicit exertions of market power by allowing AMS to closely scrutinize contract modifications that jeopardize grower welfare during the transition period.

In keeping with the requirements in § 201.102(d)(2), AMS expects LPDs to explain why the annual gross payment averages for the previous five years may not provide an accurate representation of projected future payments. AMS also expects a distinct explanation of how any changes the LPD is proposing under the new contract are necessary to comply each part of final § 201.106. That is, changes made to comply with § 201.106(a) and (b) should be explained. AMS strongly encourages LPDs to explain changes needed to comply with § 201.106(b) first, and then apply a conversion scale from whatever updated approach is adopted to comply with § 201.106(a).

AMS will evaluate the reported contract modifications and associated documentation to assess grower welfare, given that growers will be particularly susceptible to economic hold-up concerns. In particular, AMS will consider the following variables: (1) the number of flock placements annually; (2) the stocking density; and (3) the distributional range of payments. If, upon consideration of these variables, AMS identifies contract modifications that negatively impact grower welfare or that include supply reductions from the complex, the Agency will closely scrutinize the modifications, including rates, for fairness and reasonableness.

It is crucial that growers are meaningfully informed about the terms of the grower arrangements and the expected compensation for their

services so that they can make financially sound decisions and identify potential economic hold-up. The reporting requirements will only be in effect for three years including and from the effective date of this rule.

During the three-year transition period, LPDs must evaluate average grower compensation at the complex level for each of the three calendar years commencing with and including the rule's effective date to determine if they need to submit their contract to AMS for review. The rule requires LPDs to use the average grower compensation across the complex, because this analysis shows if an LPD has cut grower compensation overall. The rule uses averages because performance-based compensation is unpredictable on a grower-by-grower basis and because using total grower compensation at the complex would be overinclusive. For example, grower turnover might skew an analysis based on total grower compensation. This makes the § 201.106(c) method of evaluation comparable to how unfair levels of performance-based compensation are defined under § 201.106(b).

AMS chose a transition period of three years for several reasons. First, it is nearly impossible to evaluate the changes to grower pay made to contracts within 180 days or even a single year with any level of confidence. Many contracts are three, five, or ten years in length, so it may take up to a year of payments to even begin evaluating the financial effect of changes. Reviewing payments within a 180-day period may not indicate what growers would earn in a year and would be limited in scope and value; any conclusions based on that limited review would be speculative, and violations of the Act cannot be based on speculation. After a full year of operation following contract modification, the realization of grower performance outcomes and practical application of the compensation structure are known and translated into actual grower payments. This will facilitate AMS's analysis of the actual distribution of grower payments and overall level of compensation that resulted from the new compensation structure and allow for a more fulsome evaluation of fairness concerns. It also allows AMS to consider the market environment as context for LPD actions.

Additionally, this new rule may necessitate adjustments to the compensation structures used in grower contracts, and it will take time for growers to become used to the new regulation. AMS needs to look at how the overall market is adjusting to this new reality and prevent evasion during

that adjustment period. For example, an LPD may make a series of small contract changes, which would require AMS to review the overall market adjustments, not just the initial changes. Failure to capture the full implications of the transition period would put growers at risk from LPD market power and bargaining imbalances between LPDs and growers.

AMS underscores that this is a monitoring and reporting requirement, owing to the ongoing risk to growers that the contracts could be modified and re-modified during this transition period. This contract review will help the Agency decide whether to conduct more specific oversight and enforcement while the new regulatory regime is implemented.

Three years is the period of financial information that banks request from borrowers, such as growers, and so it provides a reasonable period for AMS to engage in these market-monitoring activities. After three years, AMS agents will continue to monitor contracts and ensure they are following the requirements of this final rule, but LPDs will not need to submit contract modifications.

In the proposed rule, we asked for public comment on this issue, and received overall support for a provision to protect growers that rely on existing contracts from holdups and potential market abuse. Specifically, we asked the following question: “To minimize transition risks to growers, should AMS include a requirement that LPDs submit to AMS for review any contracts modified or revised to comply with new § 201.106?”¹⁷ The comments received in response to this specific question were mixed in their support and are addressed below in sections V.A.iv. and v.

Because the Secretary will subject the updated contracts to close scrutiny for unfairness, the Secretary would seek access to the dealer’s business records. During any investigation, AMS may examine any changes to average annual gross payment per pound for growers in the complex and any changes to average payment per square foot increased. Each investigation will consider the individual facts and circumstances of each situation, as these considerations are important in examining whether growers were held at least no worse off during the contract modification process. Although the final rule is designed to benefit growers and reduce unfair and deceptive practices, growers face a significant risk of unfair practices owing to the risk of hold-up when they may be required to change their contracts so that LPDs comply with this

rule. Based on AMS’s experience implementing rules, LPDs may seek during any compliance and implementation period to extract changes to the contract unrelated to the regulatory requirements of this rule. The purpose of providing contracts to AMS is to identify unfair practices or otherwise unlawful reductions to payment that are favorable to LPDs and harmful to growers.

B. Operation of Broiler Grower Ranking Systems (§ 201.110)

AMS is finalizing new § 201.110, “Operation of broiler grower ranking systems,” which regulates how LPDs operate ranking systems (*i.e.*, tournaments) for contract broiler growers, establishing a duty of fair comparison when calculating comparison-based compensation among a group of poultry growers in a settlement group. This section contains factors for the Secretary to consider when evaluating whether LPDs have abided by the duty of fair comparison requirement. When LPDs are unable to make a fair comparison for one or more growers, they are required to use a non-comparison compensation method as specified in the contract. LPDs are required to document how they design and operate their poultry grower ranking systems in a manner that is consistent with the duty of fair comparison. The documentation must show that LPDs take measures to mitigate the impact of inequitable distribution of inputs and flock production practices on grower performance and, hence, comparison-based compensation.

The purpose of the rule is to ensure that comparison-based compensation reflects grower effort, not factors that injure the grower, such as feed or chick quality or timing of feed delivery that are outside of grower control but within the control of LPDs. The problem this rule seeks to address is how LPDs manage variation in quality or timing of inputs, flock production practices, and how LPDs handle growers’ concerns (*i.e.*, groupings, responsiveness to problems). AMS certainly believes that rewarding grower effort is fair, but unfair and deceptive comparison systems are not.

For example, breeding hens have a lifecycle of 50 weeks. They produce optimal chicks between weeks 20–34, but they also produce chicks that have value outside the optimal window. The LPD has a financial incentive to grow all these chicks to maturity, and thus will distribute a mix of higher and lower quality chicks in any one settlement period to its growers. Those growers

receiving a higher proportion of suboptimal chicks are disadvantaged in a relative comparison to growers who received a higher proportion of optimal chicks.

In theory, LPDs would provide uniformly high-quality inputs (such as chicks and feed) and appropriate production practices (such as flock density) to all growers to ensure maximum efficiency, product quality, and profit. LPDs would also ensure tournament groupings are reasonably random or otherwise not biased and would also reasonably control for problems that growers faced (such as accidental delivery of the wrong feed). However, inputs are natural systems and, therefore, variation in input quality necessarily exists. This variation in input quality affects performance. Moreover, human error can be present in vertically integrated systems as well, for example, the accidental delivery of feed designed for older birds. LPDs want to obtain the full value from all usable inputs and are not inclined to dispose of lower quality chicks or feed to ensure growers only get the highest quality inputs. Thus, LPDs routinely distribute lower quality, lesser performing inputs to their contract growers, even though growers who receive those inputs will likely receive lower compensation than their peer growers in the same tournament that receive higher quality, higher performing inputs. Within a given poultry complex (group of growers serving a single processing plant), a significant share of each grower’s compensation is determined by their rank in tournaments between growers at the complex, even though a proportion of performance variation across growers is attributable to variation in inputs, including feed and chick quality, timing of feed delivery and flock pick-ups.

LPDs purport that this system works to promote fair competition in the market for grower services. From an LPD’s perspective, as outlined in several public comments, a grower receiving poorly performing inputs and a low rank in one tournament is how the system works; over the long term, according to the commenter, the grower will likely receive better-performing inputs that help to balance out one tournament’s losses. LPDs also stated in their public comments that they have no incentive to furnish a grower with poorly performing inputs and/or otherwise mistreat growers.

In practice, LPDs assertions do not bear out. LPDs have limited financial incentive to expend extra efforts to evenly distribute optimal inputs and production practices across growers in a

poultry settlement pool or even to some extent to promptly address problems. LPDs have not provided supporting evidence that long-term provision of inputs balance out uniformly. Even if over the long-term the variability, on average, balances out, there will be growers who do not benefit from the balancing or for whom the balancing comes too late to address the harms caused by variability. LPDs' assurances of long-term balancing out do not provide comfort to the grower facing decreasing ability to pay for immediate operating expenses—and who does not have the extra cash to buffer one tournament's losses. Furthermore, under the current compensation system, LPDs have little motivation to limit performance variability, exercise appropriate care in input distribution, or generally create reasonable uniformity regarding other aspects of tournament operations.

As growers and grower advocacy organizations have asserted, LPDs often provide the “noisy” grower (who exercises their dissatisfaction or seeks redress for bad treatment) “bad” or otherwise inappropriate or untimely inputs or flock production practices, or even organize them into comparison groupings designed to adversely affect their performance. This can even occur for those seeking timely assistance or correction for supposedly inadvertent mistakes (e.g., feed delivered to new chicks that is designed for older birds, and hence is not edible by the younger birds). Growers have consistently reported over the years that LPDs commonly exercise punitive control over inputs, production practices, tournament groupings, and the availability of assistance for ordinary problems. These circumstances suggest an environment characterized by unavoidable unfairness and oppressive methods that adversely affect growers' and even LPDs' ability to compete on the merits. Growers who receive bad treatment cannot competitively discipline an LPD by negotiating better terms or choosing a different LPD. They must accede to continued poor treatment by the LPD.

LPDs' practice of basing grower compensation on factors beyond growers' control distorts the competitive market for grower services. LPDs possess power—whether regionally, within the contract relationship with growers who depend on that relationship to pay down debt, and/or through information asymmetry (*i.e.*, through knowing detailed information about inputs and growers' finances while growers know relatively little). This power allows them to reduce

growers' compensation to unfair levels they know growers can barely bear; in turn, growers' reduced financial stability further reduces their countervailing power. Another feature of this practice is that LPDs are not actually allocating more funds to better compensate higher-performing growers: they fix overall compensation to their growers from tournament to tournament and deduct pay from those who performed below the average to reward those who performed above average. In so doing, they prevent growers from actually earning compensation commensurate to services—a circumstance that numerous commenters described experiencing but possessed little recourse to counterbalance, *i.e.*, “Take it or leave it.” This practice further erodes the competitive conditions in the market for grower services. Numerous commenters discussed how just a few below-average rankings caused them to not be able to afford operational expenses and perform worse and worse; and/or exit. By basing compensation on factors outside of actual grower services, LPDs also distort the actual price signal for grower services. And, by fixing overall compensation and deducting from the bottom to reward the top, they prevent honest competitors that actually allocate more funds for better-performing growers. Altogether, AMS believes these are unfair and deceptive practices under the Act.

LPDs harm growers when they compare growers where inputs, production practices, tournament groupings, and assistance are not equitably distributed. Grower pay becomes undeservedly low and fosters unlawful variability in both performance and compensation that have no relationship to the grower's work, initiative, or skill. Growers have no control over how inputs, production practices, tournament groupings and assistance are allocated, owing to the vertically integrated model of broiler chicken production. Unfair comparisons do not benefit growers or competition, and indeed frustrate the LPDs' claimed purpose of the tournament structure. The tournament is a form of performance payment that is intended to incentivize grower deployment of effort, skill, and investment to foster more efficient use of the inputs provided by the LPD. Purportedly, tournaments capture actual differences in grower performance during a given period, while adjusting for overall conditions affecting performance, such as adverse weather conditions, that affect all growers in the complex. The

rule sets out reasonable alternatives to these harms that do not undermine the benefits to growers from the vertically integrated production system or from using comparisons to establish flexible baselines for evaluating grower performance, within its appropriate limits.

AMS notes that growers get paid by the pound and start with a static number of chickens. Thus, they have contractually inherent incentives to grow their chickens to the target weight and to minimize the death loss of chickens, even in the absence of a performance payment. Yet AMS also acknowledges that ensuring growers' use of the minimum amount of inputs, such as feed, to achieve maximum growout is also an important part of the overall mix of cost efficiencies. AMS agrees, to the extent that the pool of growers in a tournament is sufficiently random and that the necessary conditions for equitable comparison are met, a tournament may spur growers to operate more efficiently as they seek higher comparison-based compensation, while reasonably guarding against commonly shared external conditions. Yet as discussed in the proposed rule and reflected in comments from grower groups and others, those conditions are often not met. Nor, indeed, are arbitrary or inequitable differences in inputs and production practices inherently essential features required to deliver the benefits of the poultry industry's vertically integrated production and comparison-based performance compensation system. In fact, arbitrary or inequitable practices undermine these benefits, producing instead arbitrary or otherwise inequitable grower pay differences that run contrary to the industry's avowed purpose of the tournament system.²²

Because the tournament system determines a component of grower pay, LPD practices that impair a fair comparison of grower performance cause a misallocation of performance compensation, thereby unfairly reducing the compensation that may otherwise be due to some growers. Studies²³ have shown that differences

²² See, e.g., “How the Tournament System Works,” National Chicken Council (informing farmers that: “1 All farmers are provided the same quality of chicks, the same feed, and access to veterinary care. 2 Farmers who invest in more advanced facilities, as well as use the best management practices will likely produce higher quality chickens more efficiently. 3 Farmers receive a base pay (per their contract) and potentially a bonus, based on the health and quantity of the flock (tournament system).”); available at <https://www.chickencheck.in/faq/tournament-system/> (last accessed May 22, 2024).

²³ Dozier III, W.A., et al. “Stocking Density Effects on Growth Performance and Processing Yields of

in production practices and inputs, such as stocking density, slaughter weight, bird gender, and breeder flock age, can impact the performance metrics used in determining the performance adjustments in tournament payment systems. If LPDs provide all growers in a tournament group similar-quality inputs and compare growers using similar flock production practices, or if they take steps to balance these differences over time or otherwise adjust pay to account for the relevant differences, these production factors under LPD control are unlikely to unfairly affect growers.

However, when LPDs rank growers who received lower quality (*i.e.*, lesser performing) inputs or less favorable flock production practices against growers who received higher quality (*i.e.*, higher performing) inputs or more favorable flock production practices the former group will likely receive lower pay than the latter group due to factors beyond their control. The ranking in the tournament will not reflect the grower's actual performance; it will reflect the inputs and flock distribution practices the grower received and the grower's performance relative to that of other growers. This is an unfair practice unless the LPD took effective steps to make appropriate adjustments to the compensation structure for this settlement group to reasonably neutralize the impact of the inequitable distribution of inputs and flock production practices within the ranking group. The problem this section of the rule addresses is how tournaments can be designed to effectively counteract the impact of inequitable tournament practices and lead to a fair comparison in poultry ranking systems.

Some LPDs have taken steps to design their compensation systems to appropriately account for the

maldistribution of inputs and production practices within a poultry ranking group. In response to the Advance Notice of Proposed Rulemaking that preceded the proposed rule for this final rule, LPDs and their trade associations described different steps LPDs have taken to correct for the inequitable distribution of inputs and production practices among growers and resulting comparisons. A meat industry trade organization indicated that LPDs are known to reduce unpredictability in grower outcomes by having contracts that evaluate performance over multiple flocks and adjust pay for factors outside growers' control. For example, some LPDs adjust payments for different densities of birds placed or provide credits for excess seven-day death loss.

Complementing these examples, AMS investigations have also found that some LPDs will attempt to ensure that broiler growers do not receive chicks from young laying hens too often because this can negatively affect growers' tournament performance. Some LPDs will communicate and correct ordinary problems on a timely basis. This helps growers avoid unintentionally punitive outcomes than would otherwise be the case. Yet, while LPDs assert that quality communication and fair operation are universal, AMS has found through interviews and comment review that LPD behavior currently depends extensively on the goodwill of the LPD, commonly via the manager of the local complex, and LPDs are not uniformly consistent in addressing issues that lead to unfair outcomes. Some local complexes make discretionary decisions that harm growers.

For instance, while LPDs regularly maintain extensive grower manuals, LPDs are not obligated to have their manuals address the range of situations that undermine a fair comparison or monitor whether the local complexes comply with that manual in practice. Growers need a poultry ranking system that meets a reasonably reliable standard. For there to be fair payments under sections 202(a) and 410 of the Act, LPDs must properly adjust their comparison-based compensation systems used in poultry grower ranking systems. Rules, like this final rule, must reasonably neutralize the impact of inequitable distribution of inputs and flock distribution practices on poultry grower compensation.

Because different inputs and flock production practices affect performance under the tournament, LPD decisions are an outsized component of grower payments. When an LPD operates a tournament that uses arbitrary or

inequitable delivery of inputs and production practices without establishing systems to mitigate material differences in inputs and production practices among growers in a comparison group or otherwise reasonably neutralize comparison impacts, the LPD has committed an unfair and deceptive practice under the Act. Such a practice is unfair because it uses criteria outside the growers' control to evaluate their performance. It is deceptive because it purports to evaluate growers on their effort when in fact it does not, often leading to payment rates that are wildly fluctuating and unpredictable. The duty of fair comparison established in this rule also arises out of the Act's prohibitions on unfair practices, unjust discrimination, the manipulation of prices, and failure to pay. Comparison-based compensation systems can be used to proactively cause harm to one or more growers by placing them in grower settlement groups that are inappropriate based on distribution of inputs or flock production practices. LPDs likewise can use league composition (*i.e.*, the formation of settlement groups) to manipulate prices downward for a given grower or group of growers. Finally, such practices can lead to a failure to pay for services provided. Violations of the Act include an LPD failing to maintain policies and procedures necessary to document the company's compliance with those fair comparison duties, owing to the Act's recordkeeping authorities (7 U.S.C. 221).

AMS is adding a new § 201.110, "Operation of broiler grower ranking systems," to regulate LPDs' operation of poultry grower ranking systems (*i.e.*, tournaments) for broiler growers. Paragraph (a) establishes an LPD duty of fair comparison in tournaments. This duty of fair comparison requires LPDs to structure their tournament system to provide a fair comparison among growers. AMS acknowledges that sometimes a fair comparison is not possible due to unforeseen differences in inputs or other circumstances, in which case an LPD must compensate growers through a non-comparison method specified in the contract that reflects a reasonable compensation to the grower for its services. Paragraph (b) establishes basic documentation that LPDs must maintain regarding how they design and operate their poultry grower ranking systems for broiler growers.

i. Section 201.110(a)—Fair Comparison

Paragraph (a)(1) requires LPDs that use comparison-based compensation systems for their poultry growers to design and operate their poultry grower

Heavy Broilers," Poultry Science 84 (2005): 1332–1338; Puro, Diego et al. "Broiler performance at different stocking densities." Journal of Applied Poultry Research 4.1:55–60 (1995). Burke, William and Peter J. Sharp. "Sex Differences in Body Weight of Chicken Embryos." Poultry Science 68.6 (1989): 805–810; Beg, Mah, et al. Effects of Separate Sex Growing on Performance and Metabolic Disorders of Broilers. Diss. Faculty of Animal Science and Veterinary Medicine, Sher-e-Bangla Agricultural University, Dhaka, Bangladesh, 2016; Wilson, H.R. "Interrelationships of Egg Size, Chick Size, Posthatching Growth and Hatchability." World's Poultry Science Journal 47.1 (1991): 5–20; Washburn, K.W., and R.A. Guill. "Relationship of Embryo Weight as a Percent of Egg Weight to Efficiency of Feed Utilization in the Hatched Chick." Poultry Science 53.2 (1974): 766–769; Weatherup, S.T.C., and W.H. Foster. "A Description of the Curve Relating Egg Weight and Age of Hen." British Poultry Science 21.6 (1980): 511–519; University of Kentucky/Kentucky Poultry Federation, Poultry Production Manual, <https://afs.ca.uky.edu/poultry/production-manual> (uky.edu), last accessed 08/21/2023.

ranking system (*i.e.*, comparison-based compensations system) in a way that provides a fair comparison among growers. This final rule uses in various places the definition of “poultry grower ranking system”—commonly called the tournament contract—already set forth in PSD regulations at § 201.2.²⁴ Recognizing that LPDs have long claimed that tournament contracts are designed to promote efficiency, not frustrate it, AMS has written this rule to affirm the duty to fairly compare growers. Specifically, this rule requires LPDs to advance a fair comparison among growers in a poultry ranking group based on grower effort and skill. Measuring performance based on input quality—which is outside of the grower’s control—is unfair and deceptive. LPDs have a multitude of means to maintain fair comparisons. This includes correcting for: input quality variations, inappropriate feed type delivery, gaps in feed delivery, variation in production practices such as flock density, pick-up time or pick-up weight across the comparison group. LPDs can manage fair comparisons through extending the period over which the comparisons are made, adjusting payment for certain inputs or production practice differences, or removing growers from tournaments where a fair comparison is not possible. LPDs can ensure league composition (ranking groups) are reasonably random and robust enough to establish a fair comparison baseline. LPDs can also establish processes for responding to complaints in a timely manner or making appropriate adjustments to comparisons. But LPDs violate the Act when they do not design and operate their comparison poultry compensation system in a manner that delivers a fair comparison among growers within any given ranking group.

Paragraph (a)(2) of § 201.110 establishes the factors the Secretary will consider in determining whether an LPD reasonably designed or operated its poultry grower ranking system to deliver a fair comparison among growers or whether the LPD must utilize a non-comparison compensation method. This provision establishes a violation for either the LPD’s failure to design or failure to operate a poultry grower ranking system to deliver a fair comparison among growers. In the first instance, AMS could bring an enforcement action for an LPD’s failure

to design the ranking system in a manner that would deliver a fair comparison; such an action would be based upon the processes set forth in the documentation required under paragraph (b) of this section. In the second instance, AMS could bring an enforcement action based upon an LPD’s failure to operate the ranking system in a manner consistent with the duty of fair comparison. Such a failure could be because the LPD was not following the documented processes or because in practice the documented processes do not deliver a fair comparison. The factors listed in § 201.110 (a)(2)(i) through (vi) are designed to establish what constitutes reasonable delivery of a fair comparison. That is, the Secretary will examine these factors when determining whether the LPD has reasonably designed or operated their ranking system. Reasonableness should be viewed as an objective test that accounts for growers’ contract expectations, basic considerations of equity, and the LPD’s ability and willingness to prevent harms to growers resulting from factors outside growers’ control. However, it should also provide some flexibility to LPDs to achieve distinct goals provided they are well-designed, justified, and not otherwise unfair or deceptive.

Paragraphs (a)(2)(i) and (ii) of § 201.110 address whether an LPD’s distribution of inputs and assignment of flock production practices caused material differences in performance that growers cannot avoid, and whether the LPD made appropriate adjustments to compensation. Fair comparison of growers requires that growers do not receive a distribution of inputs or assignment of production practices that cause material differences in performance from other growers to whom they are being compared and are caused by factors outside of a grower’s control. Material differences in performance are differences that meaningfully (from the perspective of the grower) impact grower payments.

To comply with these requirements, LPDs must identify inputs and flock production practices under their control that impact grower payment and ensure that these factors do not meaningfully impact grower payments. LPDs also must improve their monitoring of how inputs and flock production practices are allocated across growers, and, as appropriate, adjust such allocations to reduce the unequal distribution among growers within a settlement group or across a given time period. An LPD could still provide certain growers with different inputs, for example because an LPD believed certain growers were

better at raising particular types or quality of birds (*e.g.*, chicks from older hens), provided it adjusted compensation if material differences in performance affected the comparison. The LPD would also be free to use a non-comparison method for those growers.

LPDs must adjust how grower pay is calculated if a fair comparison is impractical due to unavoidable inequitable allocations. For example, the LPD may determine that a five-flock average may be appropriate for determining a grower’s pay when the LPD provided chicks for that grower are later discovered to be diseased, and no fair comparison is reasonably possible, practical, or appropriate for that grower within the tournament for that flock. Any adjustment to how grower compensation is determined must use a non-comparison method specified in the contract that reflects reasonable compensation to the grower for its services. The contract should set forth the preferred approach(es) of the parties. Ensuring that agreed-to payment adjustments are fair will be part of regular AMS poultry compliance reviews. An average of the last five settlements by the grower is considered a non-comparison method for the purpose of the tournament settlement that the grower is being excluded from, even though the average is affected by the previous comparisons (unless unusual facts and circumstances call into question the fairness of such an approach).

Section 201.110(a)(2)(iii) addresses whether the designated time period used in an LPD’s comparison is appropriate, including whether the LPD uses one or more groupings, rankings, or comparisons of growers to mitigate the effects of any differences in inputs over the designated time period. Fair comparison of growers does not require that LPDs provide all growers precisely equal inputs and identical production practices for each flock. This rule permits LPDs to minimize production inefficiencies that would arise from a standard requiring strict equality in inputs, while avoiding an unfair comparison of grower performance. If the LPDs compare growers fairly over reasonable period of time, randomly selecting inputs is one way, in most cases, to minimize the effect of the flock-to-flock variance in inputs. Companies may use non-random distribution, including temporarily correct for what would otherwise be an inequitable distribution of inputs under an otherwise random system, provided they ensure comparisons are fair.

²⁴ Poultry grower ranking system means a system where the contract between the live poultry dealer and the poultry grower provides for payment to the poultry grower based upon a grouping, ranking, or comparison of poultry growers delivering poultry during a specified period.

AMS considers a period of one year or less to be a reasonable timeframe across which to compare growers' performance because it provides sufficient time to limit variation from one event while ensuring that LPDs treat growers fairly over a reasonable timeline. The one-year period coincides with commonly used five-flock averages and with one-year comparisons used in some live poultry growing arrangements.

Paragraph (a)(2)(iv) of § 201.110 addresses whether conditions and circumstances outside the control of the LPD render comparison impractical or inappropriate. A settlement group may have differences in LPD-provided inputs, LPD-assigned production practices, or other factors beyond the control of LPDs and growers that render a reliable comparison impossible. The Secretary will consider the facts and circumstances applicable to each case. One example might be the previously described situation where an LPD unknowingly delivered chicks to a grower that are later discovered to be diseased so that no fair comparison is possible.

Section 201.110(a)(2)(v) addresses whether an LPD has made reasonable efforts to resolve in a timely manner grower concerns regarding the LPD's exercise of discretion over the implementation of its fair comparison processes. In determining compliance with this requirement, through compliance reviews or in response to a complaint, AMS will consider whether an LPD has demonstrated enough responsiveness and commitment to resolving legitimate concerns to avoid potential secondary harm to the grower. What constitutes "reasonable efforts" and "timely" resolution of a grower's concerns will depend on the facts and circumstances of each case, with particular attention placed on whether and how the situation adversely impacts the fairness of the comparison(s) for the grower. For example, if a grower raises immediate and urgent concerns about feed quality, such as the delivery of feed meant for older chicks than the grower has, the LPD should have in place processes to—and in fact, actually—resolve this concern as soon as possible to minimize any additional undue damage to the grower's flock due to lack of proper nutrition. If a grower raises concerns about feed persistently being delivered late or in an insufficient quantity, the Agency will examine the LPD's "reasonable efforts" taken to adjust the delivery method. Additionally, an LPD is prohibited from retaliating against a grower in any manner for raising concerns as to

whether a fair comparison method was used.

Lastly, § 201.110(a)(2)(vi) states that the Secretary shall consider any other factor relevant to a fair comparison among broiler growers in a poultry ranking system. This provision gives AMS the authority to address any other facts or circumstances that adversely affected the fairness of the design or operation of the poultry grower ranking system. AMS will determine compliance by examining the facts and circumstances, and in particular, whether the LPD took specific actions to undermine the comparison process. For example, this prong allows AMS to consider whether an LPD's intentional grouping of certain growers in a poultry ranking group to manipulate or adversely affect comparison-based outcomes constitutes a violation of the Act.

When determining whether an LPD has designed and operated its broiler grower ranking system to provide a fair comparison among growers, AMS will consider the fair comparison factors set forth in § 201.110(a)(2) against how and to what degree comparison factors account for total grower compensation. When relative grower performance pay accounts for a very small portion of grower compensation, AMS expects differences in inputs and flock production practices to cause fewer material differences in pay. AMS expects this dynamic to operate on a sliding scale; the smaller the role of comparison pay in total grower compensation, the smaller the effect of variations in inputs and flock production practices on total compensation. AMS will also consider the design of the formula to determine its impact on the magnitude or distribution of compensation, if any.

In some situations, differences among LPD-provided inputs, LPD-assigned flock production practices, or factors beyond the control of both LPDs and growers make a reliable comparison impossible, impractical, or inappropriate for one or more growers. In such cases, § 201.110(a)(3) requires that an LPD must fairly compensate growers through a non-comparison method specified in the contract that reflects reasonable compensation to the grower or growers for their services. For example, if an LPD is unable to pick up a flock in a timely manner because of processing disruptions (as occurred during the COVID-19 pandemic), the LPD may remove the grower from the settlement rather than compare that grower's flock performance against growers delivering flocks of a significantly different age. In such cases,

the LPD must compensate the grower using a reasonable non-comparison alternative. Multiple approaches could be considered reasonable depending on the circumstances, and LPD costs are an appropriate consideration as part of those particular facts and circumstances. AMS is aware that LPDs often pay the grower an amount equal to the average rate they received over their previous five flocks. The non-comparison method is intended to fairly compensate the grower. Therefore, absent special circumstances where a rationale and an agreement to do otherwise are reasonable and appropriate (and documented as such), the non-comparison compensation method needs to equal or exceed the pay that the comparison-based compensation rate would have delivered. AMS will rely on the documentation of written processes set out in § 201.110(b), as well as the facts and circumstances of specific occurrences, to evaluate compliance.

ii. Section 201.110(b)—Documentation

Paragraph (b) of § 201.110 details the documentation an LPD must establish and maintain of its processes for the design and operation of its poultry grower ranking system for broiler growers that is consistent with the duty of fair comparison. This paragraph has changed considerably from the proposed rule to provide greater flexibility in meeting the terms of this regulation. AMS also revised paragraph (b) in response to commenters' concerns that the specific documentation requirements laid out in the proposed rule were very similar to documentation requirements delineated in existing regulations at § 201.102(b) and that burdening LPD service technicians with increased paperwork would take away from their core responsibilities of attending to the production needs of growers.

In the final rule, § 201.110(b) sets forth documentation requirements regarding LPDs' duty to ensure the fair design and operation of broiler grower ranking systems. Under section 401 of the Act, AMS is authorized to prescribe "the manner and form in which such accounts, records, and memoranda shall be kept" whenever the Secretary finds that the records of an LPD do not fully and correctly disclose the LPD's business transactions (7 U.S.C. 221). Paragraph (b)(1) requires that LPDs establish and maintain written documentation of their processes for the design and operation of a poultry grower ranking system that is consistent with the duty of fair comparison. This rule requires documentation to include

written processes, referred to as policies and procedures, regarding the process for (i) inputs under LPD control, (ii) flock production practices (iii) league composition, (iv) the evaluation period, (v) non-comparison factors, and (vi) LPD communication and cooperation with growers. These processes must provide a general description of the items that the rule requires to be included, with sufficient detail to provide a typical user of the documentation—such as a local poultry complex manager that directs the operation of the complex's tournament—with an understanding of how duty of fair comparison is to be operationalized within this complex's poultry grower ranking systems.

To simplify the documentation requirements and minimize paperwork burdens for poultry complex service technicians, AMS revised paragraph § 201.110(b)(1)(i), "Inputs under live poultry dealer control," from what was proposed by removing subparagraphs (b)(1)(i)(A) through (E), which delineated detailed requirements pertaining to identification, management, and adjustment of differences in input distribution to growers, and how LPDs adjust compensation calculations based on the inputs a grower receives. In the final rule, paragraph (b)(1)(i) contains no subparagraphs and simply requires that the LPD's written processes include how and when the LPD assigns, adjusts, or otherwise accounts for similarities and differences of quality and quantity in the delivery of inputs to growers. The removal of subparagraphs (A) through (E) simplifies the requirement by including one all-encompassing requirement that LPDs must explain how they assign, adjust or otherwise account for similarities and differences of quality and quantity in the delivery of inputs to growers. Revised paragraph (b)(1)(i) clearly requires that LPDs address all the ways that variation in inputs can impact a poultry growing ranking system, while giving LPDs flexibility in how to mitigate the impact of uneven distribution of LPD-provided inputs on fair comparison in the tournament and, hence, comparison-based grower pay. In sum, AMS determined that the deleted subparagraphs were not needed to establish that LPDs must explain in their written documentation how they account for the possible distortions and resulting inequities that can manifest in poultry grower ranking systems when they fail to properly account for variations in inputs.

Under paragraph (b)(1)(i), LPDs are required to create a written process for how and when the LPD assigns, adjusts,

or otherwise accounts for similarities and differences of quality and quantity in the delivery of inputs to growers. This provision requires LPDs to have a defined process governing how they will ensure the duty of fair comparison is met. Such a process needs to explain how the LPD will operate its poultry complex and its related poultry grower ranking system, so growers have fair opportunity to compete on a level playing field in individual flock settlements or in a comparison settlement that stretches beyond individual flocks, where the impact of variation in quality, quantity, or timing of inputs may be significantly reduced or eliminated. LPDs unfairly harm growers when they distribute inputs in a manner that disadvantages a grower relative to other growers in said tournament(s) and base their compensation accordingly. Growers cannot control the nature of the inputs they receive from their LPD, whether that be quality of chicks or feed, appropriateness of feed delivered for stage of growth, gaps in feed delivery, or delivery of veterinary services. Receipt of low-quality, insufficient, or inappropriate inputs can unfairly impact growers' performance in tournaments if the LPD does not have appropriate processes in place for mitigating such variation in input delivery. LPD processes required under paragraph (b)(1)(i) must include ongoing accounting and monitoring of inputs supplied to each producer using objective measures of quality and performance that are generally accepted in the industry. Such monitoring and accounting should aim for as minimal variation as possible in input delivery quality or quantity across the members of one or more grower poultry ranking groups, and appropriate mechanisms for detecting and correcting for input variations in a timely manner. Such processes should address key areas of concern, including allocation of chicks that differ in quality and performance, variation in quality or quantity of feed, or variation in medication across grower groupings. LPDs may include policies and procedures for balancing disparity of inputs either within a single flock or over multiple flocks as appropriate and feasible.

In the final rule, AMS also simplified § 201.110(b)(1)(ii), "Flock production practices," from that which was proposed. AMS removed subparagraphs (b)(1)(ii)(A) through (E), which described, in detail, the processes LPDs must include in the design and operation of their poultry grower ranking systems pertaining to

assignment of flock density at delivery, timing of pick-up, adjustment of comparison based on different assignment flock production practices, and adjustment of compensation calculations based on the grower's receipt of specific flock production practices. In the final rule, paragraph (b)(1)(ii) contains no subparagraphs and simply requires that written processes include how and when the LPD assigns, adjusts, or otherwise accounts for differences in production practices. The removal of subparagraphs (A) through (E) simplifies the requirement by including one all-encompassing requirement that LPDs must explain how they assign, adjust, or otherwise account for similarities and differences regarding assignment of flock production practices. Revised paragraph (b)(1)(ii) clearly requires that LPD address the ways that variation in flock production practices assigned to growers can impact a poultry growing ranking system, while providing flexibility on the appropriate processes LPDs can establish to mitigate the negative impact LPD-assigned production practices can have on fair comparison in the tournament(s) and, therefore, comparison-based grower pay. In sum, AMS determined that the deleted subparagraphs were not needed to establish that LPDs must explain how they account for the possible distortions and resulting inequities that can manifest in poultry grower ranking systems when LPDs fail to account for variations in flock production practices.

Under paragraph (b)(1)(ii), LPDs must maintain written documentation of its processes for how and when the LPD assigns, adjusts, or otherwise accounts for differences in production practices across growers in a poultry ranking system. Similar to paragraph (b)(1)(i), such processes should include ongoing monitoring of how flock production practices are allocated across different growers in one or more poultry grower ranking systems, and mechanisms for adjusting for disparities in flock production allocations in a reasonable time frame such that additional harm does not result. Such processes governing flock production processes should cover how and when the LPD assigns density at delivery; how and when the LPD manages pickup of birds with respect to slaughter weight and bird age; how and when the LPD adjusts how a grower is compared to other growers with different assigned flock production practices or otherwise adjusts the flock production practices the grower receives; any steps the LPD takes to adjust compensation

calculations based on suboptimal allocation of flock production practices to growers; and how and when the LPD minimizes, adjusts, or otherwise accounts for differences in production practices. LPDs can unfairly manipulate grower payments when they compare growers even within a single tournament settlement group within which the LPD has assigned different types of production practices to growers in the group. Under this rule, LPDs must develop policies and procedures that describe the processes for ongoing accounting and monitoring of LPD-determined flock production practices allocated to each producer. The LPD's processes must provide a consistent approach to minimize differences in production practice assignments and describe methods to compensate growers for differences that result in harms.

In the final rule, AMS also simplified paragraph (b)(1)(iii) of § 201.110 from what was proposed. In the final rule, AMS removed subparagraphs (A) through (C) from paragraph (b)(1)(iii) and instead separated out the requirements into three distinct paragraphs: (b)(1)(iii), "League composition;" (b)(1)(iv), "Evaluation period;" and (b)(1)(v), "Non-comparison."

Under the final rule, paragraph (b)(1)(iii), "League composition," requires LPDs to create written processes governing league composition, which is how LPDs assign groups of growers to settlement groups. AMS revised this paragraph for simplicity and readability. Formerly, the provision was contained in paragraph (b)(1)(iii)(C), reading, "If the live poultry dealer groups growers for settlement in any manner other than the one used in recent settlements, how the dealer determines such groupings." Settlement groupings, also called league composition, are most commonly based on their chronological availability for slaughter within the complex but could also be based on housing type or other commonalities across a group of growers. Generally, the settlement grouping is determined by flock placement timing, which commonly varies based on the timing needs of the growers. For example, growers may need additional time between flocks for cleaning, maintenance, vacation, or other similar reasons.

Paragraph (b)(1)(iii) of this rule serves to identify practices or circumstances that diverge from these ordinary reasons for determining settlement groupings. While legitimate reasons exist for deviating from a strict chronological availability-based grouping, this

provision is principally meant to ensure that LPDs do not use league composition to interfere with fair comparison by intentionally grouping specific growers together to lower the pay of one or more members of the settlement group, or to otherwise manipulate pay to deliberately benefit certain growers over others.

Under § 201.110(b)(1)(iv) of the final rule, "Evaluation period," the LPD is required to maintain written documentation of how it establishes a reasonable time period over which the LPD evaluates the duty of fair comparison. This provision was proposed with slightly different phrasing as paragraph (b)(1)(iii)(A). This provision requires the LPD to describe its process for how it determines the number of settlement groupings over which grower comparisons will be made. The duty of fair comparison requires that LPDs design and operate their poultry growing ranking systems to provide a fair comparison among growers. This means that the comparison must genuinely reflect effort by the growers, not variability in inputs or flock production practices, which are outside of the growers' control and thus not criteria that form the basis of a fair comparison. It may be that over the course of a year variations in inputs or flock production practices will cancel each other out. The evaluation period must account for the length of its growers' contracts and the reasonable expectation of renewal. If the duty of fair comparison requires five flocks, then the contracts need to span at least five flocks, or if they do not, there must be a very high likelihood that the contract will be renewed such that the growers will receive the five flocks and thus be subject to a fair comparison that evens out fluctuations in input quality or quantity or flock production practices.

In the final rule, § 201.110(b)(1)(v), "Non-comparison," requires that an LPD's written processes explain when the LPD might remove a grower from a ranking group, and how the LPD will compensate growers removed from a ranking group to satisfy the non-comparison compensation method required under § 201.110(a)(3). This provision was proposed as paragraph (b)(1)(iii)(B) in similar language. There are myriad reasons why an LPD may decide to remove a grower from a ranking group. For example, LPDs may not have enough comparable growers with which to make a reliable comparison in the current grouping and may use growers settling in previous periods to make a reliable comparison. Likewise, a specific grower may have

received undesirable inputs or an assignment of production practices that materially impacted the grower's performance, necessitating the removal of the grower from the grouping and compensation under a non-comparison compensation method. Under this provision, the LPD is required to explain how and when the LPD removes a grower from a ranking group because the grower received unfavorable inputs or production practices and how it will fairly compensate such growers through a non-comparison compensation method.

In the final rule, § 201.110(b)(1)(vi), "Communication and cooperation," is very similar to the provision as proposed, with the only notable change being the paragraph designation: in the proposed rule, the paragraph was designated paragraph (b)(1)(iv); in the final rule, the paragraph is designated paragraph (b)(1)(vi). This paragraph requires LPDs to create written processes for how the LPD will resolve a grower's concerns with the LPD's exercise of discretion over the implementation of the policies required by this section, including the timeliness of the resolution. A tournament system cannot be fair if it fails to permit growers to contest, without fear of retribution, negligent or malicious actions taken by the LPD that may impact grower performance. The rule provides flexibility on how LPDs can satisfy this requirement. A range of procedures are available, such as timely communication with complex management, communication with LPD headquarters, and grower councils, wherein disputes are resolved with input from other growers. The implementation of processes to manage and resolve grower disputes can serve to alert LPDs to potential unfairness in their comparison of growers and enable them to resolve issues in a timely manner.

In the final rule, AMS removed proposed § 201.110(b)(2), "Compliance review." In the proposed rule, this paragraph delineated detailed compliance review procedures for the processes set out in paragraph (b)(1) of this section. AMS removed this requirement in response to comments that such self-audits are a somewhat burdensome requirement for LPDs that can be eliminated with minimal effect on effective compliance. Rather than requiring self-audits, AMS will review the policies and procedures required under § 201.110(b)(1) through its ongoing compliance review process. This will ensure regular review of LPDs' compliance with the provisions of this

regulation with minimal additional recordkeeping burden on LPDs.

In the final rule, § 201.110(b)(2), “Record retention,” mirrors that which was proposed, with the only notable change being the paragraph designation: in the proposed rule, the paragraph was designated paragraph (b)(3); in the final rule, the paragraph is designated paragraph (b)(2). This paragraph requires LPDs to retain all written records relevant to their compliance with paragraph (b) for no less than five years from the date of record creation. These records should be made available to AMS upon request. Relevant records include, for example, copies of existing processes (policies and procedures); written documentation of LPD processes used within the last five years, including documentation of inputs and flock production practices provided to growers; written documentation of league composition; written documentation of grower complaints and their resolution; board minutes discussing compliance with this section for five years from the date of the board meeting; current and expired grower contracts for five years for the date of last effectiveness of the contract; disclosures provided to growers for five years from the date of the disclosure is provided to the grower; information on payments to growers or other forms of adjustment made to ensure a fair tournament, etc. Under the regulation, LPDs must retain these records for five years to enable the Agency to monitor the evolution of compliance practices over time in this area and to ensure that records are available for what may be complex evidentiary cases. As noted earlier in this section, section 401 of the P&S Act authorizes AMS to prescribe the manner and form in which LPDs keep business records. This recordkeeping requirement will enhance LPD management’s ability to establish and monitor compliance, as well as AMS’s ability to supervise and enforce the rule.

iii. Compliance and Enforcement

Compliance with § 201.110(b) requires LPDs to retain records that document the LPD’s design and operation of broiler grower ranking systems in a manner that is consistent with the duty of fair comparison. These policies and procedures are necessary to document compliance precisely because the options for delivering a fair comparison are so diverse. Policies and procedures developed pursuant to this rule should describe the LPD’s framework for assigning inputs and LPD-determined flock production practices, comparing grower

performance, and resolving growers’ concerns regarding the LPDs’ implementation of its policies and procedures. Recordkeeping should enable periodic review by the LPD to examine and report on the LPD’s compliance with its established written processes and, as such, with its compliance with the duty of fair comparison.

Enforcement of § 201.110 can occur in several ways. Growers can contact AMS–PSD to submit a complaint regarding an alleged violation of § 201.110. PSD would then investigate, which could lead to referral to DOJ for appropriate action or, where failure to pay is implicated, to USDA enforcement through administrative action.²⁵ AMS will also review LPD contracts, along with other required records from the LPD, in connection with routine compliance reviews and investigations to ensure LPD compliance. Injured individuals also have a right to proceed directly in Federal court.

C. Broiler Grower Capital Improvement Disclosure Document (§ 201.112)

AMS is finalizing new § 201.112, “Broiler grower Capital Improvement Disclosure Document,” which requires that LPDs provide growers with a Capital Improvement Disclosure Document (Disclosure Document). Paragraph (a) requires that when an LPD requests that a grower make an additional capital investment, the LPD must provide the grower with a Disclosure Document. Paragraph (b) describes the required disclosures in the Disclosure Document. AMS made slight modifications to provisions of paragraph (b), which will be described below. AMS also modified proposed § 201.112 in response to public comment by adding a new paragraph (c), which requires the LPD to assist with translating the Disclosure Document.

The inclusion of § 201.112 is necessary because LPDs often request or require that growers make costly additional capital investments, which may benefit LPDs and growers in some ways, but may also be problematic and unfair. The LPD requesting an additional capital investment may be deploying bargaining leverage and forcing the grower to bear unreasonable risk, and the purposes, processes, and outcomes of the additional capital investment may be opaque, complicated, or otherwise difficult to evaluate. Additional capital investments

can also further serve to lock in growers to specific LPDs, making it harder to switch. Growers, however, are often not in a position to choose not to make an additional capital investment. Many growers come under significant pressure from LPDs to make a requested additional capital investment. Even when a grower has sufficient bargaining leverage to negotiate the terms of compensation, the LPD may not provide sufficient information for the grower to assess the full risk and reward of undertaking the additional capital investment. Indeed, based on AMS’s knowledge of industry disclosure practices and decades of hearing complaints from growers, growers today often undertake additional capital investments for the LPD without the opportunity to fully understand the additional capital investment’s purpose, design, risks, and impacts on their financial well-being; or, are pressured in some way to make those investments.²⁶ Information asymmetry impairs growers’ ability to negotiate, effectively exercise independent decision-making to reject an additional capital investment, and, more broadly, manage their farming operation upon choosing

²⁶ MacDonald, James M. 2014, Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB-126, USDA Economic Research Service, https://www.ers.usda.gov/webdocs/publications/43869/48159_eib126.pdf?v=1829.6 (In a 2011 survey of contract growers, sixty percent of growers making any capital expenditures reported that the LPD required those expenditures). AMS–FTTP–22–0046–0799 (“Poultry companies require capital improvements that do not improve my bottom line. I must pay for the capital improvements, which may not be a capital improvement that will benefit my operation. It will not benefit the quality of the bird. The benefit is not clearly proven or explained, just I am required to make the improvement or get paid less or dropped as a grower.”); AMS–FTTP–22–0046–0737 (“For years, I’ve been forced to upgrade my farms facilities at my own expense just to maintain contracts. These costly and often unnecessary upgrades, dictated by companies like [name redacted], have left me in debt and struggling to cover basic expenses. The financial burden is unsustainable and has made it incredibly challenging to keep my farm afloat”); AMS–FTTP–22–0046–0176 (“For way too long these poultry integrators have been let off the hook for bullying, forcing their contract growers into making large investments in upgrades that will never see a payback beyond the initial investment to build the infrastructure to keep their growers under their total control and blaming growers for everything that goes wrong . . .”). United States Department of Justice, United States Department of Agriculture, (May 2010), Public Workshops Exploring Competition in Agriculture, <https://www.justice.gov/archives/atr/events/public-workshops-agriculture-and-antitrust-enforcement-issues-our-21st-century-economy-10> (“It’s typical for growers to be asked to do expensive upgrades on their poultry houses before this first loan of this building has been paid off. I know because I was one of those growers. The threats put before you, the communication, the threat is put before you, if you do not do this, they’re not going to bring you any more chickens to grow”).

²⁵ Additional information on reporting violations of the P&S Act can be found here: <https://www.ams.usda.gov/services/enforcement/psd/reporting-violations> (last accessed 11/13/2023).

to make the additional capital investment. When information asymmetries prevent growers from evaluating whether they are able to recoup their investment or whether they can engage in other farming practices that could achieve the goals of the additional capital investment, growers cannot effectively protect their financial interests or freely exercise decision-making with respect to their farming operation. Growers and AMS may also be unable to identify circumstances where LPDs are seeking to compete through additional capital investment practices that shift or hide costs to growers, which subverts the competitive process.

AMS has identified as deceptive those LPD contracting practices that fail to disclose key information about additional capital investments. Growers make critical investment decisions in reliance on the information required by this rule, most of which is not currently provided by LPDs. AMS emphasizes that disclosure under new § 201.112 is not, and is not intended to be, a remedy to unfairness in and of itself; rather, disclosure provides AMS and growers with information necessary to enforce their rights under existing § 201.216, “Additional capital investments criteria,” and the P&S Act more broadly, when terms are unfair. Without sufficient, simple, and clear disclosures, growers cannot assess the benefits or risks of making the investment. Indeed, given the role of performance pay in determining total grower compensation under the tournament, some voluntary additional capital investments may seem mandatory if growers want to maintain existing revenue levels, even if growers don’t fully understand the purposes and expected outcomes of the requested additional capital investment. Furthermore, growers experience considerable pressure to accept LPDs’ additional capital investment requests given LPDs’ market power, or substantial bargaining power, and growers’ relatively weak market position, including commonly a lack of meaningful choice among LPDs. A majority of broiler growers cannot change LPDs if their current relationship sours.²⁷

AMS notes that the existing regulation in § 201.216 is intended to allow the

Agency to partially mitigate additional capital investment problems for growers. The existing regulation sets forth criteria for whether additional capital investments would be an unfair practice or other violation of the Act, including whether the grower can decide against the additional capital investments; whether the additional capital investments were a result of coercion, retaliation, or threats by the LPD; and whether the additional capital investments can result in reasonable recoupment, or adequate compensation for the additional capital investments, among other non-exhaustive criteria. However, AMS has found that the presence of the criteria alone is insufficient to effectively address problems stemming from additional capital investments. For example, insufficient information about additional capital investments impacts the criteria at § 201.216(a) that seek to preserve the grower’s discretion to decline an additional capital investment. Lacking sufficient information about additional capital investments, a grower cannot effectively assess whether they would still be able to compete against other growers without the additional capital investment.

The Act requires production contracts to disclose the possibility of additional capital investment (7 U.S.C. 197a(b)). However, the majority of contracts contain no information relating to when or how additional capital investments may be required, nor the costs or risks of any such additional capital investment, nor what, if any, limits there are on an LPD’s ability to unilaterally impose additional capital investments that do not materially improve production efficiency or meet consumer demands. To better enable growers and AMS to guard against unfairness and to prevent deception, LPDs must disclose more information regarding the purposes, processes, and outcomes of additional capital investments they request from broiler growers. The disclosures must occur before growers take on the financial burden and risks of the additional capital investment. The provision of such information is not, in and of itself, the cure for unfairness, but rather a key tool for AMS and growers to halt abusive practices by arming them with the ability to identify those challenges sooner. The disclosures required in § 201.112 accomplish these goals. Furthermore, the act of disclosing information does not, in and of itself, render the action lawful. Even if disclosed, certain actions may be unfair

or deceptive practices under the P&S Act. Disclosure alone does not mitigate the legal or ethical ramifications of such practices.

The Agency has an existing regulation, 9 CFR 201.216, which sets forth a non-exclusive list of criteria the Secretary may consider in determining if a required additional capital investment violates the Act. In future cases, the § 201.112 disclosures on additional capital investments will improve the Secretary’s analysis of § 201.216. Whether the Secretary considers recoupment of the additional capital investment to be reasonable includes consideration of the projected returns under § 201.112(b)(6), the contract terms, and the return to an average grower operating under the LPD’s contract. AMS underscores the importance of length of the contract to secure a full opportunity for recoupment. AMS recognizes that growers in many instances cannot avoid the LPD’s unfair exercise of market power or bargaining leverage, and that the LPD failing to sufficiently and fairly compensate growers for an additional capital investment is not a cognizable benefit to growers or to competition.

i. Section 201.112(a)—Disclosure Requirement

In the final rule, paragraph (a) of § 201.112 requires that when an LPD requests that a broiler grower make an additional capital investment, the LPD must provide the broiler grower with a Disclosure Document that contains the information required by paragraph (b) of this section. AMS slightly modified this provision from the proposed rule by adding the paragraph heading, “Disclosure requirement.” Information provided in the Disclosure Document will help growers protect themselves at an earlier stage—before the investment—from unfair practices, by enabling them to report to AMS potentially unfair additional capital investment practices or bring their own action. Improved documentation will also enable AMS to take earlier and more effective action against problematic additional capital investment practices. Transparency will also enable some growers, where sufficient choice exists, to make better additional investment decisions. Importantly, clear disclosure of additional capital investment parameters will enhance growers’ ability to enforce their rights relating to unfair practices under § 201.216 (such as recoupment and discretion to refuse to make an additional capital investment), as well as other provisions of the P&S Act and regulations. Disclosure alone is

²⁷ MacDonald, James M. 2014. Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB-126, USDA Economic Research Service (Roughly 22 percent of growers operate in a pure monopsonistic local market, and that 52 percent of broiler growers (farms), accounting for 55 percent of broilers produced and 56 percent of total production, report having only one or two LPDs in their local areas).

not a remedy for an additional capital investment that is unfair, but the disclosures required by new § 201.112 will create a record that will facilitate the Agency's ability to enforce the Act under existing § 201.216.

This requirement applies prospectively to requests for additional capital investments. However, if the LPD has previously provided any disclosure to the grower that was incomplete or inaccurate, the company should consider revising it and providing an updated copy to the grower to minimize the risks of having engaged in a violation of deceptive practices.

ii. Section 201.112(b)—Disclosure Contents

Section 201.112(b) lists the items the Disclosure Document is required to disclose. AMS slightly modified this provision from the proposed rule by adding the paragraph heading, "Disclosure contents." The required disclosures must be prominently presented in a clear, concise, and understandable manner. Paragraph (b)(1) requires that the Disclosure Document provide the purpose of the additional capital investment for both the LPD and the grower and a summary of all research and other supporting material that the LPD has relied upon in justifying the additional capital investment. LPDs almost always have superior information regarding the outcomes of and risks around the contemplated additional capital investment. LPDs commonly research and design additional capital investments and usually have a plan or intended outcomes with respect to their request for the adoption of an additional capital investment. Growers have limited to no access to that information, yet they are often asked to expend hundreds of thousands or even millions of dollars to implement additional capital investments. As part of any assessment of risks or benefits relating to an additional capital investment, growers must be provided the information necessary to understand the intended purpose of the additional capital investment and have access to any research or other supporting material regarding that additional capital investment. For example, growers may make different decisions about their approach to additional capital investment depending on whether it is intended to be performance-enhancing (e.g., tunnel ventilation), whether it is intended to enable a change in the product offered (e.g., a switch to "No Antibiotics Ever"), or whether it changes the nature of the

controls and risks (e.g., automation and monitoring). Omissions of this information prevent growers from making an informed business decision, negotiating effectively for adequate compensation, or determining if and how the original bargain for exchange has been modified or altered. Thus, an LPD's failure to adequately disclose this information is deceptive and harmful to growers because that failure imposes undue financial risk and increases the likelihood of a poor financial outcome on the investment.

Paragraph (b)(2) of § 201.112 requires LPDs to provide clear additional capital investment financial incentives and schedules to growers. Under paragraph (b)(2), LPDs are required to disclose to the grower all financial incentives and compensation associated with the additional capital investment. The Disclosure Document shall clearly delineate how long such financial incentives or changes in grower compensation will last and the degree to which benefits accruing to growers making such investments are contingent on how widely they are adopted by other growers. Compensation and financial incentives are broad terms and may include changes to grower base pay or performance pay, payments specifically linked to adoption of the particular technology resulting from the additional capital investment, and any other changes to the economics of the grower's relationship with the poultry company associated with making the additional capital investment or its implementation once made. Clearly disclosing financial incentives will assist the grower in assessing the relative risks of non-recoupment, as the reliability of those incentives may vary based on the duration of the contract and whether other growers are likely to incorporate the additional capital investment technology in a way that would make recoupment through performance pay less reliable.

Paragraph (b)(3) of § 201.112 requires that LPDs disclose all construction schedules related to the request for the additional capital investment. Clearly disclosing expected grower construction schedules and other repayment schedules also will assist the grower in assessing incentives and risks relating to borrowing, construction, and payment timing. This disclosure will position growers to better analyze the business risk in undertaking an additional capital investment, including the operational risks relating to implementing the additional capital investment and risks of LPD strict enforcement of these implementation requirements. For example, comments (discussed in

further detail below in section V., "Comment Analysis") noted concerns about LPDs not being sufficiently lenient regarding construction schedules. By enabling growers to clearly understand each component of the additional capital investment requested by the LPD, the required disclosures will address key information asymmetries that exist between the LPD and the grower with respect to LPD's purposes, bases, and expectations for an additional capital investment. Growers will be better positioned to evaluate the true costs and risks from the additional capital investment, as well as the operational implications for their farming enterprise.

As proposed, paragraphs (b)(1) through (3) of § 201.112 included language requiring that LPDs describe within their Disclosure Document: (1) "any relevant" research or other supporting material that the LPD has relied upon in justifying the additional capital investment; (2) "all relevant" financial incentives and compensation for the grower associated with the additional capital investment; and (3) "all relevant" construction schedules related to the request for additional capital investment. After consideration and review of public comments, it became clear that the term "relevant" as proposed was ambiguous and confusing. Commenters expressed uncertainty regarding how to determine compliance with these requirements. Some stakeholders believed that the term "relevant" created an ambiguous requirement that could result in the inclusion of unnecessary documents that may not in fact be "relevant" to satisfy the required disclosures. AMS finds these comments persuasive and, thus, AMS has struck the term "relevant" from paragraphs (b)(1) through (3) of § 201.112. After the change, paragraphs (b)(1) through (3) require LPDs to submit: (1) all research and other supporting material that the LPD has relied upon in justifying the additional capital investment; (2) all financial incentives and compensation for the grower associated with the additional capital investment; and (3) all construction schedules related to the request for additional capital investment. The removal of the word "relevant" will ease the burden on LPDs by removing ambiguity regarding which disclosures are required to be included in the Disclosure Document. This technical change does not increase the burden of the disclosure requirement; it merely removes ambiguous phrasing while retaining the same disclosure requirement proposed in the proposed

rule. This change will prevent inconsistencies in LPDs' interpretation of what disclosures are required by paragraphs (b)(1) through (3).

In the final rule, § 201.112(b)(4) requires that LPDs disclose their expectations regarding housing specifications associated with the additional capital investment. LPD housing specifications are critical components to any additional capital investment. The provision of these basic details regarding the additional capital investment will enable a grower to understand the workings, process, and design characteristics of the requested additional capital investment. They thus would enable a grower to identify business risks associated with undertaking the additional capital investment, as well as any unfair or otherwise impermissible additional capital investment practices prohibited under § 201.216. This provision remains unchanged from the proposed rule.

In the final rule, AMS revised § 201.112(b)(5). As proposed, paragraph (b)(5) required that LPDs disclose any required or approved manufacturers or vendors. In the proposed rule, AMS solicited comment on whether paragraph (b)(5) should also require the disclosure of any material financial benefits that the LPD, or any officer, director, employee or family member of any such person, receives from the use of the required or approved vendor.²⁸ Commenters indicated that LPDs should not be allowed to require growers to use certain equipment or vendors, especially when those LPDs hold any amount of financial interest in those equipment companies or specifically required vendors. Therefore, in the final rule AMS expanded paragraph (b)(5) to require disclosure not only of required or approved manufacturers or vendors, but also all financial benefits that the LPD or any officer, director, decision-making employee, or close family member thereof receives from the use of the required or approved manufacturer or vendor.

In the additional capital investment Disclosure Document, the LPD must disclose any required or approved manufacturers or vendors, and any financial benefits that the LPD or its officers (such as CEO, President, Secretary, etc.), members of its board of directors, decision-making employees, or close family members of any such person, will receive from using such a manufacturer or vendor. Decision-making employees refers to those employees who are involved with the decision-making for the additional

capital investment and its implementation. A close family member covers an immediate or other family member where a reasonable person would question the impartiality of the business judgment of the decision-maker. This component of the Disclosure Document applies to possible conflicts of interest that may influence specifications for required or approved manufacturers or vendors.

The additional language is similar to an existing disclosure requirement under the Federal Trade Commission's Franchise Rule, but requires disclosure of benefits from more individuals.²⁹ AMS found this addition persuasive because it is designed to promote a similar purpose by protecting the more financially vulnerable party—who is making a significant investment—from incurring debt or otherwise expending scarce resources, not solely to achieve the investment's purpose, but rather as a reflection of the presence of a conflict of interest on the part of the less financially vulnerable party (the LPD).

Section 201.112(b)(6) requires that LPDs provide a financial analysis of projected returns the grower can expect related to the additional capital investment, including any assumptions, risks, or uncertainties, sufficient to allow the grower to make their own projections. The language of the final rule is slightly simplified from that proposed to remove the hyphenated text and incorporate that same language closer to the end of the sentence. This technical change improves the readability of the provision without changing its meaning as proposed. This provision is designed to enable the grower to evaluate the reliability of the financial returns that the grower could receive over the duration of the contract. Such information would include, where relevant, assumptions regarding the expected likelihood of whether other growers will adopt the additional capital investment and the impacts on the reliability of returns in relation to the incentives. Financial analysis of projected returns is critical to enabling growers to understand the opportunities, and hence the risks, they may be taking on. For example, revenue projections should include assumptions that can be relied upon by growers in relation to annual flock placements, stocking density, and the expected distribution of performance pay. Omission of this information is central to the inability for growers to effectively identify whether they can adequately recoup the additional capital investment

or whether the additional capital investment is otherwise unfair.

Disclosure under § 201.112 is more detailed than LPD disclosure under the existing regulation in § 201.102(d)(2). The existing disclosures provide guidance to the grower with respect to the relative risks associated with contracting with the LPD to prevent deception before it harms the producer. The disclosures required in this final rule focus on ensuring that growers are aware of known or reasonably expected sources of returns, risks, and costs (including costs such as labor, operating, maintenance, and other costs associated with a request for an additional capital investment). Thus, § 201.102(d)(2)(i) and (ii)³⁰ is a focused revenue disclosure, and references situations where contracts are modified due to additional capital investment or otherwise and requires a projection from LPDs when contract modifications dilute the value of the 5-year revenue tables required in § 201.102(d)(1). If § 201.112 is applicable to the LPD and incorporates what is otherwise required under § 201.102(d)(2)(i) and (ii), the LPD can use one set of disclosures for both § 201.112 and § 201.102(d)(2)(i) and (ii).

Finally, § 201.112(b)(7) requires that LPDs include in the Disclosure Document a specific statement that the Disclosure Document has not been reviewed by USDA, and that false and misleading statements or material omissions may violate State and/or Federal laws.³¹ The statement must also indicate that violations of Federal and State laws may be determined to be unfair, unjustly discriminatory, or

³⁰ (2) If poultry housing specifications for broiler growers under contract with the complex are modified such that an additional capital investment may be required, or if the 5-year averages provided under paragraph (d)(1) of this section do not accurately represent projected grower gross annual payments under the terms of the applicable broiler growing arrangement for any reason, the live poultry dealer must provide the following information:

(i) Tables providing projections of average annual gross payments to broiler growers under contract with the complex with the same housing specifications for the term of the broiler growing arrangement at five quintile levels or by mean and standard deviation expressed as dollars per farm facility square foot.

(ii) An explanation of why the annual gross payment averages for the previous 5 years, as provided under paragraph (d)(1) of this section, do not provide an accurate representation of projected future payments, including the basic assumptions underlying the projections provided under paragraph (d)(2)(i) of this section.

³¹ This mirrors language in the FTC Franchise Rule at 16 CFR 436(e)(2) that refers to the FTC's position on Franchise Disclosure Documents (FDDs), specifying that while the FTC requires franchisors to provide accurate disclosures, it does not verify the content of the FDD, nor does it endorse the franchise offering.

²⁸ 89 FR 49002, 49025 (June 10, 2024).

²⁹ 16 CFR 436.5(h)(6).

deceptive and unlawful under the P&S Act, as amended. AMS does not intend for the Disclosure Document to be a means by which LPDs may waive any unfairness provisions in law or regulation. AMS maintains that a determination of unfairness is dependent on the facts and circumstances of each case. The required statement must also include Packers and Stockyard Division contact information that growers can use to report violations and other concerns. Lastly, the statement must provide website contact information for those seeking additional information on rights and responsibilities under the P&S Act. This provision is unchanged from the proposed rule.

AMS underscores that the information required to be set out in the Disclosure Document is not currently provided to most growers or in all circumstances. These omissions present material risk of deceiving growers, as well as subjecting them to potentially unfair practices which they are unable to identify at an early enough stage to halt them in their incipency.

iii. Section 201.112(c)—Translation

In the final rule, § 201.112 contains a new paragraph (c). In the proposed rule, AMS asked commenters what considerations, if any, AMS should take into account with respect to the timing, delivery, or readability with respect to the Disclosure Document.³² AMS also specifically asked commenters whether it should include a provision requiring that LPDs make reasonable efforts to assist growers in translating the Disclosure Document and to ensure that growers are aware of their right to request translation assistance.³³ In response to the proposed rule, including specific questions posed related to translation, some commenters requested that translations of the Disclosure Document be made available in languages other than English. Therefore, AMS is adding paragraph (c) to § 201.112, which requires that, upon delivery of the Disclosure Document to the grower the LPD must make reasonable efforts to ensure that the grower is aware of their right to request translation assistance and must assist the grower in translating the Disclosure Document. Reasonable efforts include, but are not limited to, providing current contact information for professional translation service providers, trade associations with translator resources, relevant community groups, or any other person or organization that

provides translation services in the poultry grower's geographic area. Depending on the facts and circumstances (such as convenience, expense, and timeliness of the translation), reasonable efforts may also include allowing the grower access to a computer-generated translation of the Disclosure Document and additional time to review any translated Disclosure Document. An LPD may not restrict a broiler grower or prospective broiler grower from discussing or sharing the Disclosure Document for purposes of translation with a person or organization that provides language translation services. Nothing in the rule prevents companies from providing a translation, provided it is complete, accurate, and not misleading.

This addition of translation assistance is necessary because language barriers can prevent poultry growers from understanding the Disclosure Document, which would thwart the purpose of § 201.112. If growers do not have a reasonable opportunity to understand the Disclosure Document due to language barriers, the goal of remedying deception is thwarted. Notably, the translation requirements under § 201.102(g)(4) apply to § 201.112 if the latter is applicable to the LPD and incorporates what is otherwise required under § 201.102(d)(2)(i) and (ii) in a single disclosure that meets the requirements of both § 201.112 and § 201.102(d)(2)(i) and (ii).

iv. Compliance and Enforcement

Compliance with § 201.112 requires LPDs to include the information and topics described in § 201.112(b)(1) through (7) in the Disclosure Document and provide that document to growers when requesting an additional capital investment. LPDs are also required to inform growers of their right to request translation assistance and/or assist growers with translation of the Disclosure Document, if necessary.

Enforcement of § 201.112 could occur in several ways. Growers could contact AMS (PSD) to submit a complaint regarding an alleged violation of § 201.112. PSD would investigate, which could lead to a referral to DOJ for appropriate action or, where failure to pay is implicated, USDA enforcement through administrative action.⁴⁴ As necessary for compliance enforcement or during investigations, PSD will review Disclosure Documents to ensure completeness. Injured individuals also have a right to proceed in Federal court.

D. Severability (§ 201.290)

AMS is adding § 201.290, "Severability," to subpart N to confirm

that if any provision of this rule, any component of any provision, or any provision of subpart N is declared invalid or if the applicability thereof to any person or circumstances is held invalid, it is AMS's intention that the validity of the remainder of the provision or the applicability thereof to other persons or circumstances shall not be affected thereby with the remaining provision, or component of any provision, to continue in effect. Such a provision is typical in AMS regulations that cover different topics and is included here as a matter of housekeeping.

This rule aims to address different harms common in the broiler production industry: lack of payment transparency in broiler growing arrangements, unfairness in tournament operations, and lack of disclosure from LPDs regarding additional capital investments. Each of the new sections can operate independently in the absence of the others. Conduct that violates one section is not dependent on protections put in place by other sections. For example, if an LPD discounts the rate of compensation provided in a broiler grower arrangement in violation of § 201.106, the Agency would still be able to enforce this provision even if the provision requiring the fair operation of broiler grower ranking systems (§ 201.110) were struck down. These are not inextricably connected regulations: § 201.110 focuses on establishing a fair comparison among growers in a tournament, while the focus of § 201.106 is ensuring clear (no discounting) and reliable (not unreasonably variable) rates of compensation disclosed in the contract. As another example, if the provision regarding additional capital investments (§ 201.112) was struck, AMS would still retain criteria under § 201.216 to evaluate whether requiring an additional capital investment constitutes a violation of the P&S Act.

AMS intends that the severability provision operate to the fullest extent possible. For example, under § 201.110(b)(1), "Policies and procedures," if the league composition requirement in paragraph (b)(1)(iii) is severed, this does not necessarily negate the benefits or make unenforceable the other processes requirements contained in paragraphs (b)(1)(i) (inputs under LPD control), (ii) (flock production practices under LPD control), and (iv) (evaluation period), etc. Similarly, AMS intends that the severability provision apply to all of subpart N. If one of the new regulations implemented via this final rule is severed, this does not make

³² 89 FR 49002, 49025 (June 10, 2024).

³³ *Ibid.*

unenforceable the existing provisions in subpart N. In other words, if the benefits of a section in subpart N remain intact without the unenforceable provision, AMS's intent is to retain the enforceable provisions of the section. AMS notes that this discussion is illustrative and not exhaustive.

V. Comment Analysis

Overview

The Poultry Grower Payment Systems and Capital Improvement Systems proposed rule, published on June 10, 2024, received 758 comments, some with multiple signatories, over a 60-day comment period. Of these comments, 671 were in clear support of the rule (the majority of these consisting of form letters from advocacy campaigns), while 13 comments were in clear opposition to the rule and the remaining 74 were ambiguous or unclear. A variety of stakeholders commented on the proposed rule, including farmers' coalitions, government entities, advocacy organizations, industry trade organizations, processors, producers, and other non-affiliated, individual parties. Topics that garnered considerable attention in the proposed rule, both positive and negative, included the rate of compensation, transition and implementation costs, the duty of fair comparison, and reasonable recoupment of required additional capital investments. A common theme among the majority of supportive comments, particularly by growers, was the fear of retaliation underlying their concerns about LPD practices.

Many farmers' coalitions, advocacy groups, and individual producers argued that LPDs would easily find ways to deny producers fair payment, especially during the industry's transition to adopt the proposed changes. For example, while many commenters supported § 201.106's 25 percent comparison-based compensation presumption, most of these supporters requested other changes to the final rule, such as requiring performance-based pay to be applied at the individual level and pairing it with a requirement of a fair minimum base pay. Other common recommendations for financial safeguards included making the option for non-comparison-based pay more accessible to producers and requiring that producers' contracts be long enough to ensure a reasonable rate of return for their loans.

Another common theme among commenters was the fear of LPD retaliation against producers who made unfairness claims, requested non-

comparison-based pay, refused to take on an additional capital investment, etc. Many individual producers shared personal experiences of retaliation, often in the form of intentionally unequal inputs and threatened or actual contract termination, for speaking out against unfair practices. Many commenters emphasized the inherent power imbalance between both parties, pointing out that producers, who carry high amounts of debt, depend on LPDs for paying down the debt. Moreover, commenters described feeling or receiving intimidation against making unfairness claims and pressure to adhere to unfair terms. For instance, commenters described receiving unexpected deductions or variability in pay and had no choice but to accept their circumstance. Commenters recounted struggling to make ends meet as a result. If they ranked lower than other growers for one or more settlements, the resulting decrease(s) in compensation left them unable to afford necessary expenses. Some commenters stated that experiencing these losses forced them to sell their families' farms, driving them out of the industry entirely. Many commenters requested that the final rule include specific protections against retaliation for producers who made unfairness claims against their LPD or who refused to take on an additional capital investment required by their LPD. Many other commenters requested greater protections for producers who receive unequal inputs from their LPDs, describing numerous input variables that can be and have been exploited by LPDs to deliberately lower producers' placement in their tournament.

Conversely, comments in opposition, many from industry representatives, defended the current system and expressed concerns about the proposed rule. These commenters asserted that the rule is unfair to growers who are successfully operating in the current system and that the rule would unfairly punish high performers. These commenters also stated that the rule disregarded the self-interest of LPDs in ensuring grower success. Opposing commenters further stated the rule would be overly burdensome for the industry to implement.

A. Section 201.106

i. Transparency in Pay

Comment: Many commenters, especially growers and advocacy organizations, highlighted the need for stronger protections, greater transparency, and a more equitable balance of power within the poultry

industry. Commenters emphasized that greater transparency from LPDs is essential for a fair and equitable payment system. Specific concerns stemming from inadequate transparency included the inability to predict income due to fluctuations in flock-to-flock payments, and payments below the base price due to factors outside of growers' control. Commenters also suggested safeguards to prevent unfair payment deductions related to stocking density and other external factors. Advocacy groups raised concerns about the potential for LPDs to exploit the system and drive down grower base pay.

Other commenters, especially industry stakeholders, emphasized existing measures and cautioned against government intervention. These commenters asserted that growers face no uncertainty regarding income or input costs and opposed a fixed base price. They also asserted that most contracts already include minimum compensation floors and expressed concern that raising base pay would be unsustainable and lead to higher consumer prices. One commenter suggested that AMS identify and address potential gaps in grower education and outreach.

AMS response: AMS agrees with the comments that asserted the need for stronger protections, greater transparency, and a more equitable balance of power. Accordingly, AMS modified the proposed § 201.106 to include provisions that further these goals. Paragraph (a) will prevent LPDs from reducing a poultry grower's compensation based on the grower's ranking, grouping, or comparison to others. This will improve growers' ability to predict income. As discussed below, paragraph (b) will establish a presumptive limit on comparison-based performance pay, which will enhance growers' ability to predict their income from a contract by reducing variability from that rate due to fluctuations in flock-to-flock payments. Paragraph (c) works to prevent LPDs from exploiting their market power and associated bargaining power by requiring LPDs to notify the Administrator if there are any contract modifications that result in a reduced payment to poultry growers.

Existing regulation fails to protect poultry growers from injury in the manner Congress intended. Contrary to LPDs' claims, growers do face uncertainty regarding income, because the payment they will receive is not known until the growing cycle is complete and all growers' outputs are compared and performance payments are distributed. AMS has consistently heard reports from growers receiving

deductions or excessively variable compensation from LPDs such that their compensation does not align with the LPDs' initial representations.³⁴ Accordingly, a high percentage of growers' operations have sustained net negative incomes—an outcome that growers most likely do not anticipate before agreeing to contract with their LPDs.³⁵ Moreover, AMS has reviewed broiler growing contracts for decades during routine regulatory reviews of LPD's payment practices. While many contracts that AMS has reviewed already include minimum compensation provisions, these provisions are not an industry-wide practice, and do not cure the deception or unfairness arising from deductions in the rates of compensation in the contract, especially the base price, because the minimum price could be far below the base price or even the lower bounds of base plus performance pay. Moreover, requiring that minimum compensation be disclosed allows growers who have the option of contracting between multiple LPDs to meaningfully compare their options,

enhancing competition in the market for grower services in certain geographies. Nor is this an unworkable or unreasonable requirement; some LPDs have already adopted the reforms included in this final rule, and so this regulation builds on existing, successful models that that commenters said some LPDs have already found workable and effective.

Also, contrary to some commenters' claims, nothing in the regulation requires the base pay to be increased or otherwise be fixed in a manner that would affect supply or the price of chicken for consumers; rather, it is designed to address inadequate poultry grower compensation arising from deceptive and unfair practices by LPDs. Simply, § 201.106(a) enables LPDs to continue to set a base pay and provide bonuses based on a grower's grouping, ranking, or comparison to others, or through other payment incentives schemes. AMS acknowledges that grower education and outreach may be useful but believes that the responsibility to eliminate deception starts with the legal responsibilities Congress placed on the LPDs when it amended the Packers and Stockyards Act. This includes clear contract terms and transparent communication between LPDs and growers.

AMS notes that § 201.102 requires disclosure of stocking density in production contracts. Reductions in stocking density are best addressed under those disclosure requirements. AMS acknowledges that § 201.106 may not address every form of unfair practice that a grower may experience, such as reductions in flock placements or stocking density, and AMS remains committed to robust enforcement of section 202 of the Act to address the full range of potentially unfair practices that growers may face.

AMS agrees that USDA-sponsored education and outreach helps growers' make informed decisions. AMS is taking steps to increase producer education and outreach, including, for example, by establishing the *farmerfairness.gov* portal to facilitate ease of access for submitting complaints. AMS intends to expand education and outreach regarding this rule and other regulatory requirements. Disclosure and education, although beneficial, are unlikely to address unfairness because of the substantial difference in bargaining power between LPDs and growers. AMS's responsibility, however, is to enforce the Act. Better information concerning an unfair practice does not make the practice fair, nor alleviate the need for regulation.

ii. Performance Pay

Comment: Growers and supporting organizations highlighted the need for a more balanced system that protects growers from income volatility and unfair deductions related to factors outside of their control. Many commenters explicitly endorsed a 25 percent cap, citing the potential to curb the negative impacts of the tournament system while preserving performance-based incentives. Several advocacy groups supported calculating the variance at the individual grower level rather than the complex level to allow growers to make more informed financial calculations, better determine whether they are being treated unfairly by LPDs, and to limit the potential for favoritism and retaliation against individual growers. To strengthen fairness and transparency, commenters emphasized the need for objectively measurable bonus criteria and the importance of pairing the cap with a fair minimum base pay. One commenter suggested allowing exceptions for exceeding the 25 percent cap with proper justification. Another pointed to the bonus cap model in the turkey industry and a farm bureau suggested a 20 percent pay difference between growers. Several commenters indicated that bonuses should be linked to factors within a grower's control.

Some industry representatives emphasized the role of performance incentives in driving productivity. Commenters argued that limiting performance bonuses would disincentivize growers and negatively impact productivity. Some commenters questioned the basis for the 25 percent figure.

Many stakeholders expressed concern about the feasibility of case-by-case enforcement to ensure fair comparison-based bonuses. Comments reveal a consensus among stakeholders that case-by-case enforcement alone is insufficient to guarantee fair comparison-based compensation. Advocacy organizations argued that case-by-case enforcement is ineffective and inefficient and places an undue burden on growers who seek redress. These organizations cited past instances in which this approach failed to adequately protect grower interests. One commenter raised a concern about case-by-case enforcement's vulnerability to changing political landscapes, thereby creating uncertainty for growers and potentially discouraging them from reporting unfair practices. Many stakeholders advocated for clear regulations and proactive measures to prevent unfair bonuses rather than

³⁴ *United States v. Cargill Meat Solutions Corp.*, 1:22-cv-01821-ELH (D. Md. July 25, 2022) (LPDs did not adequately disclose the risk inherent in the tournament systems to growers, so growers could not reasonably evaluate the range of potential financial outcomes, manage their risks, or compare competing poultry processors); AMS-FTPP-22-0046-0777 (“[W]e were told our houses would be paid off raking in the money in 10 years[.] I am now out to twice that still in debt. . . .”); AMS-FTPP-22-0046-0876 (“In our communications with growers, we have learned that when they signed their initial poultry contract, most had expectations that their contract relationship with a poultry company would be one of mutual respect where both parties shared in the risks and rewards of producing chicken for consumers. They expected a transparent system that would reward them for their hard work and management services. Instead, what they quickly found was a dictatorial system that gives growers an unpredictable and often inadequate income stream, and allows poultry companies to shift risks onto growers, without fairly sharing in the economic rewards commensurate with their financial investment and services provided”); AMS-FTPP-22-0046-0156 (“Frequently, that deception begins even before poultry growers sign their contracts. It is a common story for growers to be attracted by unrealistic financial models and integrators’ promises of support. Once the contracts are signed, though, growers find themselves on the short end of a massive power imbalance”).

³⁵ MacDonald, James, Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB-126, USDA Economic Research Service (2014), https://www.ers.usda.gov/webdocs/publications/43869/48159_eib126.pdf?v=1829.6 (In 2011, nearly a third of smaller farms and nearly a fifth of larger farms realized negative net farm income); AMS-FTPP-22-0046-0780 (“I’ve been a poultry grower for almost 15 years and it is a shame that you have to have multiple jobs just to make ends meet. . . . Everyone is struggling in this economy right now and we have massive debt loads, insurance and utilities have skyrocketed parts are extremely high and even just the basic necessities to live are at critical levels. . . .”).

relying solely on enforcement. For example, one commenter requested that USDA establish guidelines defining unfair performance payment structures, proposing a presumption of unfairness for bonuses exceeding 25 percent of total compensation. The commenter also suggested that contracts offered to indebted growers could serve as potential evidence of anti-competitive practices, particularly by processors with significant market power.

AMS response: In the proposed rule, AMS specifically inquired whether it is presumptively unfair for comparison-based compensation to equal or exceed 25 percent of total compensation (base pay rate plus comparison-based) for any grower and asked a range of questions around the appropriateness of the specific threshold, how to calculate it, and how it would affect the industry. These questions included inquiries highlighting the role of the 25 percent presumption as a potentially binding constraint and how LPDs might respond in the compensation structures.

AMS agrees with the majority of commenters suggesting that comparison-based performance pay should be presumptively limited in order to balance the interests of growers and LPDs and prevent unfair outcomes. Grower concerns regarding thin margins, debt load, input variability, and tournament composition invoke equity issues that must be balanced with performance and productivity incentives. While useful as an incentive and a means to allocate pay, flock performance metrics, specifically feed conversion, as a proxy to grower effort are imperfect. Feed conversion itself is affected by variables beyond grower effort. AMS is not aware of existing technological innovations that could serve to better isolate grower effort or a measurement that would be exclusively under grower control.

Flock performance metrics serve some purposes in the assessment of grower effort and the allocation of grower payments. AMS's experience in analyzing performance payments suggest that ranking systems can be a useful and reasonably equitable mechanism for pay allocation with proper regulation in magnitude. Performance payments can reward grower effort without being an unlawfully deceptive or unfair practice.

In considering the appropriate form of regulation, AMS considered the variety of grower ranking systems currently in practice and the possible evolution and redesign of those systems, such that the purpose of the regulation would be resistant to circumvention while also providing an appropriate level of

flexibility to maintain an incentive structure. As referenced in the proposed rule, a presumptive limitation on performance pay magnitude strikes that balance. As a presumption, enforcement will occur based on an inquiry into specific factual circumstances. Based on currently available information, a bright line standard is likely to be overly rigid and may serve to deprive successful growers of the expected value of their services. Allowing LPDs to provide a rebuttal to justify exceeding the prescribed performance pay magnitude is a desirable feature for growers and LPDs alike because payment systems may reflect different circumstances at different complexes. Again, facts and circumstances matter, in particular around the variability of performance for the birds in question, the housing specifications, etc., as 25 percent may still be an appropriate limit. Whether the LPD took appropriate measures to comply with the duty of fair comparison under § 201.110 or otherwise mitigated other identifiable risks of unfair variability relating to the larger magnitude of the tournament will also be important. To underscore, AMS expects the presumption will not be easily overcome.

AMS acknowledges that some commenters preferred application of the presumption at the individual settlement level. AMS is concerned that application at the individual level will be difficult to monitor and enforce and could also result in overly rigid limitations on individual performance outcomes in flock settlements. That could dilute or distort grower performance incentives, including through capturing statistical outliers, which could result in restriction of performance payments that reduce aggregate grower revenue in ways that AMS believes are not presently necessary to address unfairness and deception under the tournament. Applying the presumption as an aggregate analysis at the complex-wide level offers several benefits to LPDs and growers. It allows smoothing of outliers from individual settlements and allows LPDs to focus on the design of the incentive system without requiring compliance on a grower-by-grower, individual settlement basis. An application at the complex-wide level will, nevertheless, have sufficient limitation on the available funds for comparison-based performance payments for individuals—owing simply to the constraint on funds for those purposes—so as to achieve the desired goal of right-sizing the

magnitude of the tournament for individual growers.

In considering the appropriate threshold at which to institute the presumption, AMS first reviewed a limited sample of existing ranking systems. AMS reviewed one to five years of confidential grower compensation data for four individual broiler complexes that AMS gathered in prior investigations. This sample included small, medium, and large bird sizes and some of the largest broiler LPDs that operate several other complexes across the U.S. Aggregate performance payments at these four complexes were 11.4, 17.4, 20.5, and 25.4 percent of total grower payments. AMS is not aware of any complex with performance payments that are as much as 26 percent of total payments. As noted above, in the proposed rule, AMS solicited comment regarding a 25 percent limitation on comparison or “performance” payments. Additionally, Wayne-Sanderson Farms, one of the three largest LPDs, recently agreed to a similar performance pay limitation at the 25 percent.³⁶ Governmental commenters noted the 25 percent cap has proven workable for both a major LPD and the growers contracted with Wayne-Sanderson. As numerous LPDs will likely need to modify contracts to achieve compliance under § 201.106(a) of this rule, finding that the industry upper bound of performance pay magnitude approaches 25 percent is also a relevant data point in AMS's determination that 25 percent is appropriate as the presumptive threshold for this regulation.

With respect to objectively measurable bonus criteria, AMS agrees that comparisons must be fair, and § 201.110 below sets out AMS's approach to mitigating comparisons based on inappropriate approaches to inputs, production practices, and related matters. AMS is not adopting further specificity with respect to bonus criteria in § 201.106 because AMS has designed this portion of the rule to operate in a simpler, more easily enforceable manner, including § 201.106(a)'s prohibition on deductions to any rate of compensation and § 201.106(b)'s limitation on the magnitude of performance pay overall.

³⁶ *United States v. Cargill Meat Solutions Corp.*, 1:22-cv-01821-ELH (D. Md. July 25, 2022); *United States v. Cargill Meat Solutions Corp.*, et al. (2022). Proposed final judgments and competitive impact statement. **Federal Register**. Retrieved from <https://www.federalregister.gov/documents/2022/09/16/2022-20014/united-states-v-cargill-meat-solutions-corp-et-al-proposed-final-judgments-and-competitive-impact>.

With respect to the importance of pairing the cap with a fair minimum base pay, AMS has adopted transition rules under § 201.106(c) to monitor and guard against unfair changes to aggregate compensation for growers. AMS sets out additional views on rates of return below.

AMS appreciates the commenter's suggestion regarding the bonus cap model in the turkey industry and the farm bureau suggestion of a 20 percent pay difference between growers. AMS did not consider the turkey industry in this final rule because contracting practices in the turkey industry are more diverse, in part owing to the biological differences in the birds which to some extent mute differences in outcomes, and so this rule would not necessarily be sufficiently tailored for that sector. However, the comment underscores the reasonableness of AMS's approach of a presumptive 25 percent limitation on aggregate performance compensation.

iii. Rate of Return

Comment: Grower and grower association commenters expressed concern around ensuring a reasonable rate of return for their labor and investments. Many commenters expressed broad concerns of monopsony power suppressing grower compensation. Some commenters stated the minimum base pay should reflect more competitive conditions, such as geographies where growers have the option to contract with three or more LPDs. Commenters stated that the minimum base pay should be sufficient to allow growers to make a reasonable return over the course of the contract, provided that the grower follows the LPD's required management practices and contract guarantees. One commenter suggested defining reasonable return as, at a minimum, enough net income to compensate poultry growers' labor hours at the state minimum wage rate. Others called for set minimum base pay, minimum flock placements and flock densities combining to allow growers to comfortably make loan payments plus a reasonable return. Commenters called for a more equitable and transparent compensation system that guarantees a reasonable rate of return, provides greater financial security, and addresses the power imbalance between growers and LPDs.

Grower commenters reported being underpaid and struggling to cover production costs, service debt, and earn a livable wage. Commenters highlighted a lack of adjustments for inflation, and penalties for factors outside their

control as contributors to insufficient compensation. They assert that the current payment structure often makes necessary capital improvements financially risky for growers, thereby hindering their ability to reinvest in their operations. Commenters also claimed that the current payment system lacks transparency regarding how performance payments are determined, the minimum price per pound rates, feed quality and ingredient details, breeder flock age and health, and chick hatch times and temperatures. Some commenters urged AMS to include in the final rule a presumption that an LPD is in violation of the P&S Act if the LPD does not offer a minimum base pay rate that is reasonably expected to cover the costs of operation, service debt associated with initial investments and capital improvements, and provide a reasonable rate of return. Commenters also advocated for a fairer system of deductions for condemned birds, arguing that deductions should be based on the actual weight of condemned birds rather than the flock's average weight.

To ensure fairness and sustainability, commenters proposed several solutions to the proposed question regarding whether AMS should prescriptively require grower base pay to earn "reasonable return," assuming they follow production practices. Many commenters recommended establishing a minimum base pay that: (1) ensures a livable income and covers basic production costs; (2) includes provisions for inflation adjustments to maintain real income over time; (3) allows for debt service, enabling growers to invest in their operations without undue financial strain; and (4) provides an opportunity for a reasonable return on investment, recognizing the inherent risks and capital requirements in poultry growing. Several commenters suggested a shift toward a base pay based on square footage, potentially with a bonus component determined through a tournament system. This approach aims to provide a more stable and predictable income stream for growers. However, one producer expressed concern that square foot pay would lower bird quality and reduce animal welfare.

Commenters also called for increased transparency from LPDs, including more detailed documentation and reporting requirements. This would provide growers with a clearer understanding of how their pay is calculated and enable better monitoring of potential unfair practices. Finally, commenters emphasized the need for mechanisms that protect growers from debt burdens

and provide a greater assurance of a return on their investments. Suggested measures include limiting the financial burden on growers for capital improvements mandated by processors and establishing mechanisms to share the risks associated with market fluctuations or unforeseen events.

AMS response: AMS appreciates the challenges that many growers face in negotiating fair pay, especially given the levels of concentration in many local markets, the take-it-or-leave-it form of LPD contracts, and the prevalence of the reports on troubling practices in the poultry industry. AMS aims to promote an industry market structure that can secure payment rates and contract terms for all growers that: (1) ensure a livable income and covers basic production costs; (2) include provisions for inflation adjustments to maintain real income over time; (3) allow for debt service, enabling growers to invest in their operations without undue financial strain; and (4) provide an opportunity for a reasonable return on investment, recognizing the inherent risks and capital requirements in poultry growing. AMS also recognizes the value of basing payment, in many circumstances, on square footage, potentially with a bonus component determined through a tournament system. In many cases, such a compensation structure could create a more stable and predictable income stream for growers because there would be a guaranteed payment rate based on factor that does not change.

This final rule seeks to make targeted reforms based on the information and strategies available to AMS at this time. In this final rule, AMS does not purport to alleviate all potential unfair aspects of the tournament system or of the integrated model of broiler production in concentrated markets. AMS believes that general principles of unfairness prohibit an unlawful exercise of market power or bargaining power that injures growers, including by providing returns that are below a reasonable return. AMS does not, however, identify a strict framework that prescribes exactly how to ensure competitive compensation. Rather, at present, AMS will apply a case-by-case enforcement approach to protect growers from unfair and unlawful market power or bargaining that denies growers reasonable compensation. In conducting its analysis, AMS expects to rely heavily on the facts and circumstances, including but not limited to:

- Relative levels of market power (including the number of LPDs growers can contract with in a given geography, whether there is meaningful choice in

contracting practices among LPDs in a given locality, the extent to which risk or other unfair contract terms are shifted to growers, the extent to which contracts are meaningfully negotiated, etc.), and other differences in bargaining power between growers and relevant LPDs;

- The type and nature of the unfair conduct (e.g., express or tacit collusion via information sharing, the presence of express or implied no-poach agreements, whether the tournament system was being utilized in a manner to prevent growers from negotiating or securing competitive compensation, the LPD's treatment of days out and condemnation within the tournament system, etc.);

- What constitutes competitive pay for growout services, especially in geographies where more LPDs are present;

- The rates of payment under the contract; in particular, whether the base rate a grower can expect to receive for performing fully under the contract can ensure a reasonable return;

- The costs of providing growout services over the contract, including appropriately and reasonably measured labor costs;

- The levels of contractually guaranteed and otherwise relied upon flock placements and density;

- Whether the length of the contract and reliance expectations on renewal are sufficient to assure reasonable return;

- The inclusion of cost-of-living adjustments or opportunities to secure those adjustments in contract renewals; and

- Where additional capital investment is required, factors relevant to additional capital investment, including those set forth in § 201.216 and the information set forth as required under § 201.112.

AMS underscores that many growers face high levels of local market power or bargaining power by LPDs, exacerbated by hold-up concerns arising from high levels of investment and reliance on LPDs for critical inputs. Moreover, growers face limited opportunities to avoid take-it-or-leave-it terms from their LPDs, including cuts to flocks or nonrenewals of contracts. In general, AMS expects this enforcement approach will, in practice, reinforce the principle that an LPD must provide a reasonable opportunity for a grower that delivers under the contract to earn a reasonable return over the life of the contract if they comply generally with the specified production practices.

AMS appreciates the commenters' interest in further enhancing transparency. AMS notes that this final

rule increases transparency for growers around rates of compensation (§ 201.106) and additional capital investments (§ 201.112), and also sets more fair standards around, and enhances transparency into, LPD practices relating to input and production practice distribution. It also complements other regulatory initiatives that AMS has already finalized to provide transparency around contracting and input distribution (88 FR 83210, November 28, 2023). AMS intends now to turn its focus to the important task of monitoring the implementation of existing mandates to evaluate the remaining gaps and needs.

AMS also appreciates grower comments around the challenges that debt burdens place on growers and on the importance of more fairly sharing the burden of market fluctuations or unforeseen events. A central purpose of § 201.112 is to enhance the information available to growers and to AMS to ensure the fairness of additional capital investments, and therefore LPDs' accountability, under § 201.216 and section 202 of the Act. For example, an LPD's failure to ensure the reasonable ability for a grower to recoup the cost of a required (including ostensibly requested but in practice coerced) additional capital investment would, on its own, be dispositive to show a violation of § 201.216. AMS recognizes that growers cannot avoid the unfair exercise of market power. Failing to sufficiently and fairly compensate growers is not a cognizable benefit to growers or to competition. (AMS's approach is discussed below in section V.C.ii., "Additional capital investment unfairness.")

With respect to new housing, as opposed to additional capital investments, AMS has also separately finalized the *Transparency in Poultry Grower Contracting and Tournaments* (Transparency Rule) rule that provides significantly enhanced transparency over the preexisting system.³⁷ As described in the Transparency Rule, these disclosures include returns broken out by quintile and other information delivered in a disclosure document when the grower receives any housing specifications and would be contemplating making additional investments. AMS expects to monitor the implementation of that rule and would, for example, examine circumstances where the disclosures were deceptive or misleading relating to securing the new grower's commitment to invest in housing.

³⁷ 88 FR 83210, November 28, 2023.

iv. Transition and Implementation

Comment: AMS asked what risks growers and/or LPDs might face during any transition to the proposed § 201.106. Concerns about transition and implementation risks for growers and LPDs centered on potential shifts in the market power dynamics and the administrative compliance burdens. Some commenters, especially grower advocates, farmers' coalitions, and legal institutions, were concerned about the potential for LPDs to exploit the new regulations by arbitrarily lowering base pay rates. They argued that this could undermine the intended fairness that the rule aims to achieve and called for explicit prohibitions against such practices.

A governmental commenter suggested that, for the duration of a reasonable transition period, USDA require that current payments remain overall comparable, so that LPDs cannot arbitrarily lower grower base pay or overall compensation during the transition period or impose other unfair contract terms. This commenter also suggested that USDA require that modified contracts have, at a minimum, the same length as the period covered by the grower's initial contract.

Advocacy associations urged USDA to closely monitor the industry's transition and establish fair minimum rates that are not lower than the average pay under the current comparison system. To minimize transition risks to growers, one advocacy association noted that AMS should not require submission of all contracts that are modified to comply with new § 201.106, in order to avoid a bottleneck in contract negotiations. Instead, they recommend that AMS require LPDs to submit representative contracts that show how they are calculating a fair base pay. The commenter also suggested an accountability mechanism rather than a pre-approval process so that LPDs can deliver to AMS the information necessary for the Agency to determine whether contract modifications are happening in compliance with § 201.106 and the Act.

Another advocacy association urged AMS to presume undue buyer power exists whenever an LPD offers a grower in debt a contract that, based on the minimum income possible from the contract's guaranteed flock placements, stocking density, and firm base price, does not give the grower enough income to pay off their debt. The commenter also stated that AMS should include a requirement that LPDs submit to AMS for review any contracts modified or revised to comply with new § 201.106

and should also require all LPDs to submit compensation data for review. This data can be used as a basis for requiring all integrators to offer base prices that rise to a truly competitive level, and that are consistent with grower cash flow and loan servicing expectations under original contracts.

AMS response: In response to these concerns, AMS is adding paragraph (c) to the final rule, so that if an LPD modifies a contract and reduces aggregate compensation to growers,³⁸ the LPD must submit notice of the change to AMS and include copies of the original contract and new contract, as well as any related Disclosure Documents. AMS can then adequately assess that reductions in aggregate grower compensation does not violate section 202 of the Act. Aggregate compensation enables sufficient flexibility for LPDs to adjust supply and deliveries based on changing market conditions. In any case, AMS regularly conducts compliance reviews of LPDs.

AMS has also considered the concerns that industry stakeholders have presented regarding the importance of LPDs having the ability to adjust payment to maintain a functioning market. This regulation allows for reductions to compensation that do not otherwise violate section 202 of the P&S Act. The LPDs are required to submit the prior contract, the new contract, and any Disclosure Documents related thereto. This is not a time-consuming or costly requirement as this information is already readily available to LPDs. It also does not stifle innovation as it does not impact novel contracting practices so long as they are fair and not deceptive. The regulation does not prevent contracts from being updated; it only requires a minimum level of review to ensure that the changes are not unfair or deceptive.

AMS is not, at this time, specifically requiring that modified contracts have, at a minimum, the same length as the period covered by the grower's initial contract. Instead, AMS is focusing on ensuring the grower compensation in aggregate remain unchanged for the initial period of compliance, as AMS views that factor as being at greater risk of immediate, unavoidable abuse from LPDs than the length of contract per se.

v. Benefit, Burden, and Cost

Comment: Several commenters emphasized the need for safeguards against LPDs leveraging their market power or bargaining power to offset any

losses incurred due to the rule. They argued that such protections are needed to ensure fair compensation for growers. On the other hand, industry stakeholders were concerned about the administrative burden of compliance. Processor commenters were opposed to submitting revised contracts and compensation data to USDA on the grounds that it is unnecessary and could lead to delays and increased costs and stifle innovation in contract structures. They argued that allowing LPDs to adjust base pay rates, within reason, is necessary to maintain a functioning market. An industry commenter stated the rule would require renegotiation of thousands of grower contracts, a potentially disruptive and costly process. The commenter pointed to the potential for uncertainty, economic risk, and nullification of lawful contracts.

AMS response: AMS acknowledges that this regulation would require renegotiation of many existing grower contracts. Due to sunk capital costs and thin margins, poultry growers are generally at a distinct disadvantage in the face of contract renegotiation and renewal. As explained in this final rule, however, AMS has determined the current structure of many contracts is unfair and deceptive and therefore unlawful under the Act. AMS is providing an extended effective date for the provisions of this final rule to provide additional time for LPDs and growers to modify contracts or otherwise renew under a new, legally compliant system. In addition, AMS recognizes that growers may be at risk of unfairness during any transition period and, accordingly, is adopting a transition requirement for LPDs to submit contracts upon modification or renewal if those contract changes result in decreased grower compensation. This requirement is designed to enable a smooth transition to the new system. AMS review will not delay contracts, as AMS will not be approving the contracts under § 201.106(c), but rather will be identifying unfair practices and potentially commencing enforcement. AMS's purpose is, as commenters urged, to safeguard growers against LPDs leveraging their market power to offset any costs they incur due to the rule's fairer and less deceptive approach to payment systems.

AMS rejects the view that this rule would stifle innovation in contract structures. It provides a small number of basic safeguards for the protection of growers, but otherwise does not dictate the specific manner in which LPDs compensate growers for their services. AMS is aware of a wide variation of existing contractual approaches to

compensation which would remain permissible under this final rule. For example, some contracts compensate on a per pound base rate while others use a square footage contract for base payments or a combination. Performance pay will still be permitted at an appropriate magnitude, and LPDs may continue to use a range of approaches for comparison-based pay, including flock-by-flock comparisons or longer rolling averages as some contracts currently do.

LPDs are also free to adjust base pay rates upwards based on grouping, ranking or comparison, which aligns with some industry views that the tournament system, within reason, is necessary to maintain a functioning market. LPDs can also continue to deduct growers' payment for noncompliance with contractual requirements, provided it is not based on the outcomes of the tournament.

B. Section 201.110

i. Input Variability

Comment: Overall, commenters broadly agreed that input variability poses a significant challenge to fair grower compensation within performance-based payment systems. While commenters acknowledged the difficulty of controlling certain inputs such as chick quality, stakeholders disagreed on the degree of control and intentionality surrounding input variability. Generally, growers pointed to examples of inconsistencies that impacted their performance, including inconsistencies in chick quality and hen age, which suggest a lack of control and potential for unfair outcomes. Industry commenters emphasized the challenges of controlling the inputs, such as chick quality, countering that they also lack control over certain inputs, particularly when ordered in bulk, which would make intentional manipulation difficult. One commenter challenged the assumption that input variability is intentional, controllable, and material, and asserted that USDA lacked evidence to prove the assumptions.

Regarding the impact of input variability on grower performance and fairness, commenters argued that since growers have limited control over key inputs (e.g., chick quality, feed delivery, or disease management), basing payments on performance relative to these inputs is inherently unfair. They emphasized that settlement outcomes under these conditions do not accurately reflect grower management skills or effort. Other commenters expressed concern that excessive variability in inputs such as chick

³⁸ Defined as "less than the prior annual-calendar year's complex-wide average gross payment to the grower."

health, feed delivery, and flock pickup within a settlement group creates significant financial risk for growers, especially over multiple flocks.

Industry stakeholders argued that requiring LPDs to control all input variations is impractical and could lead to inflexible systems that ultimately harm growers.

AMS response: AMS has gathered significant evidence from poultry growers that input variability in poultry tournaments can lead to unfair comparisons, and lead to inappropriate burdening of risk onto growers. AMS does not need to find that input and production practice variability is intentional, fully controllable, or material in all instances by the LPD to reach the conclusion, based on academic evidence, regulatory experience, and complaints from growers, that it exists and can and should be mitigated by LPDs. AMS has identified at least the following differences that may affect grower performance: breed,³⁹ bird sex,⁴⁰ breeder stock age,⁴¹ stocking density,⁴²

consistency of feed availability,⁴³ and the type and administration of veterinary medicines.⁴⁴ AMS also notes that chick genetics are currently proprietary and largely controlled by two companies, one of which is owned by one of the nation's largest LPDs.⁴⁵

This rule aims to set conditions on performance-based payment systems in contract poultry growing such that poultry growers are compared based on factors under their control. When poultry companies take appropriate measures, as prescribed in this rule to ensure a fair comparison, then contract poultry growing reduces a significant amount of risk to growers because the LPD provides the inputs.

The purpose of this rule is to establish a framework for fair comparisons to prevent unfair and deceptive practices that reduce pay. To the extent that input variability is creating unfairness, the rule requires LPDs to mitigate the impacts of input variability on the comparison. AMS recognizes that LPDs have an incentive to get full economic value of less productive chicks. Yet it is incumbent upon them under the Packers and Stockyards Act—and this rule's explicit duty of fair comparison—to structure their comparison-based compensation system to make a fair comparison among growers. Input differences should not be a significant variable over time in the determination of grower compensation. As commenters noted, excessive variability in input quality, timing, and flock pickup can cause significant harm to growers, hence the inclusion of explicit duties imposed on LPDs in this rule with respect to the design and operation of comparison-based poultry compensation schemes. Furthermore, LPDs must institute a non-comparison-based system when it is impossible for the LPD to conduct a fair comparison due to extenuating circumstances.

ii. Application, Material Difference, and Non-Comparison Method

Comment: While there was broad agreement on the importance of fair compensation for all growers, some commenters expressed concern about the rule's practicality, administrative burdens, and potential confusion regarding the definition of "material differences in performance." Commenters, especially farmers' coalitions and advocacy groups, endorsed the duty of fair comparison, viewing it as a key step toward ensuring equitable treatment for growers operating outside of tournament systems. They emphasized the need for transparent, data-driven mechanisms that guarantee fair compensation regardless of payment model.

Commenters both in support of and in opposition to the proposed rule requested further clarity for the definition of "material differences in performance" so that growers know when they have suffered a specific prohibited harm and can confidently request an investigation. Commenters also favored a presumption of unfairness rather than a material threshold for change in pay. One commenter asserted that any material or numeric threshold for change in pay would be inappropriate, and that AMS should establish the presumption that providing unequal inputs to growers within the same settlement group is material to grower performance, and another commenter advocated for the use of a presumption to provide greater clarity and notify growers of problems to be addressed.

AMS response: The preamble to this final rule explains that "Material differences in performance are differences that meaningfully (from the perspective of the grower) impact grower payments." AMS chose not to publish a dollar amount because a given change in performance may have disparate impacts on growers, depending on the ratio of performance pay to total pay, the overall size of the grower's operation, their level of indebtedness, or other factors pertaining to a grower's financial position.

AMS is not adopting a presumption of unfairness for differences in inputs because there are always differences in inputs in natural systems. The use of a presumption would be overinclusive and unhelpful in guiding LPDs in improving the fairness of their comparisons in relation to inputs, production practices, and related factors set out in the duty of fair comparison. Material change in pay is a more

³⁹ See, e.g., Muir, W.M. and SE Aggrey. *Poultry Genetics, Breeding, and BioTechnology* (2003).

⁴⁰ See Burke, William, and Peter J. Sharp. "Sex Differences in Body Weight of Chicken Embryos." *Poultry Science* 68.6 (1989): 805–810; and Beg, Mah, et al. *Effects of Separate Sex Growing on Performance and Metabolic Disorders of Broilers*. Diss. Faculty of Animal Science and Veterinary Medicine, Sher-e-Bangla Agricultural University, Dhaka, Bangladesh, 2016.

⁴¹ Breeder stock age: See Washburn, K.W., and R.A. Guill. "Relationship of Embryo Weight as a Percent of Egg Weight to Efficiency of Feed Utilization in the Hatched Chick." *Poultry Science* 53.2 (1974): 766–769; Weatherup, S.T.C., and W.H. Foster. "A Description of the Curve Relating Egg Weight and Age of Hen." *British Poultry Science* 21.6 (1980): 511–519; Wilson, H.R. "Interrelationships of Egg Size, Chick Size, Posthatching Growth and Hatchability." *World's Poultry Science Journal* 47.1 (1991): 5–20; Goodwin, K. "Effect of Hatching Egg Size and Chick Size Upon Subsequent Growth Rate in Chickens." *Poultry Science* 40 (1961): 1408–1409; Morris, R.H., D.F. Hessels, and R.J. Bishop. "The Relationship Between Hatching Egg Weight and Subsequent Performance of Broiler Chickens." *British Poultry Science* 9.4 (1968): 305–315; Peebles, E. David, et al. "Effects of Breeder Age and Dietary Fat on Subsequent Broiler Performance. 1. Growth, Mortality, and Feed Conversion." *Poultry Science* 78.4 (1999): 505–511. AMS notes additionally that research in this and related areas has limitations. It is older and results are mixed. AMS is concerned that publicly available research has stagnated, despite the introduction of new breed strains in the intervening years. Because integrators now own the genetics companies, AMS has additional concerns that research has, in effect, been privatized, creating informational asymmetries. Based on regulatory experience and on public comments, growers believe these factors affect performance.

⁴² Dozier III, W.A., et al. "Stocking Density Effects on Growth Performance and Processing Yields of Heavy Broilers." *Poultry Science* 84 (2005): 1332–1338; Puron, Diego et al. "Broiler performance at different stocking densities." *Journal of Applied Poultry Research* 4.1:55–60 (1995).

⁴³ Dozier III, W.A., et al. "Effects of Early Skip-A-Day Feed Removal on Broiler Live Performance and Carcass Yield." *Journal of Applied Poultry Research* 11.3 (2002): 297–303.

⁴⁴ Treatments may be necessary to mitigate disease within a single poultry house or an entire flock, or to boost the performance of suboptimal progeny from impaired breeder flocks, as described above. These treatments may affect the flock's growth rate or mortality. See Wells, R.G., and C.G. Belyawin. "Egg quality-current problems and recent advances." *Poultry science symposium series*. No. 636.513 W4. 1987. (citing Spackman, D. "The Effects of Disease on Egg Quality.").

⁴⁵ Hendrickson, M. et al. "The Food System: Concentration and Its Impacts," 3, (2020), <https://farmaction.us/concentrationreport/>, ("Globally, just two firms control 99% of turkey genetics, 94% of laying hen genetics, and 91% of broiler genetics, and just three firms control 47% of swine genetics (ETC Group 2013; Shand and Wetter 2019)").

appropriate target because the comparison affects the grower's pay.

Comment: Commenters stressed the importance of clearly outlining non-comparison methods within production contracts before they become necessary to provide growers with a clear understanding of their rights and options should tournament-based comparisons become unfair or impractical. Both industry stakeholders and advocacy groups acknowledge the need for clearer guidance on determining when fair comparison is no longer feasible and advocated for more specific criteria to guide both LPDs and growers. Commenters also expressed concern that implementation should appropriately address growers' circumstances.

AMS response: Fair comparison of growers requires that growers do not receive a distribution of inputs or assignment of production practices that causes material differences in performance from other growers to whom they are being compared. Factors outside of a grower's control should not meaningfully (from the perspective of the grower) impact grower payments. This is a facts and circumstances analysis.

Per § 201.110(a)(3), the non-comparison method must be included in the contract; therefore, growers will know what this method is before it is used. Per § 201.110(b)(1)(v), "Non-comparison," requires that an LPD's written processes explain when the LPD might remove a grower from a ranking group, and how the LPD will compensate growers removed from a ranking group to satisfy the non-comparison compensation method required under § 201.110(a)(3). There are myriad reasons why a grower may need to be removed from a ranking group. For example, there may not be enough comparable growers with which to make a reliable comparison in the current grouping and the LPD may use growers settling in previous periods to make a reliable comparison. Likewise, a specific grower may have received undesirable inputs or an assignment of production practices that materially impacted the grower's performance, necessitating the removal of the grower from the grouping and compensation under a non-comparison compensation method. Under this provision, the LPD must explain how and when the LPD removes a grower from a ranking group because the grower received unfavorable inputs or production practices and how it will fairly compensate such growers through a non-comparison compensation method.

Comment: A common theme across comments was addressing the inherent power imbalance between growers and LPDs, including the need to protect growers from retaliation. Commenters advocated for independent compliance reviews, potentially involving grower feedback, to ensure LPDs comply with the duty of fair comparison. However, some commenters contend that such requirements would create excessive paperwork burdens for LPDs, potentially hindering their ability to address grower needs effectively.

AMS response: AMS monitors and regulates power imbalances in the poultry industry in accordance with the Act and associated regulations. AMS's regulations at § 201.304 prohibit retaliation for asserting any of the rights granted under the Act or part 201 or asserting contract rights (9 CFR 201.304(b)(2)(vii)). AMS's regulations also prohibit retaliation by LPDs against poultry growers for speaking with government officials for the purposes of seeking redress for grievances brought under the Acts (9 CFR 201.304(b)(2)(i)). Moreover, this regulation aims to prevent injury from specific practices by LPDs—who possess local market power or bargaining power over growers. Out of concern that the compliance review process will divert poultry technicians from their primary responsibility to assist poultry growers with production issues, AMS has simplified the documentation requirements under § 201.110(b)(1). This new streamlined documentation requirement gives LPDs the needed flexibility to efficiently incorporate compliance with this rule into their standard business practices. Additionally, this section was streamlined in part because the Transparency Rule had similar documentation requirements.⁴⁶

Comment: To refine comparison-based payment systems, one commenter suggested using shorter rolling averages for performance comparisons; a short rolling average mitigates the impact of seasonal variations and new breeder flocks on grower pay, and therefore might create a more level playing field and prevent unfair disadvantages stemming from factors outside a grower's control. Another commenter advocated for contract provisions that would automatically adjust grower pay or provide avenues for redress when external factors, such as chick quality, veterinary care access, and feed quality negatively impact performance.

AMS response: AMS agrees that the duty of fair comparison requires integrators to use an appropriate time

period for comparing growers. Use of an inappropriate time period for the comparison-based compensation may be unfair or deceptive, and therefore constitute a violation of the Act. The final regulatory text indicates that one factor for the Secretary to consider when determining if a fair comparison has been made in the design or operation of a poultry grower ranking system is "whether the designated time period used in the live poultry dealer's comparison is appropriate, including whether the live poultry dealer uses one or more groupings, rankings, or comparisons of growers to mitigate the effects of any differences in inputs over the designated time period." Under the duty of fair comparison provision, growers will be compensated through a non-comparison method when a fair comparison-based compensation scheme is impossible.

iii. Appeal, Dispute Resolution

Comment: An industry stakeholder expressed concern that the language surrounding "reasonable efforts" was not detailed enough and that this could create uncertainty for LPDs, potentially leading to inconsistent application and legal challenges. To provide greater clarity and specificity regarding the definition of "reasonable efforts," one commenter suggested defining the term through concrete examples of both reasonable and unreasonable behavior to provide clearer expectations for both growers and LPDs. Another commenter proposed specific actions that LPDs should take to demonstrate "reasonable efforts," including (1) allowing for grower-installed feed scales to verify feed amounts, (2) permitting third-party veterinarian selection for sick flock assessments, (3) providing options for growers to independently assess LPD-controlled inputs, and (4) offering non-comparison compensation without fear of retaliation. Emphasizing grower agency, one commenter recommended empowering growers with the ability to independently verify inputs and performance factors.

An industry commenter noted that, in order to fairly address and resolve a situation, an LPD will *always* depend on the facts and circumstances of each case. The commenter noted that there are a multitude of factors for each situation, making a set policy or procedure not conducive to the dispute resolution process.

AMS response: As noted above, fairness requires a poultry ranking system that meets a reasonably reliable standard. LPDs must properly adjust the comparison-based compensation systems used in their poultry grower

⁴⁶ 88 FR 83210, November 28, 2023.

ranking systems to reasonably neutralize the impact of inequitable distribution of inputs and assignment of flock production practices on poultry grower compensation, as well as to reasonably neutralize the impact of communication and dispute resolution challenges that are not effectively and timely addressed.

Reasonableness is intended to be viewed as an objective test that accounts for standard industry practice, growers' contract expectations, basic considerations of equity, and the LPD's ability and willingness to prevent harms to growers resulting from factors outside growers' control. This objective test should also provide some flexibility to LPDs in particular facts and circumstances to achieve distinct goals in management of their operations, provided the LPD's goals are reasonably designed, appropriately documented, and not otherwise unfair or deceptive to growers.

Although "reasonable efforts" follows the typical standard applied for reasonable behavior in the law—what a reasonable person would do under similar circumstances—AMS also recognizes that enough circumstances are recurring in nature that an LPD should in many if not most cases be expected to have a regularized approach to the concern. Ultimately, what constitutes reasonable efforts will depend on the facts and circumstances of each case, with the LPD's duty focused on the fairness of the comparison(s) for the grower.

For example, if a grower raises immediate and urgent concerns about feed quality, such as the delivery of feed meant for older chicks than the grower has, the LPD should resolve this concern as soon as possible to minimize any additional undue damage to the grower's flock due to lack of proper nutrition. Or if a grower raises concerns about feed consistently being delivered late or in an insufficient quantity, the Agency would examine the LPD's effort to adjust the method of delivery. Failure to do so would likely justify placing the grower into a non-comparison method.

Without a doubt, an LPD is prohibited from retaliating against a grower in any manner for raising concerns as to whether a fair comparison method was used. Whether or not reasonable efforts specifically include LPDs allowing for grower-installed feed scales to verify feed amounts, permitting third-party veterinarian selection for sick flock assessments, or providing options for growers to independently assess LPD-controlled inputs is not something that AMS intends to determine in this rule for all circumstances. However, to the extent that LPDs face repeated grower

complaints and concerns regarding these matters and a track record of problems in resolving those complaints, reasonable efforts under particular facts and circumstances could point to the need for solutions such as those, although other less intrusive options may also be available.

Regarding the comment stating that set policies and procedures are not appropriate for how LPDs resolve issues with growers, AMS agrees that every growing operation is different, and LPDs must be careful in designing processes for resolving issues with growers that are context specific. Yet a wide range of problems are commonplace enough that LPDs should have regularized means for dealing with them. To strike an appropriate balance and enable LPD complex staff to retain focus on the important work of helping growers, AMS has changed the documentation requirements under § 201.110(b) to be less specific and, instead, simply require LPDs to describe how they account for similarities and differences in quality or quantity of inputs delivered to growers and how they account for differences in production practices across growers in a poultry grower ranking system.

iv. Benefit, Burden, and Cost

Comment: Commenters highlighted the perceived need for greater transparency and fairness in grower compensation. While grower advocates believe the rule is necessary to address systemic issues, LPDs expressed concern about potential cost increases and impacts on grower pay. Comments revealed a clear divide between grower advocates and industry representatives. Grower organizations argued that the duty of fair comparison is crucial for addressing the unfair and deceptive practice of shifting costs and risks from LPDs to growers. Advocacy groups suggested including a list of presumptive violations, such as providing unequal inputs within the same settlement group, to strengthen the rule's effectiveness. Several commenters emphasized the importance of robust anti-retaliation protections for growers who report rule violations or seek non-comparison compensation. An industry commenter expressed concern that requiring non-comparison-based pay could lead to lower overall compensation for growers.

AMS response: AMS agrees with commenters that the duty of fair comparison plays a critical role in addressing the unfair and deceptive risk-shifting of costs and risks from LPDs to growers. Regarding non-comparison-based pay, the rule clearly

states that when a fair comparison-based system is impossible, the LPD must implement a non-comparison method for calculating pay to ensure that factors outside of the growers' control do not cause harm to growers through decreased compensation for grow-out services. Even where adopted, non-comparison-based pay is not intrinsically likely to reduce average grower pay; the total amounts of pay are entirely dependent on the LPD's choices, and this rule does not ban bonuses for increased productivity or greater investment.

AMS agrees that a presumptive list of violations would assist with enforcement and has included some examples of potential violations in the appropriate section of the preamble of the final rule addressing the duty of fair comparison. Moreover, AMS agrees that growers cannot be retaliated against for reporting a violation of the duty of fair comparison and have indicated as such in this final rule. AMS included a prohibition against retaliation in the *Inclusive Competition and Market Integrity Under the Packers and Stockyards Act* final rule (89 FR 16092, March 6, 2024). LPDs cannot retaliate against growers for speaking with government officials for the purposes of seeking redresses for grievances brought under the Act.

Comment: Several commenters were concerned about the feasibility of implementing the documentation requirements for the new duty of fair comparison. Growers emphasized the need to access detailed, house-specific data on bird weights, feed consumption, and other key metrics. Some other commenters recommended additional requirements pertaining to LPD-controlled factors and assessing compliance, and one commenter recommended USDA to require LPDs to equally distribute inputs and adjust performance-based pay to account for differences in inputs and treatment. An industry commenter argued that requiring LPDs to control all variations in inputs, as implied in § 201.110(b)(1)(i), would be overly prescriptive and impractical given the scale, speed, and complexity of input delivery. The commenters argued that this could lead to inflexible systems that would ultimately harm growers. Other commenters criticized the provision for being vague, unfounded and lacking necessary explanation.

AMS response: AMS finds that comparison-based pay using factors outside growers' control constitutes an unfair practice under section 202(a) of the Act. While it is true that inputs cannot be delivered on a 100 percent

equal basis to all growers all the time, that does not mean that LPDs cannot construct payment systems that appropriately account for and mitigate the impact of input and flock production variability on grower compensation. The LPD does not need to control all variations in inputs; instead, the rule as proposed and finalized here merely requires the LPD to account for this variation in the design of a comparison-based payment system. AMS has been careful to specifically not require, nor expect, that identical inputs are delivered to all growers.

Also, the compliance reviews have been removed from the final rule because of the speed and complexity of the poultry growing process. Instead, AMS will incorporate audits of records pertaining to the duty of fair comparison into its regular audits of LPDs to lessen the compliance burden of this rule.

AMS expects the duty of fair comparison to substantially prevent unfair and deceptive practices when comparison-based pay is linked to input or flock production variation. This provision is written with sufficient specificity to tackle the problem at hand, while also allowing LPDs enough flexibility to design and operate a comparison-based compensation system that causes minimal disruption to their business operations. In fact, several LPD comments indicated they already have processes in place for addressing situations where a comparison-based pay system is not appropriate. This rule is codifying what industry stakeholders recognize as a best practice to create a level playing field and uphold the purpose of the tournament system in contract poultry growing. AMS has created new § 201.110(b)(1)(iii), “League composition,” which requires written documentation regarding how LPDs determine groupings of growers for settlement. AMS has also created new § 201.110(b)(1)(iv), “Evaluation period,” requiring LPDs to have a reasonable time period over which they shall evaluate the duty of fair comparison, and new § 201.110(b)(1)(v), “Non-comparison,” which requires LPDs to specify when they may remove growers from a ranking group and how they will compensate such growers to satisfy the non-comparison compensation method requirement under § 201.110(a)(3). This is meant to account for fluctuations across flocks while also ensuring that poultry growers do not face material harm resulting from input quality or timing variation.

Comment: Some commenters asserted that the proposed documentation requirements were burdensome and

potentially litigious. One commenter argued that AMS lacked authority to require LPDs to conduct and document self-audits to evaluate P&S Act compliance.

AMS response: As explained above in section IV., “Provisions of the Final Rule,” AMS agrees that some of the proposed documentation requirements can be streamlined. In the final rule, AMS is focused on only the most important documentation requirements that would assist AMS in reviewing LPDs’ compliance with the duty of fair comparison. Requirements for policies and procedures are not new or particularly controversial and are used widely across in the financial regulatory context to ensure firms are appropriately managing risks that cannot be entirely eliminated through regulation or otherwise. The situation is similar in the operation of broiler growing arrangements, where LPDs need to distribute inputs, production practices, and manage the needs of growers. To the extent that an LPD improves its management practices through maintaining policies and procedures, that should reduce litigation risk from unfair comparisons.

AMS is removing the provision requiring self-audits and will incorporate inspection of documentation required under § 201.110(b) into its regular compliance process. The compliance process undertaken by AMS to ensure compliance with the Act is routine, flexible, and comprehensive, thereby making it the ideal mechanism by which the provisions of this section shall be enforced. AMS regulatory staff already perform regular compliance audits of LPDs, so they are well positioned to review documentation describing the design and operation of LPDs’ poultry grower ranking systems and ensure that it complies with the duty of fair comparison.

v. Alternatives

Comment: Several stakeholders offered alternative approaches to address unfair compensation practices in the poultry industry. An advocacy group for growers proposed exploring non-comparison-based compensation models, such as contracts based on square footage, to mitigate the inherent issues of tournament systems. Another group advocated for a complete ban on tournament systems, based on the need for more stable and predictable grower income that is decoupled from relative performance within a group.

A number of commenters expressed concerns about LPDs manipulating input distribution (e.g., chick quality,

feed) as a form of retaliation against growers who challenge them or refuse to make capital investments. One commenter recommended explicitly defining unequal inputs within a settlement group as an unfair practice under the Act. Another commenter argued there are no simpler alternatives to directly addressing unfair comparisons, and that focusing on alternative compensation models or banning tournament systems wouldn’t fully address the root issue of unequal bargaining power and the potential for exploitation within the poultry industry.

AMS response: AMS is not at this time adopting the alternative approaches to address unfair compensation practices in the poultry industry because it believes that the final rule’s approaches are more effective at addressing the identified concerns around unfairness and deception given the available evidence. While AMS recognizes that non-comparison-based compensation models, such as contracts based on square footage, are popular with growers and mitigate the inherent issues of tournament systems, they have other limitations around recognizing skill, effort, and investment. AMS is not at this time, based on the available evidence, able to say that tournaments should be banned in all circumstances and replaced with those non-comparison methods, especially when AMS believes that the approaches set forth in this final rule, including prohibiting deductions and setting a presumption of 25 percent limitation on tournament magnitude, along with a clearer duty of fair comparison, offer a more narrowly tailored approach. If the approaches set forth in this final rule do not yield sufficient change in the treatment of growers, AMS will evaluate whether those facts necessitate other actions.

AMS acknowledges concerns about LPDs manipulating input distribution (e.g., chick quality, feed) as a form of retaliation against growers who challenge them or refuse to make capital investments. In a previous final rule, *Inclusive Competition and Market Integrity Under the Packers and Stockyards Act* (89 FR 16092, March 6, 2024), AMS specifically set out a range of circumstances where retaliation is prohibited (9 CFR 201.304(b)). Moreover, new § 201.110, which includes requirements for maintaining and complying with policies and procedures relating to input distribution, is designed to better protect growers against precisely those kinds of abuses. Were an LPD to adopt

policies and procedures that permitted inputs to be distributed in a retaliatory manner and compared growers on that basis, it would be in violation of the duty of fair comparison. And, if the LPD failed to comply with its policies and procedure requiring the equitable distribution of inputs and compared growers on that basis, that would also be in violation. AMS underscores that these principles (of pay not being affected by unfair input distribution) apply regardless of whether a tournament is present. Indeed, as AMS inquired in the proposed rule and affirms here, a practice (including, but not limited to, intentional, arbitrary, or punitive distribution) of unequal, dissimilar, or inappropriate inputs or flock production practices would be an unfair practice under the Act under any payment system that relies upon grower performance relative to inputs or production practices provided by the LPD (such as feed efficiency) irrespective of whether the payment system was a tournament.

C. Section 201.112

i. Additional Capital Investment Disclosure Document

Comment: Commenters including several farmers' coalitions supported the proposed additional capital investment disclosure requirements, asserting they would increase transparency and reduce deception. Several farmers' coalitions indicated the proposed transparency requirements should provide lenders with more consistent information for justifying investment viability, help prevent producers from being misled to make unviable investments, deter LPDs from making unnecessary upgrade requests, and may increase incentive pay for additional capital investments. However, industry associations and LPDs stated that it is outside USDA's statutory authority under the Act to require disclosures for additional capital investment requests. One commenter asserted that section 401 of the Act only allows AMS to require LPDs to maintain business records for AMS's benefit, not to require disclosure of records to growers, and that under section 401 AMS can only prescribe the manner and form in which regulated entities must keep transaction records if the Secretary finds that the records "do not fully and correctly disclose all transactions involved in the dealer's business." Another commenter asserted that AMS has failed to establish that disclosures are always necessary to avoid an unfair or deceptive practice or device.

AMS response: The Agency believes that the additional disclosure

information will help mitigate the information asymmetry between LPDs and poultry growers when entering into an additional capital investment agreement. When LPDs ask contract poultry growers to make additional capital investments but fail to be transparent regarding the purpose, risks, financial incentives and rates of return, those growers cannot make an informed business decision. Any failure to disclose material information essential to making critical business decisions is deceptive and also inhibits growers from identifying unfair practices in their incipency, and so violates the Act's prohibition in section 202(a) against unfair and deceptive practices. Section 407 of the Act specifically authorizes the Secretary to implement regulations to carry out the provisions of the Act. This provision is one instance of this authority. Accordingly, AMS disagrees with the notion that the Agency lacks statutory authority to promulgate the additional capital investment disclosure requirements.

In this regulation, AMS enables growers to better detect the risks in contracting because the LPDs' contracts will now show the grower the real value of the LPDs' offer, which they obscure in tournament contracts. Preventing deception and stopping unfairness in its incipency enhances competition among dealers by enabling growers to compare offers and reasonably assess entry into the business. Preventing unfairness and deception improves how markets function by forcing LPDs to compete for growers' services based on the merits of the producer's offer and prevents likely injuries to competition. Preventing deception enables growers to better assess their performance vis-à-vis other growers. Ultimately, the conduct at issue is squarely within the purposes of the Act. Where conduct "prevents an honest give and take in the market," it "deprives market participants of the benefits of competition" and "impedes . . . a well-functioning market."⁴⁷ In its report on the 1958 amendments to the Packers and Stockyards Act, the U.S. House of Representatives explained that the statute promotes both "fair competition and fair trade practices" and is designed to guard "against [producers] receiving less than the true market value of their livestock."⁴⁸

Moreover, other agencies that enforce laws prohibiting unfairness and

deception often have used disclosure to prevent deception. For example, the FTC enforces prohibitions against unfair practices, unfair methods of competition, and deceptive practices arising under the FTC Act.⁴⁹ Effective disclosure is well-established as a cure for deceptive practices that arise from information gaps in the marketplace, as exemplified by AMS's existing disclosure requirements under §§ 201.100 and 102, the FTC's franchisor-to-franchisee disclosure requirements, and a range of other mandated disclosures by Federal and State regulators. Although disclosure will not remedy an unfair practice, robust disclosure can help identify such practices, enabling remediation of unfairness at earlier stages, and so help stop harms in their incipency. AMS believes that the parallels between the FTC's section 5 authority on deceptive and unfair practices greatly outweigh any differences between the statutes because the language of both statutes is similar,⁵⁰ and it is generally recognized that Congress wrote the Act with broader application than the original FTC Act.⁵¹ It is plain from the statutory language Congress wrote—and in the floor debates and Congressional reports—that the Act empowered the Secretary to prevent unfair and deceptive practices, and not merely enforce existing antitrust law.⁵²

⁴⁹ Letter from FTC Chair Lina Khan to AMS, "Poultry Grower Tournament Systems: Fairness and Related Concerns," Docket No. AMS-FTPP-22-046, at <https://www.regulations.gov/comment/AMSFTPP-22-0046-0143>; Michael Kades, "Protecting livestock producers and chicken growers," Washington Center for Equitable Growth (May 2022). Federal Trade Commission, Policy Statement on Deception, (1983), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf. 15 U.S.C. 45(n); Fed. Trade Comm'n, Policy Statement on Unfairness, (1980), <https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness>; Fed. Trade Comm'n, Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the FTC Act, 9 (2022), <https://www.ftc.gov/legal-library/browse/policy-statement-regarding-scope-unfair-methods-competition-under-section-5-federal-trade-commission>.

⁵⁰ 15 U.S.C. 45(a)(1) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.").

⁵¹ FTC comment, submitted to *Regulations.gov* on September 10, 2024, posted on September 11, 2024. <https://www.regulations.gov/document/AMS-FTPP-21-0046-12413>.

⁵² The House of Representatives' report on the P&S Act stated that the P&S Act was the "most comprehensive measure and extends farther than any previous law in the regulation of private business, in time of peace, except possibly the Interstate Commerce Act." The Conference Report on the P&S Act stated that: "Congress intends to exercise, in the bill, the fullest control of the packers and stockyards which the Constitution permits . . ." See, Shively, J. and Roberts, J.,

⁴⁷ Federal Trade Commission, "FTC Policy Statement on Unfairness" (1980), available at <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness>. Last viewed October 9, 2024.

⁴⁸ H.R. Rep. No. 85-1048 (1957), reprinted in 1958 U.S.C.A.N. 5212, 5213.

AMS emphasizes that disclosure under new § 201.112 is not, and is not intended to be, a remedy to unfairness in and of itself; rather, disclosure provides AMS and growers with information necessary to enforce their rights under existing § 201.216, “Additional capital investments criteria,” and the P&S Act more broadly, when terms are unfair. This rule is meant to both cure deception and to identify unfairness in its incipiency to make enforcement under § 201.106 possible.

A commenter grounded opposition to the additional capital investment disclosure requirement in section 401 of the Act and argued that section 401 requires dealers to maintain records for AMS’s benefit, not for the benefit of growers. The commenter also argued that AMS is not authorized to control the content of the records required under section 401. AMS disagrees. Section 202 of the Act prohibits unfair and deceptive practices. The disclosures required in this rule seek to identify or prevent those harms. Section 401 complements these goals to the extent that disclosure is based on recordkeeping. Section 401 statutorily requires LPDs to maintain complete records of all their business transactions. Moreover, LPD obligations to retain information do not affect AMS’s ability to require the LPD to share the information to prevent unfair and deceptive practices under section 202(a) and (b) of the Act. Growers have informed the Agency that LPDs systematically withhold information that the LPDs possess concerning the design, purposes, impacts, and other aspects of the contracts the LPDs make regarding additional capital investments. This regulation targets material omissions under section 202, and the commenter’s assertions regarding section 401 ignore how additional capital investment requests fit into the business relationship between LPDs and growers. When an LPD asks a grower to make an additional capital investment, that is fundamentally a request to modify the contract that the grower must consider under circumstances where the LPD has all the information on its benefits, and the grower has none. Therefore, when the LPD requests that the grower spend money to advance the LPD’s business interests, the grower may incorrectly infer that an additional capital investment must also be in the grower’s

interest. The regulation is remedial in purpose and effect, exactly as Congress intended the Secretary to regulate when the Act passed in 1921, and when Congress amended that statute in 1987.⁵³

Regarding the comment that asserted AMS has not proven that disclosures are always necessary to avoid an unfair or deceptive act or practice, Congress did not require that regulation be “always” necessary. AMS is not required to adduce individualized evidence that the disclosure was necessary to every grower—the regulation simply must be necessary to prevent deception or identify unfairness for some growers. As a factual matter, AMS concludes that the unequal bargaining terms between growers and LPDs requires LPDs to disclose key information regarding additional capital investment requests to mitigate asymmetric information gaps that result in unfair and deceptive practices. Furthermore, transparency in the market requires disclosure of this information when LPDs request an additional capital investment in order to prevent deceptive practices.

Comment: One commenter commented on the rule explaining that AMS lacks the authority under “Section 410” to “require dealers to make a variety of “disclosures” to growers.”

AMS Response: Section 410 of the cited material, entitled “Final date for making payment to cash seller or poultry grower” deals with (a) “Delivery of full amount due,” (b) “Delay or attempt to delay collection of funds as ‘unfair practice,’ ” and (c) “Definition of cash sale.” Section 410 makes clear that Congress expected the Secretary to protect growers from receiving less than full payment. The mechanism for reducing or delaying that payment is immaterial.

The Congressional purpose of the Act was to stop unfair practices in their incipiency.⁵⁴ When an LPD fails to make available the required disclosures here, the unfair practice of reducing pay, banned by section 410, becomes undetectable because the terms surrounding payment are not clearly expressed. In other words, without having the necessary foundational terms, as per the required disclosure,

there is no way for aggrieved party or for USDA to see a reduction of pay as there has been no set baseline. Congress expected USDA to take a proactive approach to prevent this sort of harm, which hurts both the grower and the market, because it destroys the ability of growers to continue in the business and reduces the supply of growers willing to contract. Thus, among the other authorities in the Act, USDA also believes this regulation implements provisions of section 410 of the Act.

Comment: Several advocacy organizations suggested additional disclosure of cost and liability burden for environmental compliance.

AMS response: AMS appreciates these comments and understands the importance of properly allocating cost and liability burden for environmental compliance in the poultry industry. However, AMS did not consider that in the proposed rule, and P&S Act regulations in general do not impact the environment.⁵⁵ To the extent that the costs of environmental compliance are grower variable costs under particular poultry growing arrangements, they should be disclosed by the LPD under the requirement to disclose information relating to grower variable costs (9 CFR 201.102(d)(3)). Therefore, AMS made no changes to the rule as proposed based on these comments.

Comment: One commenter suggested that AMS make additional capital investment requests and disclosures public to other growers and track the frequency of additional capital investment requests and grower complaints of coercion, retaliation, or arbitrariness.

AMS response: This rule is not designed to make private business arrangements and agreements public information. Furthermore, AMS is not contemplating such a shift as the dissemination of private business arrangements and agreements would require additional regulatory provisions, justifications, and safeguards that do not fall under the purview of this rule. Rather, this rule is designed to help poultry growers understand why they are being requested to make additional capital investments, how entering into those contracts will impact their pay, how long it will take to complete additional capital investments, potential conflicts of interest with LPD personnel or their family members, required vendors/manufacturers, and expected returns from the investment. This information will help growers make

⁵³ Public Law 100–173, 101 Stat. 918.

⁵⁴ See *In Re: Corn State Meat Co., Inc.*; *Terrance P. (Terry) Prince, Jr. & James L. Wiggs.*, 45 Agric. Dec. 995, 1023 (U.S.D.A. May 8, 1986); c.f. *In Re: Danny Cobb & Crockett Livestock Sales Co., Inc.*, 48 Agric. Dec. 234, 234 (U.S.D.A. Feb. 13, 1989) (finding bonds protect against incipient violations); *In Re: Paul Rodman & David Rodman*, 47 Agric. Dec. 885, 903–04 (U.S.D.A. May 27, 1988) (finding there is a duty to prevent all unlawful acts under the P&S Act, including the potential losses from failing to maintain a custodial account).

⁵⁵ See 7 CFR 1b.4 (Listing the USDA agencies and agency units found to have no individual or cumulative effect on the human environment.).

“Competition Under the Packers and Stockyards Act: What Now?” 15 *Drake Journal of Agricultural Law* 419, 422–423 (2010); and *Current Legislation*, 22 *Columbia Law Review* 68, 69 (1922).

effective business decisions, and, when shared with AMS, identify circumstances that may be unfair.

With respect to AMS tracking the frequency of additional capital investment requests and grower complaints of coercion, retaliation, or arbitrariness, AMS agrees that market monitoring is important and invites growers to contact AMS at farmerfairness.gov or call 1-833-DIAL-PSD (1-833-342-5773) when they have concerns regarding additional capital investments they encounter and especially if they feel they are being subject to coercion, retaliation, or arbitrariness.

Comment: An advocacy association suggested that all additional capital investments should be subject to the same disclosures and prohibitions.

AMS response: The requirement to provide the disclosure will be triggered when the LPD requests the grower make an additional capital investment. There is no threshold below which this disclosure requirement does not apply. Nor are there any exclusions or exemptions for additional capital investment disclosures for other reasons.

Additional capital investment prohibitions, however, will be considered on a facts-and-circumstances basis under the criteria set forth in § 201.216 of AMS's regulations and generally under section 202 of the Act. AMS does not in this rule identify specific prohibitions. To the extent that AMS identified an additional capital investment practice that was unfair, AMS would seek to stop the practice through an enforcement action and communicate its intent to stop such practices in similar circumstances.

Comment: Several commenters suggested that LPDs should be required to make all additional capital investment contracts guaranteed for the duration of the loan required to pay for the additional capital investment.

AMS response: AMS acknowledges the concerns of the commenters and advocacy groups. If an LPD requests additional capital investments without guaranteeing that the grower will have a contract that is sufficient to recoup the costs of the investment or loan, such conduct could violate section 202 of the P&S Act, including by being unfair under section 202(a). AMS will monitor these practices and enforce on a case-by-case basis.

Comment: Several advocacy organizations supported the inclusion of LPDs' motives for the additional capital investment request in the Disclosure Document.

AMS response: AMS agrees that it is important for growers to know why an LPD requests an additional capital investment. As proposed, AMS included in § 201.112(b)(1) language requiring the LPD to disclose the purpose of the additional capital investment to both the LPD and the grower. Although AMS underscores that the inquiry should be focused on objective purposes and desired outcomes rather than a potentially vague concept of motives, the paragraph (b)(1) disclosures would mandate the full and complete presentation of any purposes of the additional capital investment. Partial disclosure of anything less than the LPD's full range of purposes would not be considered compliance with the provision because growers need to understand the full range of risks they are taking on, including to be able to identify potential sources of unfairness.

The provision also requires a summary of all research or other supporting material that the LPD has relied upon in justifying the additional capital investment. This requirement seeks to elicit the basis of the additional capital investment and permit the grower the ability to better understand, as well as evaluate, the reliability of that basis.

Overall, AMS has included this provision around purpose, research, and supporting material because alleviating some of the information asymmetry between LPDs and growers through the disclosure of purposes and motivations for an additional capital investment will help poultry growers make better business decisions. Furthermore, the requirement for information regarding purposes and motivations will help poultry growers know if that particular additional capital investment request is for experimental or research purposes, and thus appreciate the degree of risk the grower is taking on in the additional capital investment. AMS did not make any changes to the regulation as proposed in response to this comment.

Comment: Farmers' coalitions indicated a clear disclosure of financial incentives is essential to a grower's cashflow modeling. Advocacy associations requested further requirements for the analysis of projected returns. These suggested requirements include (1) a review of the projected returns by a disinterested third party and (2) the use of a standardized projected return form.

AMS response: The Agency agrees with the comment that clear disclosure of financial incentives is essential. Under the final rule, LPDs must disclose all financial incentives and

compensation for the grower associated with the additional capital investment (§ 201.112(b)(2)), along with any financial benefits that the LPD or any of its officers, directors, decision-making employees (as discussed above), or close family members receive from the use of an LPD-required manufacturer or vendor in connection with an additional capital investment (§ 201.112(b)(5)). AMS added the requirement regarding financial benefits accrued to an LPD or its affiliates as a result of an additional capital investment in the final rule to provide greater transparency regarding the financial components of an additional capital investment. For the time being, AMS is making no further changes to § 201.112.

Comment: Several commenters suggested AMS should require the use of plain language in disclosure documents, especially the descriptions of financial terms. Advocacy organizations stressed the importance of standardizing disclosure documents (e.g., the format for reporting projected returns and delivery expectations). Industry commenters requested that AMS clarify certain aspects of the disclosure document, including the description of "relevant" information and of the summary justifying an additional capital investment.

AMS response: Section 201.112(b) requires that the Disclosure Document present disclosures in a "clear, concise, and understandable manner." The Agency acknowledges the potential benefits of standardizing Disclosure Documents but is not requiring a specific form for this required disclosure.

AMS appreciates the commenters' interest in additional clarity. However, AMS declines to adopt more specific terms in the regulatory text because specificity reduces the LPDs' and growers' contracting flexibility. The nature and circumstances of additional capital investment varies. Some additional capital investments may be oriented on technology designed to enhance the efficient use of inputs or to deliver more uniform growout of birds. Other additional capital investments may be oriented towards delivering particular production practices that consumers seek, such as no antibiotics use. In those examples, the purpose and construction of the additional capital investments are quite different. Rigid specificity in the disclosure requirements may create confusion or even limit the disclosures' effectiveness. AMS's purposes for the disclosure of this information in § 201.112 is to help poultry growers understand how the additional capital investment is

intended to affect their operation and the risks and opportunities they may be taking on as a whole. AMS values comprehensive coverage rather than standardization.

With respect to the term “relevant,” AMS agrees that its inclusion in paragraphs (b)(1) through (3) is superfluous to meaning of the sentences as drafted. Accordingly, AMS is removing it in this final rule and is revising paragraph (b)(1) slightly from “any research or other supporting material” to “all research and other supporting material” to be consistent with the phrasing in paragraphs (b)(2) and (3). There is no change in the intended meaning.

Comment: Some commenters requested that translations of the Disclosure Document be made available in languages other than English.

AMS response: AMS appreciates this comment and acknowledges that disclosure has a basis in understanding; after all, the proposal included a requirement that the disclosure be “clear, concise, and understandable.” Language can be a barrier to effective disclosure. To mitigate the barriers to this disclosure, we have added paragraph § 201.112(c), which requires the LPD to “make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Capital Improvement Disclosure Document.” AMS takes note of the Civil Rights Impact Analysis located in section VI.G. of this rule that highlights the disproportionate impact of the rule on Asian-Pacific Island persons. Some commenters also indicated a need to ensure growers who are not native speakers of English can understand the disclosures. As noted by multiple commenters, non-native speakers of English are engaged in poultry growing. For example, in the early 2000s, large numbers of first-generation immigrant Hmong people, many of whom had been farmers in their native Laos, moved from urban areas in California, Minnesota, and North Carolina to the Ozark region in and around southwest Missouri and started growing poultry. Pew Research Center studies show that the English proficiency of the Hmong population in the U.S. in 2019 was only 68 percent and, among foreign-born Hmong, English proficiency is just 43 percent.⁵⁶ Data supports the concerns expressed by commenters regarding

providing poultry growers information in a manner growers are able to understand. AMS agrees that providing documents in the language growers best understand ensures fairness and reduces the risk of deception. Therefore, AMS added new language to the final rule to require that LPDs must make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Disclosure Document. Historically, many growers have been immigrants who may not be fully proficient in English; hence, this rule’s goal of preventing deception would not be fully accomplished without LPDs providing reasonable assistance to help growers understand the disclosures in their most competent language upon its delivery. Notably, the translation requirements under § 201.102(g)(4) would apply to disclosures made under § 201.112 if the latter is applicable to the LPD and incorporates what is otherwise required under § 201.102(d)(2)(i) and (ii) in a single disclosure that meets the requirements of both § 201.112 and § 201.102(d)(2)(i) and (ii).

ii. Additional Capital Investment Unfairness

Comment: Growers stated the disclosure provisions should prioritize preventing harm to growers rather than focusing on enforcement after the fact. They further asserted that full transparency from poultry companies is crucial to ensure a level playing field. Several commenters were concerned that the proposed rule did not address the power imbalances that exist when negotiating additional capital investments. This imbalance creates an inherent pressure for producers to comply with LPD requests; even “optional” or “voluntary” terms in a producer’s contract may amount to an unfair burden on producers given their fear of retaliation. Advocacy organizations and other commenters requested further provisions to protect growers from unfairness, excessive debt, and retaliation.

AMS response: AMS appreciates and agrees with the comments that preventing harm to growers is preferable to enforcement after the fact. Indeed, the purpose of this disclosure rule is to help equalize the negotiating powers between poultry growers and LPDs. There is an asymmetric power imbalance between LPDs and poultry growers when deciding to undertake an additional capital investment and the goal of the new regulation is to equalize the footing of these parties prior to agreeing to an additional capital investment. To better enable AMS and growers to protect

against unfairness and deception, the rule requires that LPDs disclose and record more information regarding the additional capital investments they request from broiler growers. The disclosures must occur before growers take on the financial burden and risks of the additional capital investment. The provision of such information is not, in and of itself, the cure for unfairness, but rather a key tool for AMS and growers to halt abusive practices by arming them with the ability to identify those challenges sooner. Indeed, disclosure has historically been one of the most powerful tools for preventing harms to growers by bringing practices to light early, and also subjecting those practices to the clarifying light of transparency.

AMS further underscores that leveling the playing field for growers is one of the main purposes of this provision. This rule is designed to reduce deception, strengthen poultry growers’ negotiating position, and aid in their ability to identify and address unfair practices. The Agency believes that this disclosure requirement for requested additional capital investments will reduce information asymmetry between LPDs and poultry growers, thus helping poultry growers make more informed business decisions about additional capital investments. Reducing information asymmetry, by definition, helps mitigate power imbalances.

However, AMS also acknowledges that this rule does not solve all challenges that growers may face arising from power imbalances between LPDs and growers, especially in concentrated local markets and in the context of hold-up risks and dependency arising from vertical contracting arrangements. To that end, AMS underscores its commitment to vigorous enforcement of § 201.216, which sets out criteria that AMS utilizes in identifying and enforcing against unfair additional capital investment practices. When the cost of the required additional capital investments cannot reasonably be expected to be recouped by the poultry grower, that failure is likely to be dispositive that the investment is unfair (§ 201.216(f)). AMS agrees with the commenter’s perspective on the importance of protecting growers from unfairness, excessive debt, and retaliation (discussed more fully below in the next comment response). Indeed, AMS is adopting this disclosure rule to enhance growers’ and AMS’s ability to identify and take swift action against unfair practices and the risk of unfair additional capital investment under existing § 201.216. That regulation sets

⁵⁶ Abby Budimen, “Hmong in the U.S. Fact Sheet,” *Pew Research Center’s Social & Demographic Trends Project* (May 24, 2022), available at <https://www.pewresearch.org/social-trends/fact-sheet/asian-americans-hmong-in-the-u-s/>.

forth criteria for whether additional capital investments would be an unfair practice or other violation of the Act. These criteria include whether the grower can decide against the additional capital investments; whether the additional capital investments were a result of coercion, retaliation, or threats by the LPD; and whether the additional capital investments can result in reasonable recoupment, or adequate compensation for the additional capital investments, among other non-exhaustive criteria. However, AMS has found that the presence of the criteria alone is insufficient to effectively address problems stemming from additional capital investments. AMS and growers lack the data necessary to analyze whether an additional capital investment violates the criteria. Moreover, if an additional capital investment is unfair, the grower has both investment and debt, and the additional capital investment is impossible to unwind. Technical specifications can make switching costly (where even possible), and alternative uses at similar compensation rates are nearly nonexistent.

Comment: Several commenters requested additional protection against retaliation for growers who refuse additional capital investment requests. Some commenters expressed concern regarding retaliation if additional capital investment requests are refused. One commenter requested AMS monitor complaints of coercion in relation to additional capital investment request refusals.

AMS response: AMS agrees that retaliation is likely to harm competition and growers. AMS's regulations at § 201.304 recognize that retaliation for asserting any of the rights granted under the Act or part 201, or asserting contract rights (9 CFR 201.304(b)(2)(vii)), violates the Act. LPDs also violate the Act if they retaliate against poultry growers for speaking with government officials for the purposes of seeking redress for grievances brought under the Acts (9 CFR 201.304(b)(2)(i)). AMS fully agrees that without those existing retaliation protections, poultry growers are in a weak position to refuse additional capital investment requests making the disclosure requirement ineffective.

AMS regularly reviews LPDs for P&S Act compliance, and AMS expects to review Disclosure Documents for compliance. Growers who experience coercion should contact AMS regarding possible violations of the Act. AMS also notes that existing § 201.216 would help address these problems. The regulation sets forth criteria for whether additional capital investments would be an unfair

practice or other violation of the Act. These criteria include whether the growers can choose to decline additional capital investments; whether the additional capital investments were a result of coercion, retaliation, or threats by the LPD; and whether the additional capital investments can result in reasonable recoupment, or adequate compensation for the additional capital investments, among other non-exhaustive criteria. AMS did not make any changes to the regulations as proposed in response to this comment.

Comment: Many commenters emphasized the need for grower protection against debt and assurance of return on investments. Advocacy organizations and others also suggested adding a requirement that LPDs shall not mandate additional capital investments unless the cost can be reasonably recouped by the grower. Advocacy organizations indicated that projected recoupment should only be evaluated based on non-performance (base) pay. Many commenters also suggested contracts should be guaranteed to match the duration of loans or ensure a reasonable rate of return to recover additional capital investment costs. Advocacy organizations suggested growers should reserve the right to renew contracts until additional capital investment debt is fully serviced.

AMS response: Under § 201.112(b)(2) and (3), LPDs would be required to disclose all relevant financial incentives and compensation associated with an additional capital investment and establish a schedule of expected grower construction for new additional capital investments. Financial incentives would include all incentives relating to the additional capital investment, including explicit incentive payment additions to base pay rates or performance compensation amounts, as well as what assumptions and risks undergird or may put at risk those incentives. Clearly disclosing financial incentives would assist the grower in assessing the relative risks of non-recoupment, as the reliability of those incentives may vary based on the duration of the contract and whether other growers are likely to incorporate the additional capital investment technology in a way that would make recoupment through performance pay less reliable. Clearly disclosing expected grower construction schedules and other repayment schedules also would assist the grower in assessing incentives and risks relating to borrowing, construction, and payment timing. Similarly, the requirement under § 201.112(b)(4) and

(5) for LPDs to clearly disclose their expectations regarding housing specifications and required or approved manufacturers or vendors will position growers to better analyze the business risk in undertaking an additional capital investment. An important goal of this rule is to give the poultry grower adequate information so that they may make an informed decision, identify risks and opportunities based on their knowledge of their own costs and earning opportunities, including as disclosed in existing regulations such as § 201.102.

AMS remains committed to protecting growers to the maximum extent possible from practices that prevent growers from fully recouping their additional capital investment. An LPD's failure to provide a reasonable opportunity for a grower to recoup the cost of a required (including ostensibly requested but in practice coerced) additional capital investments would be expected to violate § 201.216. AMS recognizes that growers cannot avoid the unfair exercise of market power and failing to sufficiently and fairly compensate growers is not a cognizable benefit to growers or to competition. Any reasonable recoupment analysis is fact-specific, but it principally relies on the following criteria: (1) the information required to be disclosed under § 201.112; (2) whether the contract term, including sufficient flock placements and density, extends at least as long as the projected timeline for returns set forth in that analysis; and (3) whether basic returns would cover the costs of the additional capital investment for the reasonable grower in the complex that performs under the contract. AMS is not adopting a requirement that projected recoupment only be evaluated based on non-performance (base) pay. The actual purpose of performance pay can vary greatly across different LPDs and even between complexes.

AMS recognizes the grower concerns that give rise to those comments, but at this time intends to take a case-by-case approach to enforcement in part because the range of grower situations require any unfairness analysis to be tailored to the particular facts and circumstances.

As noted in the paragraph above, contract term and renewals opportunities are relevant considerations in any recoupment or rate of return analysis owing to the heavy reliance interest that the grower has in the broiler growing arrangement, but AMS declines at this time to set forth a rule for all cases. AMS may revisit this determination following implementation of this rule and additional familiarity with the success

or limitations of its current case-by-case enforcement approach.

Comment: Some commenters suggested growers should be ensured leniency for delays in construction schedules due to labor and supply shortages outside their control.

AMS response: AMS acknowledges this comment regarding leniency for construction schedules, and the disclosure of the construction schedule under § 201.112(b)(3) is designed to help growers identify their risks in implementing an additional capital investment. However, as a disclosure requirement, it is intended to aid poultry growers by obligating that LPDs share relevant information regarding an additional capital investment request, so that the growers can make better decisions. It is also designed to help growers address potential unfairness relating to additional capital investment. To the extent that growers conclude that an LPD's failure to provide leniency on construction schedules caused an unavoidable harm, the grower may consider reporting the matter to AMS for investigation into whether the LPD has committed an unfair practice.

Comment: Some commenters indicated that LPDs should not be allowed to require growers to use certain equipment or vendors, especially when those LPDs hold any amount of financial interest in those equipment companies or specifically required vendors.

AMS response: AMS appreciates the concerns that this comment raises around grower freedom to operate and especially regarding conflicts of interest around additional capital investment. The Agency recognizes that growers rely on construction schedules, housing specification requirements, and approved manufacturers or vendors when implementing an additional capital investment. In this final rule, AMS is enhancing the disclosure of required equipment and vendors in § 201.112(b)(5) with an additional conflict of interest provision requiring the disclosure of "all financial benefits, if any, that the live poultry dealer or any officer, director, decision-making employee, or close family member of any such person, receives from the use of the required or approved manufacturer or vendor."

In the proposed rule, AMS asked, "Should proposed § 201.112(b)(5), which requires LPDs to disclose required or approved manufacturers or vendors, also require the disclosure of any material financial benefits that the LPD, or any officer, director, employee or family member of any such person,

receives from the use of the required or approved vendor? If so, please explain why for each party recommended to be covered, including examples and explanation where available."⁵⁷ In adopting this provision, which is similar to a disclosure that the Federal Trade Commission requires under its Franchise Rule (16 CFR 436.5(h)), AMS's goal is to help enable a grower to identify certain risks relating to the additional capital investment and potentially unfair or otherwise impermissible additional capital investment practices under § 201.116. For example, the disclosure should help growers identify conflicts of interest, favoritism, kickbacks, or financial benefits that may call into question the purposes of the additional capital investment. This should help combat the incentive problem inherent where one party has the decision-making power (LPDs) and another bears the costs (growers). LPDs are incentivized to seek out manufacturers and vendors that offer them the best incentives, not necessarily the manufacturers and vendors that offer the best deal for growers. This problem has been reported to AMS over the years to exist even at the level of complex managers who may have discretion over certain aspects of additional capital investment implementation.

Disclosure of a relationship between an LPD and its equipment or vendors does not mean that the relationship is lawful. An LPD's choice of vendor may be unfair or even anticompetitive in violation of the Act, such as contracting in bad faith or engaging in anticompetitive tying. But, at this time, AMS has designed this regulation to protect growers from unfairness and deception—for example by omissions or conflicts of interests—and not to specifically ban an LPD's choice of vendor.

iii. Benefit, Burden, and Cost

Comment: A number of stakeholders commented on the rule stating that it is similar to the Transparency Rule and that much of the information being requested in this rule is already provided to the poultry growers and that this rule is therefore frivolous. An industry commenter suggested there is sufficient regulation regarding additional capital investment issues.

AMS response: AMS recognizes the value of the Transparency Rule, including in helping growers understand financial opportunities relating to contract modifications and additional capital investment. However,

the Transparency Rule does not require the disclosure of information specific to the additional capital investment request, nor does it prohibit certain practices relating to base pay and unfair comparisons which this final rule does. LPDs possess information about the expected purposes, processes, and outcomes relating to additional capital investments that growers do not have and cannot obtain independently. Therefore, LPDs exert substantial control over growers' ability to evaluate the economic and financial feasibility of an additional capital investment while possessing the power to impose all additional capital investment costs on growers. Growers lack the bargaining power to demand the information they need to make decisions for their financial benefit. The inability to access this information frustrates growers' and AMS's ability to identify and therefore halt unfair practices in a timely manner. AMS has found transaction records around the financial incentives and the financial analysis insufficient to evaluate the compliance of additional capital investments under the Act generally. Therefore, even with the additional information that AMS and poultry dealers receive because of the Transparency Rule, this additional capital investment disclosure requirement is meant to ascertain different information than the information that results from compliance with the Transparency Rule.

AMS also disagrees with the position that there is sufficient regulation on this issue overall. Although § 201.216 sets out criteria around unfair additional capital investment, AMS has found § 201.216 challenging to implement in practice without sufficient real-time transparency into additional capital investment programs as they occur. As noted above, this is the first rule that addresses the information divide between poultry growers and LPDs regarding additional capital investment requests. Previous rules, namely the Transparency Rule, have required different kinds of information, such as settlement sheets, summaries of the LPD's litigation history with broiler growers and its bankruptcy filings over the past 5 years, whereas this rule covers only additional capital investment requests and related materials.

Comment: Some commenters were concerned about unnecessary additional capital investment requests. Farmers' coalitions proffered that transparency requirements would result in fewer unnecessary additional capital investment requests.

⁵⁷ 89 FR 49002, 49025, June 10, 2024.

AMS response: The extent to which additional transparency may reduce the amount of additional capital investment requests that are either unnecessary or that do not add clear value to farms is not a determination that AMS can make. This final rule is a transparency rule to address deceptive conduct, but it is also designed to assist growers in identifying potential unfairness in additional capital investments. An additional capital investment with a speculative purpose or one not grounded in research and reasonable estimates—a concern that growers have reported to AMS regarding additional capital investments—would be more apparent if AMS and growers are able to review an LPD's representations about the purpose of an additional capital investment, the research associated with it, and an LPD's expectation of costs, construction schedules, and approved vendors for the additional capital investment. AMS emphasizes that disclosure under new § 201.112 is not, and is not intended to be, a remedy to unfairness in and of itself; rather, disclosure provides AMS and growers with information necessary to enforce their rights under existing § 201.216, “Additional capital investments criteria,” and the P&S Act more broadly, when terms are unfair. Without sufficient, simple, and clear disclosures, growers cannot assess the benefits or risks of making the investment. Indeed, given the role of performance in determining compensation under the tournament, growers often cannot determine whether a program presented as voluntary is, for all practical purposes, mandatory without understanding the purposes, processes, and outcomes. Unfair practices, which can encompass additional capital investments, are illegal under section 202(a) of the Act, even if fully disclosed.⁵⁸ AMS did not make any changes to the rule as proposed in response to these comments.

D. Other Comments About the Proposed Rule

Comment: One processor pointed to a study prepared for the National Chicken Council that captured live chicken production statistics from 2021.⁵⁹ The survey results indicated that “current poultry grower contracting relationships are mutually beneficial, successful, and profitable for both growers and integrators.” The survey found that

among growers polled, despite options to work with different integrators, most growers have been with their current integrator for over five years and that the default rates on loans for poultry growers and integrators are low. Overall, the commenter argued that the current poultry grower compensation system works well, resulting in a highly efficient market and lower prices for consumers.

AMS response: The comment indicates that current poultry grower contracting relationships are mutually beneficial to growers and integrators and utilizes survey results showing how long current farmers have been with their company and loan default rates to demonstrate this. This rule addresses specific components of the broiler growing compensation system that AMS has received multiple complaints and comments about and that the Agency has determined constitute unfair or deceptive acts or practices. The rule does not prohibit incentive payments, which some commenters would like to retain and suggest are a beneficial part of the tournament system. The comment, however, does not necessarily measure if growers support or oppose specific provisions of this rule. Other reasons may explain the duration farmers have been with their current dealer or experience low rates of default. AMS notes that growers may not switch because of barriers to switching: even when growers have other competitor LPDs, the competitor may not be recruiting or may require LPD-specific equipment changes, among other reasons. The commenter says that, according to a survey of farmers associated with member companies of the organization submitting the comment, a small percentage of farmers depart due to contract terminations. The described methodology does not say if the survey represents all growers, including dissatisfied growers or ex-growers. This methodological consideration aside, the survey results do not address specific provisions of the rule.

The comment also cites data showing higher median incomes for broiler growers and lower loan deficiency and charge-off rates for chicken farmers compared to other types of farming operations to indicate the mutual benefits of the current poultry contracting system. While such comparisons provide some insight into the financial condition of poultry growers, they do not capture the full picture. For example, poultry growers carry the highest debt to asset ratios of

all agricultural commodity operations.⁶⁰ Additionally, the income variability for broiler growers is much higher than that for all agricultural producers or U.S. households.⁶¹

Comment: Industry associations commented on the rule, explaining that AMS only has the authority to prohibit conduct with an anticompetitive effect.

AMS response: Section 202(a) of the Act prohibits any unfair practice or device. As noted earlier, in section 407 of the Act Congress granted to the Secretary the authority to write regulations to effectuate the Act's purposes. Under the Act, this authority includes issuing regulations to, among other things, define the obligations that the Agency is charged with enforcing. AMS believes this includes the power to prevent LPDs from engaging in unfair, unjustly discriminatory or deceptive practices or devices in their contracts.

No court has held the Secretary does not have this rulemaking authority. *Been v. O.K. Indus., Inc.*, 495 F.3d 1217, 1227 (10th Cir. 2007), for example, recognized that the Secretary had the authority to promulgate rules relevant to that case, but that USDA had not done so.⁶² *Been* quoted, with approval, *Excel Corp. v. United States Department of Agriculture*, which held the Department's implementing regulation on grading prohibited a practice that was harmful to competition but the court did not require evidence of harm to competition in case itself.⁶³ Further,

⁶⁰ Giri, Anil and Subedi, Dipak, Farm Businesses Well-Positioned Financially Despite High Interest Rates, U.S. Department of Agriculture, Economic Research Service (2024), <https://www.ers.usda.gov/amber-waves/2024/july/farm-businesses-well-positioned-financially-despite-high-interest-rates/> (In 2022, poultry farms carried the highest average debt-to-asset ratio in 2022: 26.7 (6 times that for all farm businesses), 28.7 (2.6x), and 17.4 (1.3x) percent for small, midsize, and large family farm businesses, respectively; while all farm businesses carried average debt-to-asset ratios of 4.2, 10.8, and 13.1 percent, respectively).

⁶¹ Whitt, Christine, USDA Economic Research Service, Fees paid to growers for raising broiler chickens varied widely in 2020, (2022), <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=104642> (Median income does not tell the whole story. The range of household incomes earned by contract broiler growers is wider than other groups. The bottom 20 percent of contract broiler growers earns \$170,871 less than those in the top 20 percent, compared to \$123,094 for all farm households, and \$114,084 for all U.S. households. The wider range reflects, in part, the financial risks associated with contract broiler production); MacDonald, James M. 2014, Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB-126, USDA Economic Research Service, https://www.ers.usda.gov/webdocs/publications/43869/48159_eib126.pdf?v=1829.6.

⁶² See *Been v. O.K. Indus., Inc.*, 495 F.3d 1217, 1227 (10th Cir. 2007).

⁶³ *Id.* at 1230 citing *Excel Corp. v. U.S. Dept. of Agriculture*, 397 F.3d 1285, 1293 (10th Cir. 2005)

⁵⁸ See, e.g., 9 CFR 201.216, “Additional capital investments criteria.”

⁵⁹ Elam, Thomas, “Live Chicken Production Trends,” March 2022, *Live-Chicken-Production-FARMECON-LLC-2022-revision-FINAL.pdf* (nationalchickencouncil.org).

the Supreme Court, in *Mahon v. Stowers*, 416 U.S. 100, 112 (1974), recognized that USDA has the authority to issue substantive regulations.

Congress designed the P&S Act to provide broader protections than existing antitrust laws, such as the Clayton and Sherman Acts, in response to specific challenges in agricultural markets. More specifically, Congress intended to regulate practices that would violate those two antitrust laws and practices that would be unfair under the FTC Act, as well as the “special mischiefs and injuries inherent in livestock and poultry traffic.”⁶⁴ AMS rejects the comments that the statute or case law limits violations of the Act to conduct that causes an anticompetitive effect, as that term is used in the antitrust laws. Such an approach would abrogate the scope of the plain meaning of section 202 of the Act.

The existence of the P&S Act is proof that existing antitrust laws were not sufficient in protecting livestock producers and ensuring fair agricultural markets. It is well established that, to meet the needs of livestock producers more effectively, the Act provides broader protections than existing antitrust laws.⁶⁵ The statutory text, case law, and legislative history make plain that the Act’s protections extend beyond antitrust laws.⁶⁶ Accordingly, it has been the Agency’s longstanding position that because the Act addresses more and different types of harmful conduct than antitrust laws, the Agency has authority over a plethora of market behaviors, and is not limited to conduct with an anticompetitive effect.⁶⁷ Additionally,

(“‘Congress and the USDA are the arbiters of what practices will impede competition.’”).

⁶⁴ See *Spencer Livestock Comm’n Co. v. USDA*, 841 F.2d 1451, 1455 (9th Cir. 1988); *Armour & Co. v. United States*, 402 F.2d 712 (7th Cir. 1968).

⁶⁵ See, e.g., *Bruhn’s Freezer Meats of Chicago, Inc. v. U.S. Dep’t of Agric.*, 438 F.2d 1332, 1336 (8th Cir. 1971) (citing cases); *Swift & Co. v. United States*, 393 F.2d 247, 253 (7th Cir. 1968) (“The Act is remedial legislation and is to be construed liberally in accord with its purpose to prevent economic harm to producers and consumers at the expense of middlemen.”).

⁶⁶ 61 Cong. Rec. 1801 (1921), statement of Rep. Haugen; see also *Wilson & Co. v. Benson*, 286 F.2d 891, 895 (7th Cir. 1961): “The legislative history shows Congress understood the sections of the [Act] under consideration were broader in scope than the antecedent legislation.” (citing 61 Cong. Rec. 1805 (1921)). If the antitrust laws were sufficient, then DOJ’s 1920 settlement with the major packers would have been sufficient; Congress understood the words “unfair practices” to have an obviously broader effect on regulating competition than antitrust injury.

⁶⁷ Luke Herrine, “Cutthroat Business,” U. of Alabama Legal Studies Research Paper Forthcoming, Aug. 2024, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4936628; Michael Kades, “Protecting livestock producers and chicken growers,” Washington Center for Equitable

as discussed elsewhere in this document, evidence of anticompetitive injury is not required under this rule to establish violations of section 202(a) and (b).

Market abuses such as unfair or deceptive business practices by regulated entities are illegal under the Act. Addressing the harmful conduct this rule aims to prevent is squarely within the authority of the Secretary and accords with Congressional intent. Moreover, the Secretary, exercising authority to define the scope of section 202(a) and (b), has determined that the prohibited practices are likely to prevent producers from earning the full value of their services and push some producers out of the market caused by coercive or deceptive practices by LPDs.

Comment: One commenter said that AMS lacks the statutory authority to promulgate rules that have significant economic or political repercussions due to the major questions doctrine. The commenter expressed the idea that, in light of the U.S. Supreme Court decision in *West Virginia v. EPA*, 597 U.S. 697 (2022), AMS may not expand its regulatory framework to change or undermine currently used poultry growing compensation systems because it lacks clear Congressional authorization.

AMS response: AMS disagrees that the major questions doctrine applies to this rule. The Supreme Court has held that, “in certain extraordinary cases, both separation of powers principles and a practical understanding of legislative intent make us ‘reluctant to read into ambiguous statutory text’ the delegation claimed to be lurking there.”⁶⁸ Under such circumstances, courts may conclude that Congress does not “typically use oblique or elliptical language to empower an agency to make a radical or fundamental change to a statutory scheme.”⁶⁹ The major questions doctrine thus applies to some “significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have

Growth (May 2022); Peter C. Carstensen, “The Packers and Stockyards Act: A History of Failure to Date,” *The CPI Antitrust Journal* (2) (2010), available at <https://www.competitionpolicyinternational.com/assets/Uploads/CarstensenAPR-2.pdf>; Herbert Hovenkamp, “Does the Packers and Stockyards Act Require Antitrust Harm?” (Philadelphia: Faculty Scholarship at Penn Law, 2011), available at https://scholarship.law.upenn.edu/faculty_scholarship/1862.

⁶⁸ *West Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 723 (2022).

⁶⁹ *Id.* at 723 (citation and quotation marks omitted).

granted.”⁷⁰ This final rule does not fall within this category for two independent reasons: USDA is not construing an ambiguous statute, but rather is applying a statute that explicitly confers upon it the power to make necessary regulations in the context of a scheme that comprehensively regulates unfair practices in certain industries; and, even if the relevant statutory authorities are ambiguous—and they are not—this final rule does not represent the type of “transformative expansion” of the Agency’s regulatory authority that animates the major question doctrine.

First, the major questions doctrine applies only when there is ambiguity over the power conferred. Here, there is none. Congress prohibited unfair, deceptive, discriminatory, and other practices in section 202 of the Act. Further, it explicitly gave power to the Secretary to comprehensively regulate unfair practices in meatpacking and broiler production. The Secretary has the power to enforce the provisions of the Act, including sections 202 and 410.⁷¹ And separately, pursuant to section 407 of the Act, the Secretary was provided broad authority to “make such rules, regulations, and orders as may be necessary to carry out the provisions of this chapter.” The broad language here reflects Congress’ effort to grant the Secretary the flexibility necessary to prevent the P&S Act from becoming obsolete.⁷² Congress was clear in the authority it had granted, and that authority includes issuing regulations and orders relating to the Act and its remedial purposes—including, as here, the power of the Agency to construe the relevant provisions of the Act so as to provide clarity in enforcement. The Secretary has extensive power to regulate, and therefore has the authority to issue regulations such as this one. So, unlike cases where there has been some heretofore unforeseen “unheralded power,” there is no reason to believe that Congress understated the breadth of the authority it granted to the Agency to issue regulations construing the Act.

Second, this final rule does not constitute the type of “transformative expansion” of Agency authorities that animates the major question doctrine. The rule codifies USDA’s interpretation

⁷⁰ *Id.* at 724.

⁷¹ See 7 U.S.C. 193(a) (“Whenever the Secretary has reason to believe that any packer or swine contractor has violated or is violating any provision of this subchapter” he may take appropriate enforcement actions as set out in the statute).

⁷² See *Massachusetts v. E.P.A.*, 549 U.S. 497, 532 (2007) (“[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.”).

of section 202 consistent with much of the caselaw: the P&S Act is a remedial statute with a purpose that is broader than the antitrust acts.⁷³ The Agency has used its section 228 authority for the issuance of a great variety of regulations to specify obligations for bonding, registration, accounting, recordkeeping, ownership, public communications, disclosures, limitations on commissions, credit sales, weighing, payment practices and other responsibilities under the statute—so this is not a newfound substantive power; and, in any event, this is not the type of consequential rule to which the major questions doctrine would otherwise apply.

As discussed above, Congress enacted the P&S Act after many years of concern about farmers and ranchers being cheated and mistreated. Congress believed that existing antitrust and market regulatory laws, including the Sherman Act and Federal Trade Commission Act, did not sufficiently protect farmers and ranchers.

Section 407 of the Act (7 U.S.C. 228) gives the Secretary authority to “make such rules, regulations, and orders as may be necessary to carry out the provisions of this Act.” The House of Representatives’ report on the Act stated that it was the “most comprehensive measure and extends farther than any previous law in the regulation of private business, in time of peace, except possibly the interstate commerce act.”⁷⁴ The Conference Report on the Act stated that, “Congress intends to exercise, in the bill, the fullest control of the packers and stockyards which the Constitution permits. . . .”⁷⁵ Congress considered this a power beyond the authority of the FTC and the Interstate Commerce Commission. The Supreme Court said of sections 407 and 202 of the P&S Act that Congress gave: “authority [to] the Secretary of Agriculture to promulgate appropriate rules and regulations to carry out the provisions of the Act.” And, “Enforcement of [section 202 of the Act] is the responsibility of the Secretary of Agriculture, who is given authority to hold hearings and enter binding orders.”⁷⁶ The major questions doctrine is an extraordinary application of statutory interpretation, because it

has the potential to reverse an act of Congress, and, therefore, the Supreme Court has already noted that the doctrine does not apply generally. It has so far only applied in cases where the regulation would have been a questionable application of regulations with billions of dollars of effects, from regulating tobacco packaging, a nationwide moratorium on eviction, and setting limits on the carbon dioxide emissions from millions of small sources.⁷⁷ Here, however, the rule does not meet these standards. The Department has consistently interpreted unfair practices—and thus applied the Act—to protect producer welfare and advance fair-trade practices in the livestock, meat, and poultry industries in accordance with Congressional intent upon passage of the Act. The Department’s policy on unfair practices has not changed throughout the course of its enforcement of the Act.

The final rule continues this policy approach of protecting producer welfare and advancing fair trade practices in the poultry industry. This final rule advances these goals by prohibiting certain payment practices under poultry grower ranking systems, requires LPDs to adopt policies and procedures regarding their processes for operating a fair ranking system for broiler growers, and requires LPDs to provide certain information to broiler growers when the LPD requests or requires the grower to make additional capital investments. These regulations will increase transparency and address deception and unfairness in broiler grower payments, tournament operations, and capital improvement systems. The Act advances fair trade and competitive markets for the broiler industry.

Notably, commentators generally appear to assert that the 2008 Farm Bill, and the decade of rulemaking that followed, either limits the Department’s general authority to issues rules, or shows that the Department did not have that authority. This is not an accurate version of events. Starting in 1997, a series of OIG and GAO reports were highly critical of USDA’s failure to pursue unfair practices and cases of antitrust injury in meatpacking under the P&S Act. At a Senate hearing in March of 2006, Senator Chambliss noted, “[t]his act is a critical law that assures farmers and ranchers that business transactions are conducted under the principles of fair competition, open and honest trade practices, and prompt payments to producers.” These criticisms culminated in an April 2007 hearing in the House of Representatives

where advocates requested, *inter alia*, that the Secretary be required to issue rules on undue preferences and advantages, because regulation was perceived “to ensure that small and mid-sized farmers and ranchers are not forced to accepted volume-based price discrimination.” The thrust of the 2008 Farm Bill was not that the Secretary did not have the power to regulate, but that Congress demanded that power be used.

Comment: Producers were both in opposition to and in support of the tournament system. Industry associations and processors generally supported the tournament system, claiming the tournament system incentivizes and rewards high performance, resulting in market efficiency, and also removes costs and economic risk from growers by providing inputs. Industry stakeholders asserted the rule undermines the tournament system, leading to inefficiencies and potentially higher prices. Commenters cited unintended consequences including increased production costs passed on to consumers; barriers to entry for small farmers, leading to further industry consolidation; and shift in production to countries with less stringent regulations. Additionally, industry commenters claimed that capping performance-based payments might create an undesirable redistribution of income from high-performing to lower-performing growers. Lastly, the industry anticipates substantial legal and administrative costs associated with compliance, including contract amendments and legal counsel. Some producers and an industry trade organization claimed the tournament system promotes animal welfare.

Farmers’ coalitions, advocacy associations, and many individual commenters were largely opposed to the tournament system, expressing that the tournament system shifts economic risks to growers, locks them into inescapable cycles of debt, and enables retaliation. Some commenters were concerned that the tournament system appeared to pit farmers against each other, limiting knowledge sharing. Other commenters felt the tournament system is unfair due to the grower’s lack of control over production variables.

AMS response: It is important to note that AMS is not banning the tournament system. Rather, AMS is prohibiting those parts of tournament systems that are unfair practices and ensuring that those agreements serve the competitive operation of the market in a fair and non-deceptive manner. Additionally, increased transparency through this final rule should improve confidence in

⁷³ See, e.g., *Bruhn’s Freezer Meats of Chicago, Inc. v. U.S. Dep’t of Agric.*, 438 F.2d 1332, 1336 (8th Cir. 1971) (citing cases); *Swift & Co. v. United States*, 393 F.2d 247, 253 (7th Cir. 1968) (“The Act is remedial legislation and is to be construed liberally in accord with its purpose to prevent economic harm to producers and consumers at the expense of middlemen.”).

⁷⁴ House Report No. 67–77, at 2 (1921).

⁷⁵ House Report No. 67–324, at 3 (1921).

⁷⁶ *Mahon v. Stowers*, 416 U.S. 100, 107 (1974).

⁷⁷ *West Virginia*, 597 U.S. at 722.

the tournament system rather than undermine it.

In theory, the tournament system insulates growers from variation in the cost of feed and other inputs, encourages growers to perform to the best of their ability, and rewards better-performing growers. In practice, however, the tournament system also raises a number of fairness concerns for growers. If an LPD treats individual growers in a tournament differently, for example providing a grower with inferior inputs, the grower's skill does not determine their compensation.

Information asymmetry in contracting arrangements is another cause for concern. LPDs have information related decision-making that impacts grower compensation, including the methods for calculating grower payment. These methods are often intended to limit total grower compensation while maximizing production efficiency. LPDs also have information relating to the factors that are under their control and the influence of performance elements on grower compensation. LPDs have internal knowledge about the types of additional capital investments that they typically require, which growers may not anticipate. Moreover, without a guaranteed base pay rate, the complexity of the tournament system makes it difficult for growers to clearly understand what the minimum amount is that they could actually receive in payment. If the comparison-factor (*i.e.*, the bonus or deduction) is a large percentage of the total compensation, that variance in total could put the growers at significant financial risk. Tournament pay systems are also not an effective incentive system when factors outside of the grower's control determine the grower's performance.

Finally, LPDs have substantial bargaining power, and as a result, LPDs can require growers to make additional capital investments that will increase the grower's debt, and subsequently increase the grower's reliance on the LPD's contract. Such a dynamic can unfairly impose risk on the grower (for example by creating a difference in the term of the grower's loan and the grower's contract). Another concern is the variation in the quality of inputs (*e.g.*, feed or chicks) supplied by the LPD, which can impact the performance of the grower's flock. Similarly, LPDs determine the production practices on growers' farms (*e.g.*, density of bird placement, age at harvest, and weight at harvest), which greatly impact grower compensation. These factors can result in the grower's becoming financially dependent on LPDs, therefore losing the power to negotiate, and to move to

different LPDs if the terms of the growing contract are not ideal.

AMS is not aware of any evidence that tournament systems promote animal welfare, nor did the commenters provide specific examples explaining the connection beyond the general assertion that performance payments through a tournament encourage grower effort. The tournament systems control how poultry growers are compensated for their output, but the quality of inputs or production practices on farms, and even the quality of the housing and equipment, is determined by the LPD. These requirements may have the effect of improving animal welfare, but they may well also have the opposite effect. Moreover, AMS in this rule does not prohibit performance payments nor ban the tournament. Rather, the rule sets standards around the reasonable design of payment systems and scope of the operation of tournaments. These standards provide ample opportunity for LPDs to incentivize grower effort, while minimizing the downsides of the current payment systems and tournament operations as they have been reported to AMS by growers.

Comment: An industry representative stated that the proposed duty of fair comparison creates the untenable situation of extending P&S Act liability to a situation without determining whether the outcome was unfair, much less whether competition was harmed overall. The commenter cited an example in which a grower might receive a payment that aligns with the contract terms, meets the grower's expectations, and is entirely fair when viewed objectively, but the LPD does not follow written policy; in this case, under the proposed rule, the commenter asserts that the LPD would potentially be liable for an unfair practice.

AMS response: The comment appears to suggest that the regulation bans reasonable conduct. It does not.

The duty of fair comparison provision (§ 201.110(a)) establishes a violation of the Act for either failure to design or failure to operate the comparison system in a *fair* manner. Failing in that responsibility is not contract compliance; it is bad faith and failure to make the full payment to the grower.

In the first instance, AMS might bring an enforcement action for an LPD's failure to design the ranking system in a manner that would deliver a fair comparison; such an action would be based upon the processes set forth in the documentation required under paragraph (b) of § 201.110. In the second instance, AMS might bring an enforcement action based upon an LPD's failure to operate the ranking

system in a manner consistent with the duty of fair comparison. Such a failure could be because the LPD was not following the documented processes or because in practice the documented processes did not deliver a fair comparison.

The requirement to design the ranking system in a manner consistent with the duty of fair comparison is intended to prevent injury before it occurs, consistent with P&S precedent and the Act's remedial purpose. USDA, through the P&S Act, has broad authority to ensure fair practices prevail in the poultry industry, and AMS concludes this includes preventing LPDs from designing a poultry grower ranking system that can be expected to produce an unfair comparison of growers. AMS did not make any revisions to the rule as proposed in response to this comment.

Comment: Some commenters asserted that the proposed rule's disclosure requirements violate the First Amendment because they restrict and prescribe what LPDs can say to their contract growers through their contracts.

AMS response: The P&S Act prohibits unfairness and deception, and this final rule addresses harms caused by unfair and deceptive practices. While some commercial speech may be protected under the First Amendment, withholding material facts from a contracting party has never been protected speech. The rule does not restrict information that LPDs may provide to growers, rather it encourages full disclosure of material information to the grower. A disclosure requirement can be justified either because without the disclosure there is a risk of deception or there is another substantial government interest at issue. This rule's disclosure requirements meet both justifications; absent the disclosures there is a risk of deception by regulated entities and the government is otherwise advancing its interest in a fair marketplace for poultry. To this end, AMS has narrowly tailored the required disclosures to protect the growers from the types of deception and unfair practices that many growers themselves have commented occurs in LPD contract performance and negotiation and which the Act seeks to prevent.

With respect to compelled speech, AMS believes that the provision of additional factual information, related specifically to the growing arrangement, to growers is consistent with Congressional intent to benefit competition in the industry and provides growers with information needed to make informed business decisions. AMS concludes that

alleviating the asymmetric information problems in these contracts enables growers to identify the practices relating to additional capital investments that can lead to potential underpayment or other unfair and deceptive practices under the Act. Additionally, the Agency believes that the additional transparency and equalization of information asymmetry is critical for the longevity of the poultry business because it would allow poultry growers to accumulate a history of previous contracts, additional capital investment requests, and other information, which is good for long-term market conditions Congress designed the Act to promote. The First Amendment does not protect corporations from practices that deceive, and this final rule requires LPDs to share factual and uncontroversial information related to additional capital investments, contracts, and schedules with their growers to prevent deception and unfair practices. The information shared should achieve contracts that are both equitable and rely on facts, which is also consistent with the Act's prohibition on unfair and deceptive practices.

Comment: One commenter supported the proposal for the rule to be effective 180 days after publication in the **Federal Register**, unless it disrupts contract renewals or seasonal production pauses. One industry representative suggested that the 180-day implementation period is the minimum timeframe necessary for compliance, and another expressed concern that short effective dates create challenges for managing grower relationships and suggested AMS develop outreach and educational programs. Two advocacy groups suggested shorter effective dates, one at 60 days and one at 30 days. One trade association requested a 2-year implementation period.

AMS response: AMS agrees with commenters that the final rule should provide sufficient time to implement any changes it requires, and broadly with the comment that 180 days is sufficient time for compliance with the rule. However, out of an abundance of caution, AMS is setting the effective date for this rule at July 1, 2026, which is approximately 18 months following publication in the **Federal Register**. LPDs will need to amend contracts in some instances, create records processes, format the incorporation of new information in existing documents, and create Disclosure Documents using the new format. Eighteen months provides more than the length of five flocks to prepare for implementation of

the rule. AMS will have resources available to answer questions as appropriate. Additionally, based in part on the experience of recent settlements between DOJ and a large poultry company, AMS believes this period will provide sufficient time for LPDs to update their compliance systems and policies and procedures and comments complying with the rule. AMS's approach has been to address the regulatory needs of the poultry industry systematically and as swiftly as possible. And while the 2-year period suggested by a commenter would unnecessarily delay implementation, thus denying growers the benefit of the rule and exposing them to continued uncertainty, AMS acknowledges additional time beyond 180 days will help facilitate an effective transition. Accordingly, AMS is extending the effective date to July 1, 2026, which is approximately 18 months post publication.

AMS agrees that it should conduct outreach to growers and LPDs regarding these changes, implementation, and enforcement. Over the course of this rulemaking, AMS has published informational materials, including a fact sheet and a video webinar, to help the public understand the proposed rule. AMS intends to conduct further education and outreach following the finalization of the rule.

VI. Regulatory Analysis

A. Executive Orders 12866, 13563, and 14094

AMS is issuing this final rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Order 12866, as supplemented by Executive Order 13563, directs direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 further emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 amended Executive Order 12866 and directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means.

This rulemaking has been determined to be "significant" under Executive Order 12866, as supplemented by Executive Order 13563 and amended by Executive Order 14094, and, therefore, has been accordingly reviewed by the

Office of Management and Budget (OMB). As a required part of the regulatory process, Agricultural Marketing Service (AMS) prepared an economic analysis of the costs and benefits of §§ 201.106, 110, 112, and 390.

B. Regulatory Impact Analysis

AMS prepared an economic analysis of the costs and benefits of the final §§ 201.106, 110, and 112 as a required part of the regulatory process.

As described previously elsewhere in this final rule, the organization and structure of broiler production is characterized by a high degree of vertical integration, market power in regional markets, substantial investment in production capital that is specific to a single production purpose, nearly universal use of production contracts, and use of complex grower compensation systems based on relative performance. Important factors that affect grower performance, including inputs (chicks, feed, medication, etc.) and some production practices (placement density, age and weight at harvest, etc.) are controlled by the LPD. In addition, the percentage of poultry producing farms considered to be in "extreme financial stress" (defined as term debt coverage ratio less than one and a debt-to-asset ratio greater than 55 percent) is among the highest of all types of commodity production operations.⁷⁸ Market failures caused by asymmetric information, incomplete contracts, and hold-up in poultry contracting motivate specific interventions as discussed in this final rule.

Comments From the Proposed Rule and Changes to the Final Rule

After consideration of public comments, AMS decided to adopt the proposed rule as a final rule with several modifications. Live poultry dealers (LPDs) commented that the regulation would be particularly challenging if the period of time allowed for regulated entities to comply with the provisions is too short. In addition, they stated that a shortened period for implementing changes would require greater expenditures of resources to make required modifications and communicate with growers. To allow sufficient time for regulated entities to comply with the final rule and avoid excess

⁷⁸ Nigel Key, Christopher Burns, and Greg Lyons, "Financial Conditions in the U.S. Agricultural Sector: Historical Comparisons," EIB-211, U.S. Department of Agriculture, Economic Research Service (2019), <https://www.ers.usda.gov/webdocs/publications/95238/eib-211.pdf?v=4876.5>.

implementation costs, AMS is setting July 1, 2026, as the effective date for this rule, which is approximately 18 months following publication in the **Federal Register**. This extended time frame will not impact the amount or timing for estimated costs of the final rule; regulated entities are expected to incur first year costs during the 12 months preceding the effective date.

Industry trade organizations and LPDs commented that the full cost of implementing the proposed rule would be far greater than estimated by AMS. The commenters asserted that AMS greatly underestimated the costs that will be required for employing teams with highly specialized legal and technical expertise to implement the proposed rule by modifying or replacing grower contracts and communicating changes to growers. Commenters suggested that AMS did not adequately consider the total number of hours needed, but none provided quantified estimates. LPDs also commented that hourly rates paid to specialized industry professionals. Commenters also suggested that implementation of the rule would require LPDs to hire and train additional staff and pull resources away from other important activities.

AMS consulted subject matter experts who are familiar with LPDs, integrators, and broiler complex operations. These experts were auditors and supervisors with many years of experience at AMS in auditing LPDs for compliance with the Act. The final rule provides an extended period of approximately 18 months following publication in the **Federal Register** before the effective date, to permit sufficient time for implementation. Hourly rates used in cost analysis for the proposed rule were based on averages for legal, management, administrative, and information technology labor categories specifically within the agricultural sector as published and annually updated by the U.S. Bureau of Labor Statistics.⁷⁹ Although the largest corporations likely employ lawyers and other specialists at hourly rates much higher than the National average, contract development and review efforts at those companies are spread across many complexes. AMS expects that average hourly rates provide an appropriate benchmark for estimating industry average costs. AMS revisited the estimated hours to implement all provisions of the final rule based on comments that costs were

underestimated. After further discussion with subject matter experts, AMS added a modest amount of time to account for the cost of IT work in preparing § 201.112 disclosures. AMS subject matter experts who are familiar with the operations of LPDs, integrators, and broiler complexes through their experience conducting regulatory reviews of LPDs confirmed that all other costs of the proposed rule are accurate estimates and accordingly, AMS made no other changes to hourly costs or estimated numbers of hours for implementation of the rule based on this comment.

AMS received numerous comments from growers, grower groups, and advocate commenters in support of additional limitations on grower risk from excessive variability in compensation. Based on these comments, AMS has added provision § 201.106(b), which establishes a presumption that a regulated entity is in violation of the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers (performance pay) exceed 25 percent of total gross payments (including performance and all other types of grower pay). AMS again consulted its internal subject matter experts and added costs for LPDs to implement and monitor this new provision, which are discussed and quantified as direct costs. Other expected additional benefits and indirect costs resulting from this new provision cannot be quantified and are discussed separately.

AMS also solicited comment in the proposed rule on whether there was a need to protect growers against the risk that LPDs might unfairly reduce broiler grower total compensation during a transition period after implementation of the final rule. Comments on the proposed rule reflected support for adding such protections. Based on comments received, AMS added § 201.106(c), which will require LPDs to submit copies of the prior and modified contracts and disclosures to AMS if average gross grower payments at a complex show year-over-year decline following a contract modification in any of the three calendar years commencing with and including the effective date of the rule. AMS will review the information provided by LPDs to identify any potentially unfair practices related to broiler grower compensation. AMS consulted with its internal subject matter experts and added direct administrative costs for LPDs to provide information in compliance with this provision during the three-year period. AMS is not able to quantify the

potential benefits and the potential indirect costs to LPDs of this provision—these will also be discussed separately.

AMS received comments suggesting that some of the detailed documentation requirements under proposed § 201.110(b) were similar to existing documentation requirements and might create unnecessarily burdensome and complex paperwork that could burden service technicians at broiler complexes and keep them from other important responsibilities such as assisting growers. In response to these comments, AMS made several changes to § 201.110(b) in the final rule that included consolidating and streamlining the documentation requirements and removing some detailed requirements delineated under subparagraphs in the proposed rule.⁸⁰ AMS expects that these adjustments to final § 201.110(b) will add clarity and minimize potential confusion about the documentation requirements, thereby making them more effective, and that these changes will reduce recordkeeping requirements by some amount. However, based on consultation with its internal subject matter experts, AMS chose to attempt to avoid underestimating costs and did not reduce the total recordkeeping requirements or the time cost of the information collection for LPDs. Accordingly, these changes did not affect the estimation of costs or benefits in the final rule.

The proposed rule included § 201.110(b)(2), “Compliance review,” which required LPDs to conduct a bi-annual review of the processes set out in § 201.110(b)(1). AMS removed this requirement in response to comments that self-audits would be burdensome for LPDs, and that elimination of this requirement would not substantially diminish effective compliance with § 201.110. Compliance will be enforced through regular AMS review of the policies and procedures, as newly enhanced documentation, which LPDs are required to establish and maintain under § 201.110(b). Accordingly, removal of § 201.110(b)(2) eliminated the burden of compliance review on LPDs and reduced costs from the proposed to the final rule by the cost estimate in the proposed rule for that provision.

⁸⁰ As described in the preamble section III., “Summary of the Proposed Rule and Changes in the Final Rule,” these changes to proposed § 201.110(b) included simplifying 17 combined paragraphs and subparagraphs in proposed § 201.110(b)(1), “Policies and procedures,” into six simple paragraphs in final § 201.110(b)(1) and removing proposed § 201.110(b)(2), “Compliance review,” and redesignating § 201.110(b)(3), “Record retention,” as paragraph (b)(2).

⁷⁹ See U.S. Bureau of Labor Statistics, May 2023 National Occupational Employment and Wage Estimates, May 2023. <https://www.bls.gov/oes/special.requests/oesm23all.zip>.

Based on comments received, AMS added a provision at § 201.112(c) to require that the LPD make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Capital Improvement Disclosure Document. Reasonable efforts include, but are not limited to, providing current contact information for professional translation service providers, trade associations with translator resources, relevant community groups, or any other person or organization that provides translation services in the poultry grower's geographic area. Reasonable efforts, depending on the facts and circumstances (such as convenience, expense, and timeliness of the translation), may also include allowing the grower access to a computer-generated translation of the Disclosure Document and additional time to review any translated Disclosure Document.

A similar requirement was established for LPDs in § 201.102(g)(4) of the "Transparency in Poultry Grower Contracting and Tournaments" final rule.⁸¹ As LPDs already have all necessary information to make reasonable efforts to assist growers in translating disclosure documents and have made it available to growers who request the information, AMS did not add any time to its cost estimates for LPDs to comply with this new requirement.

The following analysis describes the anticipated impacts of the final rule. The value of broiler production in the U.S. for 2023 was approximately \$50.6 billion.⁸² Our analysis finds that the total direct cost of final §§ 201.106, 110, and 112 will be greatest in the first year at \$26.0 million or 0.051 percent of revenues. The broiler industry is a mature industry, and margins are likely relatively low. If profit margins are 1 to 5 percent of revenues, then first-year direct costs would be 1.0 to 5.1 percent of margins. The total direct costs are low in relation to total industry size, but they do not include any potential costs from changes in supply or demand caused by final §§ 201.106, 110, and 112. The final rule is also expected to provide many benefits of importance to broiler growers that could not be quantified. These include the value to broiler growers of improved fairness, reduced income variability, and reduced risk of fraud and deception. As a result of many factors that AMS is unable to measure due to insufficient data or

which cannot be predicted with reasonable certainty, AMS is unable to quantify benefits or indirect costs and therefore cannot make a determination about the sign or magnitude of net benefits to the industry from final §§ 201.106, 110, and 112.

Regulatory Alternatives Considered

AMS expects final §§ 201.106, 110, and 112 to mitigate costs associated with asymmetric information and LPD unfairness and deception by establishing a duty of fair comparison for LPDs in poultry grower ranking system administration, requiring LPDs to establish and document processes, requiring LPDs to adopt transparent methods of presenting grower compensation in broiler grower contracts, limiting excess income variability, and requiring LPDs to provide important information to broiler growers. Final § 201.106 will prohibit the LPD from using a grower's grouping, ranking, or comparison to other growers to reduce a rate of compensation disclosed in a broiler growing arrangement, establishes a presumption of violation when performance compensation for growers at a complex exceeds 25 percent of total compensation, and implements a three-year transition pay period with additional grower protections. Final § 201.110 will require LPDs to provide a fair comparison among growers when basing compensation upon a grouping or ranking of growers delivering during a specified period of time and to document how they comply with that duty. Final § 201.112 will require LPDs to produce and distribute disclosures when they request growers to make additional capital investments.

AMS considered four alternatives to final §§ 201.106, 110, and 112, with the second and preferred alternative being the final rule. The first alternative is the "do nothing" approach or maintaining the *status quo*. All regulations under the Packers and Stockyards Act would remain unchanged. This first alternative forms the baseline against which AMS will compare the second alternative, final §§ 201.106, 110, and 112.

AMS considered a third alternative that would leave all requirements in final §§ 201.106, 110, and 112 the same, but entirely exempt LPDs that meet the criteria to be classified as small businesses by the Small Business Administration.⁸³ This third alternative

would exempt smaller LPDs. However, since larger LPDs do most of the contracting (as quantified later in this analysis), most poultry growers would still receive the benefits of new protections under final §§ 201.106, 110, and 112. AMS considered a fourth alternative, which would be to adopt proposed §§ 201.106, 110, and 112—this alternative also includes all small and large LPDs. Below, AMS provides estimates and comparisons of the costs and benefits of the alternatives and an explanation for why the Agency selected final §§ 201.106, 110, and 112 as the preferred alternative.

Benefits of Final §§ 201.106, 110, and 112

AMS expects that final §§ 201.106, 110, and 112 will provide benefits to growers by reducing the risk of potential fraud, deception, and reduced payment for grower services by LPDs during the first three years of the final rule, improving clarity in grower payment systems, limiting excess variation in grower compensation, protecting growers against unfair reductions in compensation by LPDs during implementation of the rule, establishing a duty for fair comparison in the administration of broiler grower ranking systems, and making more information available to growers. These benefits are difficult to quantify. They depend on the extent to which the interventions will mitigate some existing unfairness and deception that results from incomplete contracts, inadequate and asymmetric information, and hold-up problems in an environment where LPDs are able to exert market power or bargaining power. Some of the benefits may vary based on the extent of competitive choice for growers in local markets. For example, in more competitive markets, increased transparency might benefit growers by empowering them to negotiate better terms with LPDs. In less competitive markets, increased transparency might assist growers in identifying potential unfairness from low compensation or abusive practices and allow them to seek assistance from AMS in more quickly remedying these problems. The size of benefits will be directly related to the extent to which the final rule will mitigate or reduce these practices. AMS is unable to quantify the benefits and will present a qualitative discussion of the potential types of benefits that growers would receive from final §§ 201.106, 110, and 112. The following discussion of unquantified benefits will proceed by final rule section.

⁸¹ 88 FR 83210, 83301 (Nov. 28, 2023).

⁸² USDA–NASS. Poultry—Production and Value 2023 Summary (April 2024).

⁸³ The Small Business Administration (SBA) defines small businesses by their North American Industry Classification System Codes (NAICS). Live poultry dealers, NAICS 311615, are considered small businesses by SBA if they have fewer than 1,250 employees (13 CFR 121.201).

Benefits of Final § 201.106

Section 201.106(a) prohibits LPDs from reducing a grower's rate of compensation based upon a grouping, ranking, or comparison of growers. The practice of discounting or reducing disclosed contract "rates" creates problems for growers in assessing and comparing broiler production contracts. Growers commonly expect that based on ordinary efforts, they will be able to obtain at least the average rate of pay for growers in a settlement group, which is typically known as the "base" pay. If growers are evaluating the expected value of these contracts based upon "base" or "average" pay rates, downside risk, which affects half of the settlement pool per flock, would be ignored. These are the types of problems that create income expectations that are unlikely to be met for a large segment of broiler growers. Growers thus cannot effectively evaluate their risks on a settlement payment by settlement payment basis, through presentation of base pay rate at the mid-point. Growers are harmed when they incur costs as a result of entering a contract with an LPD and the actual revenue and the range of payment outcomes realized are below those the grower was led to believe they would receive when reviewing the contract based on reasonably expected efforts within the control of the grower. In addition, competition in the market for broiler grower services is harmed when such deception and unfairness prevent growers from comparing competing offers from LPDs for the services of growers.

Final § 201.106(a) applies to LPDs that calculate grower compensation based upon a grouping, ranking, or comparison of growers delivering poultry during a specified period. LPDs using such a system are prohibited from using that grouping, ranking, or comparison to reduce a rate of compensation disclosed in a broiler growing arrangement. Final § 201.106(a) requires that any performance or incentive payments made to broiler growers under a poultry ranking system must be in addition to a disclosed rate of compensation (*i.e.*, any adjustments to rates of pay must be non-negative). Growers will benefit from increased certainty about the lowest possible revenue outcome under the growing arrangement. Greater certainty about minimum rate for their service can lead to improved financial planning and ability to manage financial risk. More transparent methods of presenting payments and compensation systems would also facilitate comparisons between alternative LPDs and benefit

growers who may be evaluating offers or considering agreements from more than one LPD.

In accordance with final § 201.106(a), LPDs will be expected to redefine grower payment calculation systems as appropriate to express all payments in the form of bonuses added to a stated pay rate. AMS expects that existing schedules of grower payments can be recreated such that they conform to this final rule change, assuming that no additional modifications are needed to comply with final § 201.106(b). Existing LPD methods of grower payment calculation can be expressed in an alternative format that includes only bonus adjustments added to an existing minimum rate.⁸⁴ AMS is aware that several of the largest LPDs currently have existing payment systems that express all ranking bonuses as positive adjustments added to a stated pay rate and would conform to this requirement.

Changes to presentation of grower compensation rates as required by final § 201.106(a) are not expected to change the basic structure of grower compensation schedules for relative performance payments. The benefits that will accrue to growers from the changes will result from increased clarity as growers will be better informed of minimum compensation outcomes that can occur under the broiler growing arrangement. Growers in some circumstances may, therefore, be able to negotiate more appropriate compensation systems for themselves, in the form of higher base rates, for example. There is no expectation, however, that aggregate payments to growers will increase. Clearer presentation of grower compensation methods will benefit growers by improving grower understanding of potential revenue outcomes, thereby reducing problems of inadequate and asymmetric information and improving the clarity of defined terms to address incompleteness in contracting.

Final § 201.106(b) will establish a presumption that an LPD is in violation of the Act if more than 25 percent of total compensation paid to all growers in a complex on an annual basis is based on performance. If a complex is in violation of this provision, in order to comply an LPD may either raise grower base pay, reduce grower performance pay, shift some performance pay to mechanisms not covered by the provision, or a combination of all of these. Although other alternatives would be possible,

AMS expects that the most likely outcome will be for LPDs to restructure compensation systems while keeping total grower compensation at approximately the same level. In this case, a grower compensation structure that includes less comparison-based performance pay would limit the range of potential compensation outcomes that an individual grower might observe and reduce risk from income variability.

Benefits of § 201.106(b) will accrue to broiler growers in the form of reduced income variability. For a given level of total income, growers would be likely to benefit if they receive a larger percentage of expected compensation based on fixed non-performance pay—which may include minimum base pay, fixed incentive payments for equipment standards and housing, fixed bonuses for adherence to clearly defined management practices, or other fixed targets—and a smaller percentage of compensation that is variable based on a grouping, ranking, or comparison to other growers, which makes up most forms of performance pay at present in the industry.

When income is variable, growers will likely see trade-offs in the value to them of reducing income variability compared to mean incomes. Risk neutral growers will be made better off if they value any increase they receive in less variable pay not based on performance more than they value any decrease they experience in the expected value of performance-based pay. However, a risk averse grower would value a one dollar increase in less variable but more certain compensation more than they would value a one dollar decrease in the expected value of performance-based compensation that involves risk. Overall, individual growers are likely to benefit if the value to them of any increase they receive in less variable income—from compensation that is not based on performance—is greater than the value to them of any decrease they experience in the expected value of more variable performance-based compensation.

The magnitude of benefits to growers that will result from § 201.106(b) depends on several factors that cannot be predicted with any reasonable degree of confidence. These factors include uncertainty about the number of complexes that will modify grower compensation structures in response to § 201.106(b), the manner in which such modifications would be implemented, and the number of growers at affected complexes that would be impacted by any changes. AMS is unable to analyze comprehensive grower data for all

⁸⁴ All contracts that AMS has previously reviewed include provisions for a minimum grower payment that is greater than zero.

broiler complexes and cannot predict with certainty how regulated entities will respond to this provision. For this reason, potential benefits of § 201.106(b) are discussed qualitatively and not quantified.

AMS does not have sufficient data to make an industry-wide inference on the number complexes that will need to reduce performance payments relative to total payments or the magnitude of any reductions that will be required. AMS reviewed one to five years of confidential grower compensation data for four individual broiler complexes that AMS gathered in prior investigations. This sample included small, medium, and large bird sizes and some of the largest broiler LPDs that operate several other complexes across the U.S. Aggregate performance payments at these four complexes were 11.4, 17.4, 20.5, and 25.4 percent of total grower payments. AMS is not aware of any complex with performance payments that are as much as 26 percent of total payments, and it is possible that no complex will need to reduce performance payments relative to total payments by a substantial amount to comply with final § 201.106(b).

To the extent that the complexes AMS reviewed are representative of the other complexes owned by the same firms, two or possibly three of the firms would likely already be in compliance with final § 201.106(b). In addition, the terms of a 2022 consent agreement between Wayne-Sanderson Farms, USDA, and the U.S. Department of Justice informed final § 201.106(b). In the Wayne-Sanderson Farms consent, performance payments that Wayne-Sanderson Farms pays to broiler growers was limited to 25 percent of total payments. Section 201.106 establishes a presumption that poultry growing arrangements with variable pay greater than 25 percent is presumptively unfair. It is unlikely that the unfairness presumption will have any effect on these firms, which combined account for up to 35 percent of the complexes. It is possible that other firms already limit performance payments to less than 25 percent of total payments, but AMS does not have sufficient information to confirm this with a reasonable degree of confidence.

Growers will benefit directly from changes in variability of compensation as a result of § 201.106(b) only at complexes where LPDs modify existing compensation structures to comply with the 25 percent presumption of unfairness. However, growers will also benefit from ongoing protection to the extent that this provision causes LPDs to forego future changes that would increase performance-based

compensation beyond 25 percent of total compensation.

For a given level of grower performance-based compensation at a complex, the presumption of unfairness also indirectly limits reductions to grower base pay rates. A reduction in the base pay rate will reduce the total amount of grower compensation not based on performance and must be accompanied by a proportional decrease in performance-based compensation to maintain an equivalent percentage. The presumptive limitation therefore provides an incentive for LPDs to maintain or increase existing levels of base grower compensation. This provides another benefit to growers: it serves as a backstop against the potential harm to growers that would occur if LPDs were to substantially and unfairly lower base pay rates when modifying pay structures to comply with § 201.106(a).

The distributional effects of final § 201.106(b) are likely to be unequal across individual growers: not all growers will benefit or benefit equally from this provision. Current contracting practices can vary widely between complexes even of the same LPD. As previously noted, AMS expects that the most likely outcome at complexes where grower compensation structure modifications occur will be for LPDs to keep total grower compensation at approximately the same level and reduce the percentage of compensation based on performance payments. This would change the distribution of total compensation among growers at the complex. Depending heavily upon the strategy for compliance chosen by the LPD, AMS would expect these changes to result in benefits to some growers, welfare transfers between some growers, and no change in welfare for some growers. At some complexes, AMS would expect that some amount of welfare transfer from higher performing growers to lower performing growers would result from payment structure modifications implemented to comply with the 25 percent presumption of unfairness. AMS expects some complexes to shift some performance pay to non-comparison methods, such as fixed metric performance, or to other innovative systems. Another possibility is that modifications could result in LPDs terminating or not renewing some marginally performing growers. This will be most likely to occur if LPDs seek to reduce the overall variation in grower performance at a complex as a means to comply or if payment structure modifications include increases in minimum grower payments that exceed the marginal value of services provided

by some growers. Some LPDs may seek to utilize technology to more greatly standardize outcomes, thus reducing the need to utilize higher magnitudes of performance payment. AMS underscores that actual outcomes will depend upon how LPDs respond at different complexes owing to local factors on the ground.

Performance-based compensation structures based on a grouping, ranking, or comparison of growers determine individual grower compensation using relative performance metrics that typically include feed efficiency and chick livability. Some aspects of performance can be controlled or influenced by the grower through effort and management, and to some extent investment (subject to the concerns highlighted by this rule), in the broiler operation. Other determinants of grower performance depend on actions of the LPD or other factors outside the control of the grower. Section 201.110 of this rulemaking addresses factors under control of the LPD by establishing a duty of fair comparison. As discussed elsewhere, this provision is expected to benefit producers by reducing unfair impacts on growers attributable to these factors. Nonetheless, the influence of factors controlled by LPDs on grower compensation will not and cannot be eliminated without eliminating performance-based methods of compensation. Natural variation and randomness will persist for certain production factors that influence relative performance, such as breed, sex, age of breeding flock, health at placement, and the performance of other growers, even if the LPD strictly adheres to the duty of fair comparison in the distribution of them. These factors therefore will continue to be important in determining compensation in a performance-based pay system. Provision § 201.106(b) benefits growers by establishing a presumption of unfairness based on the magnitude of performance-based compensation, thereby also limiting the share of income that will be affected by risk factors out of their control.

Growers are vulnerable to hold-up in the broiler contracting relationship: once a grower makes a housing and equipment investment to grow broilers for an LPD, that capital cannot be repurposed and the grower's choices become limited. In addition, many broiler operations operate in areas where they can potentially contract with only a very small number integrators, which severely limits the grower's ability to switch integrators. Data cited in the preamble of this final rule (MacDonald 2014) shows that more than

half of broiler growers have only one or two LPDs (integrators) in their local areas. As a result, growers lack bargaining power to protect their existing level of compensation when LPDs change contract terms. In requiring LPDs to provide the prior and modified contracts and required disclosures when contract modification or renewal results in lower year over year gross annual average grower payments at a complex, § 201.106(c) facilitates AMS intervention in unfair treatment. During a three-year transition period, LPDs will report changes to existing grower payment systems that reduce average compensation for growers at a complex.

Benefits of Final § 201.110

Market power gives LPDs a considerable bargaining advantage relative to growers in poultry contracting arrangements. As a result, growers lack negotiating power to demand, among other things, transparency around, and completeness in, and reasonable performance under contracts that would likely reduce the potential for deception and unfairness. The interventions aim to reduce potential adverse impacts of market power by establishing a duty of fair comparison that would provide protections to growers that they do not have bargaining leverage to demand. Currently, most broiler production contracts are incomplete in that they fail to clearly state important terms and provisions related to input distribution and flock production practices, how grower compensation will be handled in certain variable circumstances, settlement grouping procedures, and other aspects of broiler grower ranking system administration. LPDs commonly seek to disclaim under these contracts what should be express or implied duties and warranties around the usability or appropriateness of inputs or production practices and other aspects of broiler grower ranking system administrations. LPDs frequently offer broiler contracts to growers on a take it or leave it basis, providing growers with little insight as to methods the LPD will use to compare growers for purposes of determining compensation, including whether growers will be compared to other growers provided with similar inputs and assigned similar production practices. Moreover, during performance, growers have little to no ability to demand LPDs actually perform as could be reasonably expected under the contracts, including promptly addressing problems that may emerge during ordinary operations.

Even under a reasonable level of transparency around specific input differences, growers are often unable to make sufficient modifications to their individual efforts to manage risks to how payments are affected under a poultry grower ranking system. Nor can they avoid harms from disputes that may arise under the poultry growing arrangement. Growers reasonably assume that they will be fairly compared to other growers under a broiler grower ranking system. They are deceived if LPDs do not make a good faith effort to ensure fair comparison among participating growers when operating broiler grower ranking systems. Given the extent of LPD control over grower outcomes through the distribution of inputs such as feed and chicks or production practices such as placement density, target weight, etc., growers are forced to rely heavily on LPD good faith efforts in performing fair comparisons under broiler growing arrangements.

Consistent delivery of fair comparison requires LPDs to incur monitoring costs and take corrective actions when operating poultry grower ranking systems. In fact, many LPDs implicitly acknowledge a responsibility to fairly compare growers when they use procedures to identify and correct imbalances and provide remedies when factors beyond the growers' control affect grower payments. These include, for example, provisions to remove a grower from a broiler grower ranking system pool and to pay that grower according to another metric (such as a multi-flock average) if the LPD discovers that inputs provided to the grower were inferior—such as sick chicks. Another example would be a policy of the LPD to avoid providing a grower with inferior inputs on consecutive flocks—such as chicks from excessively young layer flocks that are considered to be lower performing, at least when using the broiler grower ranking system to determine performance pay in those circumstances. Although such policies are not uncommon, they are not currently required to be universally employed or uniformly applied by LPDs. LPDs may have legitimate business interests in providing certain growers, sometimes higher skilled growers in fact, with lower performing inputs. Yet care needs to be taken to ensure that any comparison-based method for determining performance pay be established under circumstances that do not permit or enable the LPD to intentionally disadvantage one or more growers in the ranking system.

Growers also have no means by which to ensure that LPDs consistently carry

out their responsibility under the contract or to enforce it. Further, the benefits of monitoring and correcting for unfair grower outcomes accrue to growers and not to the LPD. Therefore, LPDs have insufficient incentive to uphold their end of the bargain, especially in markets where growers have few options of alternative LPDs with whom they could contract. LPDs can therefore opportunistically minimize their costs of delivering a fair comparison at the expense of growers and, as a result, fail to deliver on their obligation for good faith and fair dealing under the contract.

Final § 201.110 addresses these problems by establishing a duty for LPDs to provide a fair comparison among growers when basing compensation on a grouping or ranking of growers delivering poultry during a specified period and requiring LPDs to document how they comply with that duty. The fair comparison requirement in final § 201.110(a) ensures that LPDs will not compare growers to other growers who have been supplied with inputs or assigned production practices that result in material differences in performance metrics used in payment calculations. Duty of fair comparison also requires that LPDs compare growers over appropriate time periods and use appropriate non-comparison payment methods. Final § 201.110(b) establishes documentation requirements in the form of processes, commonly known as policies and procedures, to facilitate LPD effective broiler grower ranking system operation under that duty, effective recordkeeping of transactions, and facilitates AMS supervision and enforcement. These provisions will benefit growers by reducing deception and unfairness in the operation of poultry grower ranking systems.

Expressly requiring LPDs to implement written processes that promote fair comparison of growers, whether through more consistent allocation of inputs and production practices or adjustments to methods and formulas, will foster more transparent, accurate, and reliable broiler grower ranking systems, and hold LPDs accountable for divergences from lawful action. Growers will benefit from this regulation because they will be less vulnerable to intentional harm due to deception, retaliation, or bad faith by LPDs. An LPD, AMS, or enforcement body can more easily evaluate grower complaints of intentional harm—for example, LPD employees targeting growers by providing inferior inputs—when they are able to consider whether the LPD has complied with its own stated policies and procedures for

ensuring fair comparison. Ongoing monitoring of the broiler grower ranking system by LPDs to fulfill the duty of fair comparison required by final § 201.110(a) will also provide safeguards to prevent growers from being substantially disadvantaged by unintentional or inadvertent outcomes. For example, an LPD will be compelled to take prescribed corrective action if it discovers that a particular grower has randomly received an unusual share of inferior inputs over multiple flocks. Procedures designed to ensure fair comparison will include monitoring to prevent natural variation in input quality and LPD-determined flock production practices among growers within a single settlement group from being allowed to persist as a pattern that disadvantages a particular grower over multiple settlement groups. By establishing a basic duty for LPDs to deliver fair comparison of growers, final § 201.110 is structured to provide LPDs flexibility in fulfilling that duty within the context of individual circumstances and complex production processes.

Benefits of § 201.110 deriving from the value to growers of fairness and equity are important. AMS is unable to quantify these benefits. However, as a result of this provision, compensation for individual growers will more closely match the level of individual grower effort, skill, and investment relative to other growers under a poultry grower compensation system that guarantees fair comparison. This provision will benefit growers by removing some of the unfairness in the distribution of grower compensation within poultry ranking payment systems. When LPDs fulfill a duty to ensure fair comparisons, no individual grower will receive consistently poor inputs while other growers with whom that grower is compared receive consistently good inputs. The expected benefits of ensuring fair comparisons among growers are highlighted by the consistent widespread reports of harm to individual growers resulting from existing unfair comparisons.⁸⁵ A reduction in the occurrence of such harms could potentially lead to reduced grower turnover.

Provisions included in final § 201.110(b)(1)(vi) will also require LPDs to maintain written processes for communication and resolution of grower concerns with the design or operation of a system that is consistent with the duty of fair comparison. These

processes should address timely resolution of such disputes. Providing an effective method of dispute resolution has the potential to help resolve disagreements involving personality conflicts which can lead to avoidable inefficiencies.

Benefits of Final § 201.112

LPDs encourage and often require broiler growers to make additional capital investments in assets that are specific to producing poultry for that LPD. Growers cannot exert bargaining power to demand essential information that would inform such investments. As a result, LPDs can induce growers to make additional investment decisions that do not benefit growers when they do not supply sufficient information for evaluation of requested upgrades. Such investments can cause financial harm to growers and increase the extent of their investments in capital that is specific to poultry production for nearby LPDs (thereby also increasing grower hold-up exposure) while still benefiting those LPDs. Moreover, broiler growers bear all the costs and risks of additional capital improvement investment. LPDs do not own the farm-based production capital and therefore do not share in these risks, although they frequently dictate grower investments. Because poultry production capital is largely owned by growers, LPDs have limited incentive to carefully consider how much required additional capital investments will improve individual grower production efficiency and whether they are likely to lead to financial success or failure. This misalignment of incentives is consistent with grower complaints that LPDs sometimes require costly investments that are unnecessary or in some cases merely cosmetic.⁸⁶ When a broiler considers a new investment, the broiler grower considers gains in productivity relative to the cost of the investment. However, when LPDs do not bear investment cost, they have incentive to maximize only their benefits and encourage growers to over-invest in poultry-specific production capital to the point of negative returns for the grower.

AMS has sought to address similar concerns through prior action. Finalized in 2011, § 201.216 sets out criteria for

when the Secretary will find additional capital investment violated the Act (76 FR 76874, December 9, 2011). However, AMS's experience since has found that the rule is insufficient to help growers or the Agency to identify problematic additional capital investment in time to act. Accordingly, the Agency in this final rule has prioritized disclosure of critical information to growers in a timely manner, to enable growers and the Agency to have ready access to the necessary information to conduct analyses under § 201.216 and under the Act generally, including to stop additional capital investment that cause unavoidable harms. AMS also is adopting final § 201.112 to prevent deception of growers related to additional capital investment, as the information being required is critical to their decision-making around the additional capital investment, whether or not the additional capital investment gives rise to unavoidable harms separate and apart from the failure to disclose.

LPDs prevent growers from making fully informed decisions and understanding the true extent of over-investment when they withhold important information about additional capital improvement investments. An increase in grower investment leads to increased grower dependency on LPDs to generate returns on that investment through poultry contracting. The presence of few or no other poultry contracting options in a grower region further focuses dependence on a single LPD. The use of incentive payments by LPDs to compensate growers for additional capital investment can help to align investment incentives. For these arrangements to work properly, growers must clearly understand the parameters of the investment and the breakdown of payment components and financial incentives offered by the LPD.

Final § 201.112 will require LPDs to provide a Capital Improvement Disclosure Document when requesting an additional capital investment over the identified threshold of \$12,500 (as defined in § 201.2(n)). This disclosure will provide information to existing growers contemplating additional capital investments about the goal or purpose of the investment, grower financial incentives, construction schedules, description of changes to housing specifications, approved manufacturers or vendors, and analysis of projected returns including the assumptions, risks, and uncertainties upon which those projections are based (paragraphs (b)(1) through (6)). As such, the Capital Improvement Disclosure Document will clearly state the

⁸⁵ Section II of this final rule, "Background," documents decades of grower comments to USDA that highlight concerns of persistent unfairness resulting from unfair comparisons in broiler grower tournaments.

⁸⁶ AMS sought feedback on proposed rulemaking in a 2022 ANPR (87 FR 34814, June 8, 2022). Some commenters noted that LPDs often supply insufficient information with respect to requested or required upgrades and deceptively induce growers to make costly additional capital investments. One commenter, for example, asserted that LPDs demand costly upgrades that some growers have reported to be arbitrary and apparently untethered to any reasonable assurance of increased compensation.

intended and expected outcome of LPD additional investment requirements.

Requiring LPDs to provide this information to growers will reduce asymmetric information that contributes to inefficient investment and resource allocation decisions, where such choice exists by growers. LPDs providing this additional information related to grower requirements reduces the cost to growers of identifying and qualifying manufacturers and vendors when making capital improvements. To the extent that disclosures assist growers in understanding the purpose of additional capital investments, those growers will be more likely to realize any potential benefits from the additional capital investment. For example, growers will be able to tailor additional capital investments to their particular operation so as to be better positioned to implement the additional capital investment and produce intended production improvements. The clarity provided by additional capital investment disclosure will reduce the likelihood of costly errors caused by miscommunication and misunderstanding and increase the likelihood that growers will be able to correctly implement additional capital investments. Final § 201.112 will generate economic benefits by addressing certain limitations on market functioning arising in part from asymmetric information. Growers operating with better information are less likely to be deceived or unfairly misled by LPDs when additional capital improvement investments are required.

Even where growers may not be able to avoid or negotiate around these terms, growers may be better able to effectuate their rights under the Act, and AMS would benefit from earlier identification of potentially unfair practices. To the extent this occurs, by addressing asymmetric information this section of the final rule will help alleviate additional hold-up of growers by LPDs. Even in cases where grower refusal may still result in other adverse consequences, growers may still be better off by preventing additional financial loss and increased specific investment and dependence on the LPD. Financial projections and other analyses of additional capital improvement investments developed by LPDs along with more complete information about investment purpose, expected benefit, and grower performance will be superior to analysis based on limited grower information.

Final § 201.112(c) will benefit growers who require translation assistance by requiring LPDs to make reasonable efforts to ensure that growers are aware

of their right to request translation assistance and to assist growers in translating the Capital Improvement Disclosure Document.

Summary of Benefits of Final §§ 201.106, 110, and 112

AMS expects that the final rule would provide substantial benefits to the industry and address issues of extreme importance to broiler growers. However, these benefits are unquantified. AMS cannot measure any impact or shift in total industry supply or any corresponding indirect effects on industry supply and demand, including price and quantity effects.

Estimation of Costs of the Final Regulations

AMS estimates cost for three alternatives. The first is the final §§ 201.106, 110, and 112, which is the preferred alternative. The second alternative is the same as final §§ 201.106, 110, and 112 with a complete exemption for LPDs that are considered small businesses by the Small Business Administration.⁸⁷ All LPDs are also included in the third alternative, which is adoption of the proposed §§ 201.106, 110, and 112. All three alternatives are compared against a baseline of *status quo*, which has no costs or benefits.

The direct costs of final §§ 201.106, 110, and 112 primarily consist of the time required for LPDs to: (1) modify and monitor grower contracts to determine compensation in a manner consistent with final § 201.106; (2) develop, document, and comply with policies and procedures for ensuring that growers are fairly compared to other growers in poultry grower ranking systems; and (3) gather and document information pertaining to grower additional capital investments and distribute it among the growers. The costs of the final rules will fall on LPDs as they modify existing contracts and compensation systems, develop and comply with new policies, and collect and disseminate required information. Costs will also fall on poultry growers based on the value of the time they put into reviewing the disclosures. Though poultry growers are expected to incur costs in reviewing information, they will be the primary beneficiaries of the information, which may be reflected in their ability to make more informed decisions (where they may have more

than one or two integrators as options in certain geographic areas). Further, growers will be able to better identify additional capital investment programs that are unfair, which either AMS or growers can challenge as a violation of the Packers and Stockyards Act. This may result in a more efficient allocation of capital within the poultry growing industry.

There were 42 LPDs in the broiler chicken market that filed a fiscal year 2023 Annual Report with AMS, and their reports indicate that they had 20,014 contracts with poultry growers during fiscal year 2023.⁸⁸ Of these, 21 LPDs are considered small businesses according to SBA classification, and these have a total of 1,208 grower contracts. Small LPDs are expected to differ from large LPDs in structure and complexity, particularly with regard to the number of contract types used, management, use of legal services, and divisions of labor. Where noted below, some components of cost estimates are calculated separately for large and small LPDs to reflect these differences.⁸⁹

AMS expects the direct costs of the final rule will be small in relation to overall production costs and will not measurably alter poultry supply. AMS also expects that neither LPDs nor poultry growers will measurably change any production practices that will impact the overall supply of poultry as a result of these direct costs.

Expected direct costs are estimated as the value of the time required to develop and implement new broiler grower contracts and grower payment systems to comply with requirements of final § 201.106; develop, implement, and maintain compliance with processes reasonably designed by the LPD to deliver fair comparisons among broiler growers in the operation of broiler contract tournament systems as required by final § 201.110; and produce and distribute disclosures when LPDs request or require growers to make additional capital investments as required by final § 201.112, as well as the time required to create and maintain any necessary additional records. Grower payment systems required by final § 201.106(a) are substantively similar to many current payment systems already in use and will therefore not require large adjustments

⁸⁸ All live poultry dealers are required to annually file PSD form 3002 "Annual Report of Live Poultry Dealers," OMB control number 0581-0308. The annual report form is available to public at <https://www.ams.usda.gov/sites/default/files/media/PSF3002.pdf>.

⁸⁹ Unless otherwise noted, estimated cost or hours estimates for small and large live poultry dealers are the same.

⁸⁷ The Small Business Administration (SBA) defines small businesses by their North American Industry Classification System Codes (NAICS). Live poultry dealers, NAICS 311615, are considered small businesses by SBA if they have fewer than 1,250 employees.

for most LPDs. AMS does not have sufficient data to predict whether the presumption of unfairness based on 25 percent performance-based grower pay will cause any LPDs to make substantial changes to grower compensation structures. The policies and procedures that LPDs would be required to develop in response to final § 201.110 are expected to result in formalization, in many cases, of existing practices LPDs are currently following, albeit sporadically or inconsistently. Nearly all of the information and records required for disclosure to growers under final § 201.112 are already kept by and/or available to LPDs.

Although LPDs will need to take several actions to comply with new requirements under final §§ 201.106, 110, and 112, these provisions are not expected to require LPDs to substantially change their existing business practices. The exception to this would occur if some LPDs currently exceed the 25 percent presumption of unfairness on performance-based grower compensation set by § 201.106(b) and will be unable to comply without substantial changes. The changes to comply would result in indirect costs. Non-quantifiable potential indirect costs to LPDs who exceed the 25 percent presumption of unfairness on performance-based grower compensation will be discussed separately within this section. AMS expects total direct costs of adjustments, contract modifications, records creation, and compliance under the final rule to be small relative to the overall size of the industry.

AMS also estimates the amount of time that growers would take to review the information provided to them by LPDs. Estimates of the amount of time required by LPDs to modify existing contracts, develop and comply with new policies, and collect and distribute required information, and for growers to review the information were provided by AMS subject matter experts. These experts were supervisors and auditors with many years of experience with AMS in auditing LPDs for compliance with the Packers and Stockyards Act. Estimates for the value of time are U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics estimates released May 2023 and costs are therefore expressed in 2023 dollars.⁹⁰ Throughout the discussion that follows, “first year” costs refers to costs that are estimated to be incurred

during the 12 months immediately preceding the effective date of the rule.

Direct Costs of Final § 201.106—Preferred Alternative

Under final § 201.106(a), LPDs will be required to redefine grower payment calculation systems as appropriate to express all payments in the form of bonuses added to a stated pay rate. AMS expects that existing schedules of grower payments can be recreated such that they comply with this final rule change. Existing LPD methods of grower payment calculation can be expressed in an alternative format that includes only bonus adjustments added to from an existing minimum pay rate. AMS expects that most LPDs will be required to make one-time changes to existing grower contracts and develop new payment systems that are consistent with these provisions. This process will also include producing and filing grower documents and communicating information about the new contract and payment system to growers and staff at each complex.

AMS estimates that the aggregate one-time costs to LPDs of updating grower contracts and developing new grower payment systems, including modifying information systems to include new calculations as well as filing, and reporting to comply with final § 201.106(a), will require 17,664 legal hours,⁹¹ 57,750 management hours, 7,360 administrative hours, and 7,360 information technology hours, costing a total of \$9,106,000⁹² in the first year.⁹³

Once LPDs have incurred a one-time cost of developing, documenting, and communicating new contracts and a new system of grower payments, AMS does not expect additional ongoing costs of implementing final § 201.106(a).

⁹¹ Small live poultry dealers are estimated to require 50% as many legal hours as large live poultry dealers on a per company basis for one-time cost of developing § 201.106 one-time changes to grower contracts and payment systems.

⁹² 17,664 legal hours × \$139.96 per hour + 57,750 management hours × \$96.40 per hour + 7,360 administrative hours × \$49.36 per hour + 7,360 information technology hours × \$95.58 per hour = \$9,106,112.

⁹³ Average hourly wage rates used to estimate dealer costs include a 41.79% markup for benefits and are as follows: Management—\$96.40, Legal—\$139.96, Administrative—\$49.36, and Information Technology—\$95.58. Hourly wage rates were established using the following BLS classifications for each labor category as follows (NAICS Code—OCC code—OCC Title): Management (3116—11—1020—General and Operations Managers) for live poultry dealers’ managers, Legal (3110—23—1011—Lawyers) for attorneys for live poultry dealers and for growers, Administrative (3116—43—6011—Executive Secretaries and Executive Administrative Assistants) for live poultry dealers’ administrative assistants, and Information Technology (3116—11—3020—Computer and Information Systems Managers) for information technology managers.

Once in place, new provisions and modifications resulting from this one-time update are not expected to lead to an increase in costs associated with the ongoing maintenance and updating of grower contracts that would occur in the normal course of business.

Final § 201.106(b) establishes a presumption of unfairness when, for a given complex, aggregate payments based upon a grouping, ranking, or comparison of growers (performance pay) exceed 25 percent of gross payment to growers on an annual basis. LPDs will need to analyze grower compensation structures at the complex-level and calculate annual performance-based grower compensation as a percentage of total compensation to ensure compliance with the 25 percent presumption established by final § 201.106(b). LPDs may choose to re-design and modify existing compensation structures where greater than 25 percent of the total grower compensation is based on performance pay. These LPDs may choose to create processes for monitoring compliance on an ongoing basis. Modifications to grower compensation structures will need to be incorporated into broiler contracts and communicated to growers.

AMS estimates that the aggregate one-time costs to LPDs of examining and evaluating existing grower compensation structures and making modifications as required to ensure ongoing compliance with final § 201.106(b), will require 7,360 legal hours, 52,500 management hours, 7,306 administrative hours, and 14,720 information technology hours, costing a total of \$7,861,000 in the first year.⁹⁴

LPDs will implement and maintain processes for monitoring ongoing compliance with § 201.106(b). AMS expects these annual ongoing costs to require in aggregate 736 legal hours, 5,250 management hours, 736 administrative hours, and 1,472 information technology hours for an aggregate annual cost of \$786,000.⁹⁵

Final § 201.106(c) requires that for each of the three calendar years commencing with and including the effective date for § 201.106, LPDs must submit to USDA a copy of the prior and modified contracts and associated disclosures if any contract modification

⁹⁴ 7,360 legal hours × \$139.96 per hour + 52,500 management hours × \$96.40 per hour + 7,360 administrative hours × \$49.36 per hour + 14,720 information technology hours × \$95.58 per hour = \$7,861,333.

⁹⁵ 736 legal hours × \$139.96 per hour + 5,250 management hours × \$96.40 per hour + 736 administrative hours × \$49.36 per hour + 1,472 information technology hours × \$95.58 per hour = \$786,133.

⁹⁰ See U.S. Bureau of Labor Statistics, *May 2023 National Occupational Employment and Wage Estimates*, May 2023. <https://www.bls.gov/oes/special.requests/oesm23all.zip>.

or renewal results in less than the prior annual-calendar year's complex-wide average gross payment to the grower. LPDs will be required to monitor changes in average annual gross payments to growers at the complex and, if necessary, provide documentation.

AMS does not expect any costs to LPDs in the first year in response to § 201.106(c). For each of the three calendar years following the effective date, LPDs will monitor grower compensation and submit any necessary documentation on an annual basis. AMS expects these annual ongoing costs to require in aggregate 736 legal hours, 5,250 management hours, 736 administrative hours, and 1,472 information technology hours for an aggregate annual cost of \$786,000.⁹⁶

Final § 201.106 concerns potential changes to the method of payment calculation and compensation structure used in grower tournament settlement systems. LPDs will provide new contracts that include these updated provisions for review by broiler growers. AMS expects that the first time a grower receives a new contract containing these modifications, he or she will require about 4 hours to review and consider all new terms and provisions. At \$62.13 per hour,⁹⁷ the total one-time cost for all broiler growers to review the new contract is \$4,974,000.⁹⁸ AMS expects that the updated contract provisions and payment systems developed by LPDs pursuant to § 201.106 will not contribute to additional ongoing contract review time by growers beyond an initial one-time review. Therefore, no ongoing future costs of grower contract review have been included for § 201.106. The ten-year aggregate total costs of final § 201.106 to LPDs are estimated to be \$26,401,000, the ten-year aggregated total costs of final § 201.106 to poultry growers are estimated to be \$4,974,000, and the combined ten-year aggregate total costs of final § 201.106 to LPDs and poultry growers are estimated to be \$31,375,000.

Unquantified Indirect Costs of § 201.106—Preferred Alternative

Many factors will affect the costs to LPDs of changing existing compensation

structures to comply with a 25 percent presumption as defined in § 201.106(b). The scope of comprehensive data that would be required for AMS to accurately measure and quantify these costs makes collection of sufficient data infeasible if such exists. Further, the nature of these costs will depend on future choices made by industry participants that cannot be predicted with reasonable certainty. The potential indirect costs—other than those direct administrative costs which are quantified separately—will be discussed qualitatively in this section.

If LPDs substantively modify existing structures of grower compensation to reduce performance-based compensation to less than 25 percent of total grower compensation, additional costs must be considered. The likelihood and magnitude of these additional indirect costs will depend on the number of complexes that will modify existing compensation structures as a result of § 201.106(b), the extent of those modifications, and resulting cost increases.

As discussed in the benefits section, AMS does not have sufficient data to make an inference on the number of complexes that will reduce performance payments relative to total payments or the magnitude of any reductions that will be required. As previously discussed, at four complexes, aggregate performance payments were 11.4, 17.4, 20.5, and 25.4 percent of total grower payments. AMS is not aware of any complex with performance payments that are as much as 26 percent of total payments, and it is possible that no complex will reduce performance payments relative to total payments by a substantial amount to avoid the presumption of unfairness established in final § 201.106(b).

To the extent that the complexes AMS reviewed are representative of the other complexes owned by the same firms, two or possibly three of the firms would likely already be in compliance with final § 201.106(b). And due to the Wayne-Sanderson Farms consent agreement with U.S. Department of Justice, it is unlikely that the regulation will have an effect on Wayne-Sanderson's existing contracts. Therefore, it is unlikely that the presumption of unfairness on performance payments will have any effect on these firms, which combined account for up to 35 percent of broiler complexes. It is possible that at other firms, performance payment makes up less than 25 percent of total payments as well, but AMS does not have sufficient information to confirm this with a reasonable degree of confidence.

Conceptually, where firms modify existing grower compensation structures at a complex in response to this rule, if reductions in performance-based payments relative to total payments adversely affect grower performance incentives and cause growers to produce broilers less efficiently, that could result in increased production costs for the firms. In general, the "tournament" system of broiler grower compensation bases payments to individual growers on their performance relative to other growers. Performance payments provide an incentive for growers to optimize factors under their control, such as effort and management, and to some extent investment (subject to the concerns around investments highlighted by this rule), to improve their own relative performance efficiency and increase income. The strength of individual performance incentives is related to the size of expected (potential) grower performance payments, which will be limited by the total amount of performance-based pay distributed among all growers. The effectiveness of incentives is also limited by the extent to which the grower can control performance. Decreasing the relative size of performance payments available to all growers at a complex might, at or above a certain level, in theory, therefore weaken performance incentives of individual growers and could result in reduced overall grower efficiency in broiler production.

AMS has no reason to believe that the 25 percent presumption adopted in this final rule would significantly change incentives. As noted above, the third largest LPD is already in compliance with the provision and some LPDs do not use the tournament system. No evidence was produced by commenters regarding the level of tournament compensation needed to optimize grower performance. Other factors, including inputs and production practices, the level of prudence and professionalism of growers, their risks of termination, and non-comparison performance payments can, for example, provide incentives for growers. Additionally, LPDs already closely monitor grower performance with a range of information they already have. Finally, the concern arises only if both the 25 percent presumption would affect incentives and if an LPD could not otherwise overcome the presumption.

AMS cannot rule out the possibility that incentives may be affected, and AMS is unable to predict specific effects with certainty. Were production efficiency in some manner to be

⁹⁶ 736 legal hours × \$139.96 per hour + 5,250 management hours × \$96.40 per hour + 736 administrative hours × \$49.36 per hour + 1,472 information technology hours × \$95.58 per hour = \$786,133.

⁹⁷ The average hourly wage rate of \$62.13 per hour used to estimate costs for a poultry grower includes a 41.79% markup for benefits. The wage rate was established using BLS classification (1152—11—0000—Management Occupations).

⁹⁸ 4 hours to review each disclosure × \$62.13 per hour × 20,014 contracts = \$4,973,879.

reduced, economic principles suggest that cost of production would increase, causing an inward shift of a firm's marginal cost curve and that those costs could be passed on to consumers. Increases in cost structures could, under that same hypothetical, affect demand for broiler growing services in certain areas, for example possibly resulting in LPDs terminating some marginal growers. As noted above, based on the regulatory record and the Agency's expert judgment based on the information and data available to AMS during the rulemaking process, AMS does not view these outcomes as likely to any material degree.

Furthermore, LPDs have tools to incentivize grower effort that would partially or entirely avoid the risks outlined above. LPDs may shift some performance pay to non-comparison methods, such as fixed metric performance or to other innovative systems, which could retain the incentives where necessary and appropriate. Other LPDs, however, may believe that the performance incentive delivered by the tournament is misplaced given the particularities of their business model or the type of bird being grown at a complex (*e.g.*, growout of "no antibiotics ever" may require different incentives and management than commoditized product). Depending on the needs of the complex, LPDs may seek to utilize technology, training, or other approaches to improve outcomes, thus reducing the need to utilize higher magnitudes of performance payments.

LPDs currently use many variations of relative performance compensation systems at broiler complexes and some LPDs do not use tournament performance compensation systems. This suggests that that setting comparison pay above 25 percent is not the only way to optimize incentives for all complexes, growers, or circumstances. AMS does not have data for every payment structure currently in use. Limited data analysis from the small sample of complexes described above shows that performance compensation at a number of complexes is less than 25 percent of total pay. This suggests that regulated entities can optimize incentives without setting comparison performance pay above 25 percent. Ultimately, AMS does not expect that LPDs will choose to abandon the tournament compensation system entirely as a result of this regulation and does not expect materially adverse effects on production efficiency.

Final § 201.106(c) requires that within a three-year transition period following the effective date, LPDs must provide

the prior and modified contracts and grower disclosures if complex-wide average gross payment to growers falls below the level of the prior calendar year. AMS considered that LPDs could face additional costs if they were prevented from lowering grower compensation for a three-year period and were not able to adjust payment structures to meet challenging and unforeseen industry conditions in the broiler industry. For example, a sharp decline in broiler demand or other type of event disrupts the broiler industry could potentially create conditions in which aggregate average grower compensation at a complex temporarily falls below its level in the prior year.

In analyzing information submitted by LPDs, AMS will consider all relevant factors, including industry conditions, when investigating unfairness. As a result, AMS expects that LPDs will be constrained only from unfair reductions in grower compensation and will not be prevented from adjustments to grower compensation that reflect legitimate business operations, such as responding to a decline in broiler demand or higher feed costs. In addition, the tendency for base levels of year over year inflation to naturally erode real grower compensation will also attenuate the need for nominal decreases. Given the restructuring of how payment calculation methods and compensation structures will be presented to growers as LPDs comply with § 201.106(a), review and analysis of documentation by AMS under this provision will focus on the unfair reductions in compensation resulting from contract modification which this provision is intended to prevent. Therefore, AMS does not expect additional costs for LPDs as a result of § 201.106(c) beyond the direct administrative costs of assessing and monitoring revised payment systems for potential reductions in grower compensation and providing documentation when required as explicitly described in the previous section.

Direct Costs of Final § 201.110—Preferred Alternative

Final § 201.110 will require LPDs to develop, maintain and comply with a set of policies and procedures that ensure the operation of a poultry grower ranking system that is consistent with the duty of fair comparison among growers, including describing processes for supplying or assigning inputs and production practices, communication and cooperation, and facilitating the conduct of ongoing compliance reviews with those processes.

Final § 201.110(a) and (b)(1)(i) through (v) describe objectives and minimum requirements for written documentation of processes, including how LPDs will operate poultry grower ranking systems that are consistent with the duty of fair comparison. Information obtained during previous AMS investigations suggests that LPDs may already have some informal policies and practices or perhaps even some contract provisions in place to address and attempt to remedy situations in which growers have been inadvertently disadvantaged by such factors. For example, AMS is aware of situations where an LPD has removed a grower that received an unreasonable share of lower quality inputs from the grower pool and paid them by another method that would not penalize relative performance (*e.g.*, a five-flock average). Under final § 201.110(a) and (b)(1)(i) through (v), all LPDs will be required to develop formal written processes that meet specific criteria outlined in the regulation.

AMS estimates that the one-time aggregate cost of developing new policies and procedures in response to final § 201.110(a) and (b)(1)(i) through (v) for LPDs will require 4,128 legal hours, 28,500 management hours, 1,472 administrative hours, and 1,472 information technology hours, costing a total of \$3,539,000 in the first year.⁹⁹ Due to differences in their structure, estimates for small LPDs were calculated with the expectation that they would employ relatively fewer legal (attorney) hours that are offset by a larger share of management hours.¹⁰⁰

LPDs will implement, monitor, and comply with new written processes for the design and operation of a poultry grower ranking system that is consistent with the duty of fair comparison; they will also maintain and update these written processes. AMS expects these annual ongoing costs to require in aggregate 1,400 legal hours,¹⁰¹ 28,336 management hours which include renewing and updating written processes at the corporate level as well as monitoring activities conducted by

⁹⁹ 4,128 legal hours × \$139.96 per hour + 28,500 management hours × \$96.40 per hour + 1,472 administrative hours × \$49.36 per hour + 1,472 information technology hours × \$95.58 per hour = \$3,538,507.

¹⁰⁰ Small live poultry dealers are estimated to require 33% as many legal hours and 133% as many management hours as large live poultry dealers on a per-complex basis for one-time cost of developing § 201.110 tournament fairness policies and procedures.

¹⁰¹ Small live poultry dealers are estimated to require 50% as many legal hours as large live poultry dealers on a per-complex basis in ongoing compliance and maintenance of § 201.110 tournament fairness policies and procedures.

managers at each complex to ensure ongoing compliance, 736 administrative hours, and 736 information technology hours for an aggregate annual cost of \$3,034,000.¹⁰²

Final § 201.110(b)(1)(vi) requires that the written processes developed must include a description of how LPDs communicate and cooperate to resolve grower concerns in a timely fashion. AMS expects that the aggregate one-time cost to LPDs of setting up communications and cooperation protocol and implementing them in the first year will require 840 legal hours, 546 management hours, 168 administrative hours, and 336 information technology hours¹⁰³ for an aggregate one-time cost of \$211,000.¹⁰⁴

Final § 201.110(b)(2) states the length of time for retaining the records relevant to an LPD's compliance with final § 201.110(b)(1) and (2). AMS considered record retention when estimating costs for final § 201.110(b)(1) and final § 201.110(b)(2) does not impose any costs independently.

AMS expects the ongoing annual costs after the first year of implementing written processes regarding communication, cooperation, and dispute resolution policies and procedures described in final § 201.110(b)(1)(vi) to require, in aggregate, 336 legal hours, 168 management hours, 84 administrative hours, and 84 information technology hours for an aggregate annual cost of \$75,000.¹⁰⁵

Written processes developed by LPDs are for internal use, to be complied with and maintained, to be provided to AMS, and as part of ongoing compliance monitoring. Under final § 201.110, LPDs are not required to provide additional disclosures to contract growers. Therefore, final § 201.110 will not impose any additional one-time or ongoing costs on growers to review

additional disclosures, and total grower costs of final § 201.110 are zero.

The ten-year total costs of final § 201.110 to all 42 live broiler poultry dealers are estimated to be \$31,736,000. Since expected grower costs for this section are zero, these also represent the total aggregate costs of § 201.110.

Direct Costs of Final § 201.112—Preferred Alternative

The new provisions in final § 201.112 will require LPDs to provide a Capital Improvement Disclosure Document any time the LPD requests existing broiler chicken growers to make an additional capital investment (\$12,500 or more per structure excluding maintenance or repair). The Capital Improvement Disclosure Document must include information about the goal or purpose of the investment, financial incentives and compensation for the grower associated with the additional capital investment, all schedules and deadlines for the investment, a description of changes to housing specifications, and analysis of projected returns.

Final § 201.112 will require LPDs to create a Capital Improvement Disclosure Document when new capital investments are required of growers. Based on information provided by subject matter experts, AMS estimates that capital upgrades will be required at 5 percent of complexes each year, triggering creation of a new disclosure document for approximately 5 percent of growers annually. Therefore, AMS estimates the annual cost of creating disclosures for additional requested grower capital investment will require 74 legal hours, 368 management hours, 74 administrative hours, and 92 information technology hours to create and provide a Capital Improvement Disclosure Document for all growers requiring additional capital improvement upgrades, for an aggregate annual cost of \$58,000.¹⁰⁶

With the exception of acknowledging receipt, the final rule will not impose any requirement on poultry growers to review the information provided by LPDs, but to benefit from the Capital Improvement Disclosure Document, growers will need to review the information provided. For final § 201.112, AMS expects that growers will take about four hours to review these documents when they are disclosed as part of a capital improvement request or requirement by the LPD. LPDs will be required to

provide disclosures to growers for any of 20,014 contracts for which additional capital investment requests are made.¹⁰⁷ AMS expects that LPDs will make additional capital investment requests for an average of 5 percent of grower contracts annually. At an estimated 4 hours of grower review time per disclosure at \$62.13 per hour, growers' aggregate annual costs will be \$249,000¹⁰⁸ for reviewing documents required by § 201.112 in the first year and in each successive year.

The ten-year aggregate total costs of final § 201.112 to LPDs are estimated to be \$582,000, the ten-year aggregated total costs of final § 201.112 to poultry growers are estimated to be \$2,487,000, and the combined ten-year aggregate total costs of final § 201.112 to LPDs and poultry growers are estimated to be \$3,069,000.

Unquantified Indirect Costs of § 201.112—Preferred Alternative

If AMS enforcement of final § 201.112 has the effect of preventing broiler growers from making unprofitable additional capital investments (those for which individual grower returns do not exceed costs), then such decisions to forgo investment will likely result in fewer benefits for LPDs, and more for growers. Because LPDs benefit from any productivity gain created by grower investments, whether or not the investment is profitable for the grower in the long-run, LPDs will not receive these benefits if additional information provided under this provision causes growers to avoid additional capital investments that they deem to be unprofitable and inefficient for their operation. AMS is not able to quantify these lost benefits to LPDs. They represent costs to LPDs, but these costs are at least partly offset by gains (or avoided losses) for growers. In addition, to the degree that an additional capital investment requires over-investment, eliminating it benefits society. Over-investment occurs when the cost of the investment exceeds the total value it generates (in terms of increased grower productivity, production cost efficiency, etc.) and the investment resources would be more productively employed in other ways. The benefits to growers and society of avoiding such investments would exceed the losses to LPDs.

¹⁰² 1,400 legal hours × \$139.96 per hour + 28,336 management hours × \$96.40 per hour + 736 administrative hours × \$49.36 per hour + 736 information technology hours × \$95.58 per hour = \$3,034,210.

¹⁰³ Small live poultry dealers are estimated to require 50% as many legal hours and 125% as many management hours, and 50% as many information technology hours as large live poultry dealers on a per company basis for one-time cost of developing § 201.110 communication, cooperation, and dispute resolution policies and procedures.

¹⁰⁴ 840 legal hours × \$139.96 per hour + 546 management hours × \$96.40 per hour + 168 administrative hours × \$49.36 per hour + 336 information technology hours × \$95.58 per hour = \$210,608.

¹⁰⁵ 336 legal hours × \$139.96 per hour + 168 management hours × \$96.40 per hour + 84 administrative hours × \$49.36 per hour + 84 information technology hours × \$95.58 per hour = \$75,397.

¹⁰⁶ 74 legal hours × \$139.96 per hour + 368 management hours × \$96.40 per hour + 74 administrative hours × \$49.36 per hour + 92 information technology hours × \$95.58 per hour = \$58,203.

¹⁰⁷ Live poultry dealers reported a combined total of 20,014 contracts for their fiscal year 2023.

¹⁰⁸ 4 hours to review each disclosure × \$62.13 per hour × 20,014 contracts × 5 percent of growers that require significant housing upgrades = \$248,694.

Combined Costs of Final §§ 201.106, 110, and 112—Preferred Alternative

Combined costs to LPDs for final §§ 201.106, 110, and 112 are expected to be \$20,775,000 in the first year, \$4,740,000 in years two through four, and \$3,954,000 in subsequent years thereafter. Information collection costs are also reported in the Paperwork Reduction Act section as the combined costs to LPDs for compliance with the reporting and recordkeeping requirements of final §§ 201.106, 110, and 112. The combined costs for poultry growers are expected to be \$5,223,000 in the first year and \$249,000 in subsequent years.

The ten-year aggregate combined costs of final §§ 201.106, 110, and 112 to LPDs are estimated to be \$58,719,000 and the present value of the ten-year total costs to be \$54,230,000 discounted at a two percent rate. The annualized aggregate combined costs of the present value (PV) of ten-year costs to LPDs discounted at a two percent rate are expected to be \$6,037,000.

The ten-year aggregate combined costs of final §§ 201.106, 110, and 112 to poultry growers are estimated to be \$7,461,000 and the present value of the ten-year total costs to be \$7,110,000 discounted at a three percent rate. The annualized aggregate combined costs of

the PV of ten-year costs to poultry growers discounted at a three percent rate are expected to be \$792,000.

The ten-year aggregate combined costs of final §§ 201.106, 110, and 112 to LPDs and poultry growers are estimated to be \$66,179,000 and the present value of the ten-year aggregate combined costs to be \$61,341,000 discounted at a two percent rate. The annualized aggregate costs of the PV of ten-year costs to LPDs and poultry growers discounted at a two percent rate are expected to be \$6,829,000. The cost estimates of final §§ 201.106, 110, and 112 presented above appear in the following table.

TABLE 1—ESTIMATED COSTS OF FINAL §§ 201.106, 110, AND 112—PREFERRED ALTERNATIVE

Preferred alternative	Expected costs *		
	Live poultry dealers	Poultry growers	Industry total
§ 201.106:			
First-Year	\$16,968,000	\$4,974,000	\$21,941,000
Ten-Year Total	26,401,000	4,974,000	31,375,000
PV of Ten-Year Discounted at 2%	25,148,000	4,876,000	30,025,000
Ten-Year Annualized at 2%	2,800,000	543,000	3,343,000
§ 201.110:			
First-Year	3,749,000	0	3,749,000
Ten-Year Total	31,736,000	0	31,736,000
PV of Ten-Year Discounted at 2%	28,559,000	0	28,559,000
Ten-Year Annualized at 2%	3,179,000	0	3,179,000
§ 201.112:			
First-Year	58,000	249,000	307,000
Ten-Year Total	582,000	2,487,000	3,069,000
PV of Ten-Year Discounted at 2%	523,000	2,234,000	2,757,000
Ten-Year Annualized at 2%	58,000	249,000	307,000
§§ 201.106, 110, and 112:			
First-Year	20,775,000	5,223,000	25,997,000
Ten-Year Total	58,719,000	7,461,000	66,179,000
PV of Ten-Year Discounted at 2%	54,230,000	7,110,000	61,341,000
Ten-Year Annualized at 2%	6,037,000	792,000	6,829,000

* Rows may not sum to Total Costs due to rounding.

Estimated Costs-and Expected Benefits of Final §§ 201.106, 110, and 112—Preferred Alternative

The value of broiler production in the U.S. for 2023 was approximately \$50.6 billion.¹⁰⁹ Total direct costs of final §§ 201.106, 110, and 112 are estimated to be greatest in the first year at \$26.0 million, or 0.051 percent of revenues. A relatively small improvement in efficiency from improved allocation of capital and labor resources in the industry would more than outweigh the direct costs of this final rule. A reduction in information asymmetry (resulting in more useful information provided to growers), grower uncertainty and risk of potential adverse outcomes, and retaliatory and deceptive practices by LPDs will lead to benefits

resulting from the final rule. The size of benefits will be directly related to the extent of these reductions. AMS expects that the final rule will provide substantial benefits the industry and address issues of extreme importance to broiler growers. However, these benefits are not quantifiable. Benefits and costs are summarized below for each provision of the rule.

Final § 201.106(a) benefits broiler growers by requiring LPDs to implement payment structures that increase clarity and certainty about the lowest possible revenue outcomes under a growing arrangement. LPDs are expected to incur one-time direct costs of developing, documenting, and communicating new contracts and a new system of grower payments and no additional ongoing costs. Since most LPDs currently employ payment structures that allow for both bonuses and discounts, AMS

expects these costs to be realized by LPDs at most complexes and the corresponding benefits to be realized by the vast majority of broiler growers.

Final § 201.106(b) establishes a presumption of unfairness when the amount of total grower compensation based on relative performance exceeds 25 percent and thereby protects growers from excess income variability. Some growers at complexes where LPDs modify compensation structures to reduce the percentage of grower pay based on relative performance may benefit from reductions in the variability of their income. The distribution of benefits is likely to be unequal, such that increases in compensation for some growers may correspond with decreases in performance-based compensation for other growers.

¹⁰⁹ USDA—NASS. Poultry—Production and Value 2023 Summary (April 2024).

In addition to direct costs to LPDs of implementing the rule, § 201.106(b) could result in additional indirect costs to broiler industry stakeholders (including LPDs, consumers, and growers) if LPDs modify existing compensation structures in ways that adversely affect grower incentives and lead to increased production costs. The magnitude of benefits and costs resulting from § 201.106(b) will depend on two important factors that cannot be measured or predicted with a reasonable degree of certainty: the number of broiler complexes that will modify existing compensation structures as a result of final § 201.106(b) and the manner in which those change will be implemented by LPDs. If few or no complexes make substantial modifications to existing compensation structures as a result of § 201.106(b), the resulting benefits to growers of reduced income variability and the indirect costs to the broiler industry will be small. All broiler growers will nonetheless benefit from ongoing protection against future increases in performance-based pay variability and reductions in base pay amounts.

Growers will benefit from additional protections under § 201.106(c) that require LPDs to submit prior and modified contracts if contract modifications result in reduced average grower compensation during a three-year transition period. This requirement will facilitate AMS monitoring and intervention, when necessary, to protect growers from unfair treatment. AMS does not expect indirect costs to broiler industry stakeholders. AMS expects the benefits of § 201.106(c) will accrue to all broiler growers and the direct costs of implementation over the three-year transition period will apply to all LPDs.

By requiring that LPDs design and operate poultry grower ranking systems to provide a fair comparison among growers, final § 201.110 will benefit broiler growers through increased fairness and reduced deception. All broiler growers will benefit to the degree that this provision improves fairness and reduces deception within poultry grower ranking systems. The direct costs of implementing and maintaining compliance with § 201.110 will be incurred by all LPDs, and AMS does not expect any other indirect costs of this provision.

Disclosures concerning additional capital investments required by final § 201.112 will provide broiler growers with better information to make financial decisions and reduce the likelihood the LPDs can deceive or mislead growers. Growers will also benefit to the extent that this

requirement provides information that facilitates improved identification and enforcement of violations under § 201.116. LPDs will incur direct costs of preparing and distributing disclosures when additional capital investments are requested by the LPD. The provision could also cause some transfer of benefits from LPDs to growers if the provision causes growers to avoid making unprofitable investments that would have benefited the LPD more than the grower.

Net total costs and benefits to the industry from final §§ 201.106, 110, and 112 cannot be quantified. Thus, AMS cannot measure any impact or shift in total industry supply or any corresponding indirect effects on industry supply and demand, including price and quantity effects.

Estimated Costs and Expected Benefits of the Small Business Exemption Alternative

AMS estimated costs for an alternative to the preferred option for the final rule. It would be the same as final §§ 201.106, 110, and 112, with the exception that the alternative would exempt LPDs that fall under the SBA definition of small businesses from all provisions of the two final rules. In the preferred alternative, the requirements in final §§ 201.106, 110, and 112 would apply to all LPDs, including those classified as small businesses.

The costs associated with this alternative are similar, but smaller than the preferred option. According to PSD records, small LPDs make up 50.0 percent of all LPDs, but have only 6.0 percent of poultry growing contracts. The estimation of the costs of the small business exemption alternative will follow the same format as the preferred alternative.

Costs of Final § 201.106—Small Business Exemption Alternative

AMS estimates that the aggregate one-time costs to LPDs of updating grower contracts and developing new grower payment systems, including modifying information systems to include new calculations as well as filing, and reporting to comply with final § 201.106(a), will require 15,936 legal hours, 54,780 management hours, 6,640 administrative hours, and 6,640 information technology hours, costing a total of \$8,474,000 in the first year under the small business exemption alternative. Once LPDs have incurred a one-time cost of developing, documenting, and communicating new contracts and a new system of grower payments, AMS does not expect additional ongoing costs of

implementing final § 201.106(a) under the small business exemption alternative.

AMS estimates that the aggregate one-time costs to LPDs of examining and evaluating existing grower compensation structures and making modifications as required to ensure ongoing compliance with final § 201.106(b), will require 6,640 legal hours, 49,800 management hours, 6,640 administrative hours, and 13,280 information technology hours, costing a total of \$7,327,000 in the first year under the small business exemption alternative.

LPDs will monitor, maintain and comply with the processes for examining excessive variability. AMS expects these annual ongoing costs to require in aggregate 664 legal hours, 4,980 management hours, 664 administrative hours, and 1,328 information technology hours for an aggregate annual cost of \$733,000 under the small business exemption alternative.

AMS does not expect any cost in the first year to set up and implement a plan in response to § 201.106(c). For each of the three calendar years following the effective date for § 201.106, AMS expects these annual ongoing costs to require in aggregate 664 legal hours, 4,980 management hours, 664 administrative hours, and 1,328 information technology hours for an aggregate annual cost of \$733,000 under the small business exemption alternative.

For final § 201.106(a), AMS expects that growers will take about 4 hours to review new contract terms and provisions when they are provided in the first year. At \$62.13 per hour, the total one-time cost for all broiler growers to review the new contract under the small business exemption alternative is \$4,674,000.¹¹⁰ AMS expects that the updated contract provisions and payment systems developed by LPDs pursuant to final § 201.106 (a) would not contribute to additional ongoing contract review time by growers beyond an initial one-time review. Therefore, no ongoing future costs of grower contract review are included.

The ten-year aggregate total costs to LPDs of final § 201.106 under the small business exemption alternative are estimated to be \$24,593,000, the ten-year aggregate total costs to broiler growers of final § 201.106 for the small business exemption alternative are estimated to be \$4,674,000, and the first-

¹¹⁰ 4 hours to review each disclosure × \$62.13 per hour × 18,806 contracts = \$4,673,667.

year and ten-year aggregate total costs to LPDs and poultry growers of final § 201.106 for the small business exemption alternative are estimated to be \$29,267,000.

Unquantified Indirect Costs of § 201.106—Small Business Exemption Alternative

AMS expects that indirect costs resulting from § 201.106(b) and (c) for the small business exemption alternative will be nearly identical to those discussed for the preferred alternative, with the only difference being the number of complexes potentially affected. In particular, small LPDs would be exempt from the presumption of unfairness under § 201.106(b) and will not incur indirect costs from modifying grower compensation structures to reduce the percentage of performance-based compensation for a complex below the presumptively unfair 25 percent of total compensation. The 10 percent of complexes that would be exempted from the regulation under this alternative are small by definition. AMS does not have access to data that would suggest whether these small LPD complexes are any more or less likely to require modifications to existing grower compensation structures that result in indirect costs than other complexes. Indirect costs for the small business exemption alternative could only be equal to or less than the preferred alternative but cannot be quantified for the same reasons.

Direct Costs of Final § 201.110—Small Business Exemption Alternative

AMS estimates that the one-time aggregate cost of developing new policies and procedures in response to final § 201.110(a) and (b)(1)(i) through (v) for LPDs will require 3,984 legal hours, 24,900 management hours, 1,328 administrative hours, and 1,328 information technology hours, costing a total of \$3,150,000 in the first year for the small business exemption alternative.

After new written processes have been developed, LPDs would be required to implement, monitor, and comply and to maintain and update them. AMS expects these annual ongoing costs for the small business exemption alternative to require in aggregate 1,328 legal hours, 25,564 management hours which include renewal and updating of written processes at the corporate level as well as monitoring activities conducted by managers at each complex to ensure ongoing compliance, 664 administrative hours, and 664 information technology

hours for an aggregate annual cost of \$2,746,000.¹¹¹

Final § 201.110(b)(1)(vi) requires that the written processes developed must include a description for how the LPD would resolve a grower's concerns with the LPD's design or operation of a poultry grower ranking system that is consistent with the duty of fair comparison that is required by this section, including the timeliness of the resolution. AMS expects that the aggregate one-time cost to LPDs of setting up communications and complaint resolution processes as described in § 201.110(b)(1)(vi) for the small business exemption alternative will require 504 legal hours, 252 management hours, 84 administrative hours, and 210 information technology hours for an aggregate one-time cost of \$119,000.¹¹²

Costs associated with final § 201.110(b)(2), "Record retention," are included in cost estimates for final § 201.110(b)(1). AMS expects that this section does not incur any additional costs.

AMS expects the ongoing annual costs of implementing communications and complaint resolution processes as described in § 201.110(b)(1)(vi) to require, for the small business exemption alternative, in aggregate, 168 legal hours, 84 management hours, 42 administrative hours, and 42 information technology hours for an aggregate annual cost of \$38,000.¹¹³ Because final § 201.110 does not require LPDs to provide additional disclosures to contract growers, final § 201.110 would not impose any additional one-time or ongoing costs on growers to review additional disclosures, and total grower costs of final § 201.110 are also zero under the small business exemption alternative.

The ten-year total costs of final § 201.110 to the 50.0 percent of live broiler poultry dealers impacted under the small business exemption alternative are estimated to be \$28,327,000. Since expected grower costs for this section are zero, these also represent the total aggregate costs of final § 201.110.

¹¹¹ 1,328 legal hours × \$139.96 per hour + 25,564 management hours × \$96.40 per hour + 664 administrative hours × \$49.36 per hour + 664 information technology hours × \$95.58 per hour = \$2,746,477.

¹¹² 504 legal hours × \$139.96 per hour + 252 management hours × \$96.40 per hour + 84 administrative hours × \$49.36 per hour + 210 information technology hours × \$95.58 per hour = \$119,051.

¹¹³ 168 legal hours × \$139.96 per hour + 84 management hours × \$96.40 per hour + 42 administrative hours × \$49.36 per hour + 42 information technology hours × \$95.58 per hour = \$37,698.

Direct Costs of Final § 201.112—Small Business Exemption Alternative

Final § 201.112 would require LPDs to create a Capital Improvement Disclosure Document when new capital investments are requested of growers. Based on information provided by subject matter experts, AMS estimates a five percent annual average probability that capital improvement upgrades will be required for growers at a complex, which would trigger creation of a new Disclosure Document. Therefore, AMS estimates the annual ongoing cost of creating Capital Improvement Disclosure Documents for the small business exemption alternative will require 66 legal hours, 332 management hours, 66 administrative hours, and 83 information technology hours to create and provide Capital Improvement Disclosure Documents for all growers requiring additional capital improvement upgrades, for an aggregate annual cost of \$53,000 for the small business exemption alternative.¹¹⁴

For final § 201.112, AMS expects that growers would take about four hours to review these documents when they are disclosed as part of a capital improvement request or requirement by the LPD. For the small business exemption alternative, LPDs would be required to provide disclosures to growers for any of the 18,806 contracts for which additional capital investment requests are made.¹¹⁵ AMS expects that LPDs will make additional capital investment requests for an average of five percent of grower contracts annually. Given that growers require an estimated 4 hours at \$62.13 per hour, growers' aggregate annual costs would be \$234,000 for reviewing documents required by final § 201.112 in the first year and in each successive year for the small business exemption alternative.¹¹⁶

The ten-year aggregate total costs of final § 201.112 under the small business exemption alternative for LPDs are estimated to be \$525,000, and the ten-year aggregated total costs to poultry growers of final § 201.112 under the small business exemption alternative are estimated to be \$2,337,000. The combined first-year aggregate total costs to LPDs and poultry growers of final

¹¹⁴ 66 legal hours × \$139.96 per hour + 332 management hours × \$96.40 per hour + 66 administrative hours × \$49.36 per hour + 83 information technology hours × \$95.58 per hour = \$52,509.

¹¹⁵ Live poultry dealers that exceed SBA classification criteria for small businesses reported a combined 18,806 poultry contracts in their Annual Reports to AMS.

¹¹⁶ 4 hours to review each disclosure × \$62.13 per hour × 18,806 contracts × 5 percent of growers that require significant housing upgrades = \$233,683.

§ 201.112 under the small business exemption alternative are estimated to be \$286,000, and the ten-year aggregate total costs are estimated to be \$2,862,000.

Combined Costs of Final §§ 201.106, 110, and 112—Small Business Exemption Alternative

Aggregate combined costs to LPDs for final §§ 201.106, 110, and 112 for the small business exemption alternative are expected to be \$19,123,000 in the first year, and \$4,302,000 in subsequent years. The combined costs for poultry growers are expected to be \$4,907,000 in the first year, \$234,000 in subsequent years.

The aggregate ten-year combined quantified costs to LPDs of final §§ 201.106, 110, and 112 for the small business exemption alternative are estimated to be \$53,445,000 and the

present value of the ten-year combined costs \$49,382,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to LPDs discounted at a two percent rate are expected to be \$5,498,000.

The aggregate ten-year combined costs to poultry growers of final §§ 201.106, 110, and 112 for the small business exemption alternative are estimated to be \$7,011,000 and the present value of the ten-year combined costs are estimated to be \$6,681,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to poultry growers discounted at a two percent rate are expected to be \$744,000.

The aggregate combined costs of final §§ 201.106, 110, and 112 under the small business exemption alternative for LPDs and poultry growers are estimated

to be \$24,030,000 in the first year and \$4,536,000 in subsequent years. The aggregate ten-year combined costs to LPDs and poultry growers of final §§ 201.106, 110, and 112 for the small business exemption alternative are estimated to be \$60,456,000 and the present value of the ten-year combined costs are estimated to be \$56,063,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to LPDs and poultry growers discounted at a two percent rate are expected to be \$6,241,000. The aggregate cost estimates of final §§ 201.106, 110, and 112 under the small business exemption alternative presented above appear in the following table. The quantified costs to the industry in the first year under the small business exemption alternative are \$24.030 million.

TABLE 2—ESTIMATED COSTS OF FINAL §§ 201.106, 110, AND 112—SMALL BUSINESS EXEMPTION ALTERNATIVE

SBE alternative	Expected cost *		
	Live poultry dealers	Poultry growers	Industry total
§ 201.106:			
First-Year	\$15,801,000	\$4,674,000	\$20,474,000
Ten-Year Total	24,593,000	4,674,000	29,267,000
PV of Ten-Year Discounted at 2%	23,426,000	4,582,000	28,008,000
Ten-Year Annualized at 2%	2,608,000	510,000	3,118,000
§ 201.110:			
First-Year	3,269,000	0	3,269,000
Ten-Year Total	28,327,000	0	28,327,000
PV of Ten-Year Discounted at 2%	25,485,000	0	25,485,000
Ten-Year Annualized at 2%	2,837,000	0	2,837,000
§ 201.112:			
First-Year	53,000	234,000	286,000
Ten-Year Total	525,000	2,337,000	2,862,000
PV of Ten-Year Discounted at 2%	472,000	2,099,000	2,571,000
Ten-Year Annualized at 2%	53,000	234,000	286,000
§§ 201.106, 110, and 112:			
First-Year	19,123,000	4,907,000	24,030,000
Ten-Year Total	53,445,000	7,011,000	60,456,000
PV of Ten-Year Discounted at 2%	49,382,000	6,681,000	56,063,000
Ten-Year Annualized at 2%	5,498,000	744,000	6,241,000

* Rows may not sum to Total Costs due to rounding.

Estimated Costs and Expected-Benefits of Final §§ 201.106, 110, and 112—Small Business Exemption Alternative

According to PSD records, only 6.0 percent of poultry growing contracts are between small LPDs and poultry growers. Thus, 94 percent of all poultry growers will receive the benefits of final §§ 201.106, 110, and 112 under the small business exemption alternative.

As with the preferred option, net total costs and benefits to the industry from §§ 201.106, 110, and 112 under the small business exemption alternative cannot be quantified. Thus, AMS cannot measure any impact or shift in total industry supply or any corresponding

indirect effects on industry supply and demand, including price and quantity effects.

The tables above indicate that the small business exemption alternative would cost the industry less than the preferred option. Although most growers contract with large poultry growers, AMS chose not to accept the alternative because exempting small business from complying with the regulations would also result in less benefits to growers.

Estimated Costs and Expected Benefits of Proposed Rule Alternative

AMS estimated costs for a third alternative to the “do nothing” option and the last of four total alternatives presented. This alternative considers adopting §§ 201.106, 110, and 112 for all small and large LPDs as originally proposed without including the changes in the final rule. These changes have already been described in extensively earlier in the document. The estimation of costs for the proposed rule alternative will proceed by describing differences in costs by major rule section and combined.

Costs of § 201.106—Proposed Rule Alternative

Final § 201.106(a) is unchanged from § 201.106 as it was proposed and as it is analyzed in this alternative. Final § 201.106(b), “Excessive variability,” and (c), “Transition,” were not included in proposed § 201.106. Neither estimates of direct time costs nor other potential indirect costs or associated benefits for these provisions are included for the proposed rule alternative. Estimated costs for § 201.106 under the proposed rule alternative are equal to one-time direct costs of final § 201.106(a).

Costs of § 201.110—Proposed Rule Alternative

Final § 201.110 requires LPDs to develop, maintain, and comply with a set of policies and procedures that are reasonably designed for the design and operation of a poultry grower ranking system that is consistent with the duty of fair comparison. As described in previous discussion of changes from the proposed to final rule, final § 201.110(a) is substantively unchanged from the proposed rule, text of final § 201.110(b)(1) has been simplified from the proposed rule to improve clarity of documentation requirements, and proposed § 201.110(b)(2), “Compliance review,” has been removed. Two other provisions of proposed § 201.110 relating to “Communication and cooperation” and “Record retention” have received paragraph number redesignations but are otherwise unchanged. Changes to § 201.110(b)(1) did not affect the estimation of hours or of costs and benefits to the rule. Estimated costs of § 201.110 under the proposed rule alternative are therefore equal to estimated direct costs for the final § 201.110 under the preferred alternative with costs for proposed § 201.110(b)(2) added.

Proposed § 201.110(b)(2), would require LPDs to conduct a compliance review of each complex no less than once every two years to ensure compliance with policies and procedures established under proposed § 201.110(a) and (b)(1). LPDs would need to first design a compliance review system to be used for conducting written review of compliance by complex managers, production supervisors, and field agents. Compliance reviews would then need to

be conducted every two years at each complex.

AMS estimates that the aggregate one-time costs of designing and initiating the compliance review process would require 2,208 legal hours, 14,720 management hours, 736 administrative hours, and 2,392 information technology hours costing \$1,993,000¹¹⁷ in the first year for LPDs to initially set up their review and compliance policies and procedures and initiate their ongoing compliance review processes.

The ongoing cost for LPDs to conduct compliance reviews for each complex every two years has been converted to an annual cost by dividing the total cost of conducting reviews on all complexes in half. This could be consistent with, for example, a system where each LPD reviews half of their complexes each year on a rolling basis or, alternatively, where a sinking fund deposit is made each year and used every other year. AMS estimates that total ongoing annual costs on the part of LPDs will require 736 legal hours, 7,360 management hours, 368 administrative hours, and 920 information technology hours to conduct and document written reviews of compliance of each complex no less than once every two years, for an aggregate annual cost of \$919,000.¹¹⁸

Costs of § 201.112—Proposed Rule Alternative

Text of § 201.112(a) and (b) was changed from the proposed to final rule primarily for the purpose of clarification or to add paragraph titles; these changes did not affect the estimation of hours or of costs and benefits to the rule. The addition of final § 201.112(c), “Translation,” from the proposed to final rule is also not expected to change hours or costs because LPDs already have all necessary information to make reasonable efforts to assist growers in translating disclosure documents and have made it available to growers who request the information. Accordingly, AMS did not add any time to its cost estimates for LPDs to comply with this new requirement. AMS cost estimates to

¹¹⁷ 2,208 legal hours × \$139.96 per hour + 14,720 management hours × \$96.40 per hour + 736 administrative hours × \$49.36 per hour + 2,392 information technology hours × \$95.58 per hour = \$1,992,996.

¹¹⁸ 736 legal hours × \$139.96 per hour + 7,360 management hours × \$96.40 per hour + 368 administrative hours × \$49.36 per hour + 920 information technology hours × \$95.58 per hour = \$918,613.

LPDs and growers of § 201.112 under the proposed rule alternative are identical to those described under the preferred alternative.

Combined Costs of §§ 201.106, 110, and 112—Proposed Rule Alternative

Aggregate combined costs to LPDs for §§ 201.106, 110, and 112 for the proposed rule alternative are expected to be \$14,906,000 in the first year, and \$4,086,000 in subsequent years. The combined costs for poultry growers are expected to be \$5,223,000 in the first year, \$249,000 in subsequent years.

The aggregate ten-year combined quantified costs to LPDs of §§ 201.106, 110, and 112 for the proposed rule alternative are estimated to be \$51,684,000 and the present value of the ten-year combined costs is \$47,314,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to LPDs discounted at a two percent rate are expected to be \$5,267,000.

The aggregate ten-year combined costs to poultry growers of §§ 201.106, 110, and 112 for the proposed rule alternative are estimated to be \$7,461,000 and the present value of the ten-year combined costs are estimated to be \$7,110,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to poultry growers discounted at a two percent rate are expected to be \$792,000.

The aggregate combined costs of final §§ 201.106, 110, and 112 under the proposed rule alternative for LPDs and poultry growers are estimated to be \$20,129,000 in the first year and \$4,335,000 in subsequent years. The aggregate ten-year combined costs to LPDs and poultry growers of §§ 201.106, 110, and 112 for the proposed rule alternative are estimated to be \$59,145,000 and the present value of the ten-year combined costs are estimated to be \$54,425,000 discounted at a two percent rate. The aggregate annualized costs of the PV of ten-year costs to LPDs and poultry growers discounted at a two percent rate are expected to be \$6,059,000. The aggregate cost estimates of final §§ 201.106, 110, and 112 under the proposed rule alternative presented above appear in the following table. The quantified costs to the industry in the first year under the proposed rule alternative are \$20.13 million.

TABLE 3—ESTIMATED COSTS OF §§ 201.106, 110, AND 112—PROPOSED RULE ALTERNATIVE

Preferred alternative	Expected cost *		
	Live poultry dealers	Poultry growers	Industry total
§ 201.106:			
First-Year	\$9,106,000	\$4,974,000	\$14,080,000
Ten-Year Total	9,106,000	4,974,000	14,080,000
PV of Ten-Year Discounted at 2%	8,928,000	4,876,000	13,804,000
Ten-Year Annualized at 2%	994,000	543,000	1,537,000
§ 201.110:			
First-Year	5,742,000	0	5,742,000
Ten-Year Total	41,996,000	0	41,996,000
PV of Ten-Year Discounted at 2%	37,864,000	0	37,864,000
Ten-Year Annualized at 2%	4,215,000	0	4,215,000
§ 201.112:			
First-Year	58,000	249,000	307,000
Ten-Year Total	582,000	2,487,000	3,069,000
PV of Ten-Year Discounted at 2%	523,000	2,234,000	2,757,000
Ten-Year Annualized at 2%	58,000	249,000	307,000
§§ 201.106, 110, and 112:			
First-Year	14,906,000	5,223,000	20,129,000
Ten-Year Total	51,684,000	7,461,000	59,145,000
PV of Ten-Year Discounted at 2%	47,314,000	7,110,000	54,425,000
Ten-Year Annualized at 2%	5,267,000	792,000	6,059,000

* Rows may not sum to Total Costs due to rounding.

Estimated Costs and Expected Benefits of §§ 201.106, 110, and 112—Proposed Rule Alternative

The expected benefits of proposed §§ 201.106, 110, and 112 as analyzed in the proposed rule alternative have been described in the discussion of benefits for the preferred option, final §§ 201.106, 110, and 112, with the exception of § 201.110(b)(2), “Compliance review,” which was removed from the proposed to final rule. Proposed § 201.110(b)(2) would require a written review of each broiler complex at least every other year to ensure compliance with the policies and procedures developed under this section. While the proposed rule would not require that LPD documentation be distributed to growers, it would be subject to USDA review to ensure ongoing maintenance and compliance. This compliance review requirement would not provide benefits separate from those generated by establishing the duty in § 201.110(a); however, documentation of regular review of LPD procedures could assist in ongoing enforcement of the proposed rule, thereby increasing the likelihood of compliance so that benefits of the proposed rule are realized by growers.

All potential non-quantifiable benefits and indirect costs of final § 201.106(b) and (c) are excluded from the proposed rule alternative. Net total costs and benefits to the industry from §§ 201.106, 110, and 112 in the proposed rule alternative cannot be quantified in relation to the total value of industry

production. Thus, AMS cannot measure any impact or shift in total industry supply or any corresponding indirect effects on industry supply and demand, including price and quantity effects.

Comments from the proposed rule have been discussed and changes to the final rule have been explained previously in this regulatory analysis. Expected benefits and costs of adopting the proposed rule are presented in this section as a third regulatory alternative to final §§ 201.106, 110, and 112. Estimated direct costs for the final rule preferred alternative are decreased by removal of proposed § 201.110(b)(2), “Compliance review” and increased by the addition of § 201.106(b) and (c). As a net result of all changes, estimated direct costs are lower for the proposed rule alternative in comparison to the final §§ 201.106, 110, and 112. The proposed rule alternative also excludes expected benefits and indirect costs of § 201.106(b) and (c). As discussed previously, commenters on the proposed rule expressed strong support for including these provisions. Under the proposed rule alternative, growers would be denied protection against excessive variation in compensation by establishing 25 percent as a presumptively unfair percentage of performance-based pay. Without protection during the transition period for implementation of these rule provisions, growers would be vulnerable to reductions in compensation by LPDs.

After considering all four regulatory alternatives, AMS determined that the

preferred alternative is the best alternative.

C. Regulatory Flexibility Act

As part of the regulatory process, a Regulatory Flexibility Analysis (RFA) is conducted in order to evaluate the effects of this final rule on small businesses.

AMS is adding final §§ 201.106, 110, and 112 to the regulations under the Packers and Stockyards Act. The regulations will establish requirements for LPDs that produce broilers with grower ranking contracts. LPDs that only produce turkeys, ducks, geese, or other fowl will not be affected. Final § 201.106 will require LPDs to develop and implement new broiler grower contracts and grower payment systems. Final § 201.110 will impose a duty on LPDs that produce broilers to establish and maintain compliance with written processes for the design and operation of poultry growing ranking systems consistent with a duty of fair comparison. Final § 201.112 would require LPDs to produce and distribute disclosures when they request growers to make additional capital investments.

Summary of the Final Rule

Final § 201.106 will prevent LPDs reducing compensation rates based on a grower's grouping, ranking, or comparison to others. All payment adjustments related to grower performance will need to be positive adjustments. LPDs are prevented from taking deductions based on relative performance rankings.

Final § 201.106 will also establish a presumptive unfairness limitation on the share of grower payments that an LPD may determine by a grower's grouping, ranking, or comparison to others. The Secretary will presume that an LPD is in violation of the Act if a payment associated with a grower's grouping, ranking, or comparison to others is more than 25 percent of the total payments to growers in a calendar year.

Final § 201.106 also creates a transition period lasting three years after the regulation becomes effective. During the transition period, if an LPD reduces the price per pound, the LPD will be required to forward to the AMS Administrator a copy of the prior and the modified contract and any LPD Disclosure Document.

Final § 201.110 will require LPDs to provide for fair comparison among growers when basing compensation on a upon a grouping or ranking of growers delivering during a specified period. Final § 201.110 also lists factors that the Secretary will consider in determining whether the system was designed to deliver a fair comparison, which include: whether growers will be compared to growers supplied with inputs or assigned production practices that result in material differences in performance metrics used in payment calculations, whether growers will be compared over appropriate time periods, whether any non-comparison payment methods applied are appropriate, whether the LPD has made reasonable efforts to timely resolve concerns a grower raises regarding the LPD's design and operation of its poultry grower ranking system, and any other factor relevant to a fair comparison.

Final § 201.110 will further require that when an LPD uses a poultry grower ranking system and cannot conduct a fair comparison for one or more growers, the LPD must compensate those growers through an appropriate non-comparison method specified in the contract that reflects reasonable compensation to the grower for its services.

Final § 201.110 will also require LPDs to establish and maintain written documentation of poultry grower ranking system policies and procedures for the design and operation of a poultry grower ranking system that is consistent with the duty of fair comparison. The written documentation must include policies and procedures regarding the manner in which LPDs will work to ensure a fair comparison among contract growers taking into account the distribution of inputs and assignment of

production variables that are controlled by the LPD, any flexibility the LPD has in performing these comparisons, and how the LPD resolves concerns regarding the design and operation of the poultry grower ranking system by the LPD.

Final § 201.112 will require LPDs to provide a Capital Improvement Disclosure Document any time the LPD requests or requires existing broiler chicken growers to make an additional capital investment that is \$12,500 or more per structure excluding maintenance or repair. The Capital Improvement Disclosure Document must include information about the goal or purpose of the investment, all schedules and deadlines for the investment, a description of changes to housing specifications, and analysis of projected returns.

Comments on the Proposed Rule and Associated Changes to the Final Rule

AMS did not receive comments from small LPDs. AMS received comments from trade associations that likely represent small LPDs, but none of their comments specifically addressed issues concerning small LPDs. After consideration of all the public comments, AMS chose to adopt the proposed rule as a final rule with several modifications. Large LPDs and trade associations commented that the regulation would be particularly challenging if the period of time allowed for regulated entities to comply with the provisions is too short.

To allow sufficient time for regulated entities to comply with the final rule and avoid excess implementation costs, AMS is setting the effective date for this rule at July 1, 2026, which is approximately 18 months following publication in the **Federal Register**. This extended time frame will not impact the amount or timing for estimated costs of the final rule because regulated entities are expected to incur costs during the year preceding the effective date.

Industry trade organizations and large LPDs commented that the full cost of implementing the proposed rule would be far greater than estimated by AMS. The commenters asserted that AMS greatly underestimated the costs that will be required for employing teams with highly specialized legal and technical expertise to implement the proposed rule by modifying or replacing grower contracts and communicating changes to growers. Commenters suggested that AMS did not adequately consider the total number of hours needed, but none provided quantified estimates. Large LPDs also commented

that hourly rates paid to specialized industry professionals such as attorneys should be much higher. Commenters also suggested that implementation of the rule would require LPDs to hire and train additional staff and pull resources away from other important activities.

For the time that small LPDs would require to comply with the rule, AMS consulted auditors and supervisors as subject matter experts who are familiar with LPDs and broiler complex operations from many years of experience employed with AMS in auditing LPDs for compliance with the Act. Small LPDs may need to hire new staff to implement the changes required by final §§ 201.106, 110, and 112, particularly in the first year. Hourly rates used in cost analysis for the proposed rule were based on averages within the agricultural sector as published and annually updated by the U.S. Bureau of Labor Statistics.¹¹⁹ AMS expects that average hourly rates provide an appropriate benchmark for estimating industry average costs. While some LPDs commented that AMS's estimates were too low, none of them recommended a different method of estimating costs.

In preparation for the final rule AMS reviewed direct costs with the subject matter experts. After doing so, AMS added modest amount of time to account for the cost of IT work in preparing disclosures in § 201.112.

AMS received comments from growers, grower groups, government agencies, and advocates in support of additional limitations on grower risk from excessive variability in compensation. Based on these comments, AMS has added provision § 201.106(b), which establishes a presumption that a regulated entity is in violation of the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers (performance pay) exceed of 25 percent of total gross payments (including performance and all other types of grower pay).

AMS added costs for LPDs to implement and monitor this new provision, which are discussed and quantified as direct administrative costs. Other expected additional benefits and indirect costs resulting from this new provision cannot be quantified and are discussed separately.

AMS also solicited comment in the proposed rule on whether there was a need to protect growers against the risk

¹¹⁹ See U.S. Bureau of Labor Statistics, May 2023 National Occupational Employment and Wage Estimates, May 2023. <https://www.bls.gov/oes/special.requests/oesm23all.zip>.

that LPDs might unfairly reduce broiler grower total compensation during a transition period after implementation of the final rule. Based on comments, AMS added § 201.106(c), which will require LPDs to submit copies of the prior and modified contracts and disclosures to AMS if average gross grower payments at a complex show year-over-year decline following a contract modification during the three calendar years commencing with and including the effective date of the rule. AMS will review the information provided by LPDs to identify any potentially unfair practices related to broiler grower compensation.

AMS expects that requirements in final § 201.106(c) will increase direct administrative costs for LPDs relative to the proposed rule. Final § 201.106(c) may increase indirect costs as well, but AMS does not have sufficient data to quantify the potential indirect costs or benefits associated with final § 201.106(c).

AMS received comments suggesting that some of the detailed documentation requirements under proposed § 201.110(b) were similar to existing documentation requirements and might create unnecessarily burdensome and complex paperwork. In response to these comments, AMS made several changes to § 201.110(b) in the final rule that included consolidating and streamlining the documentation requirements and removing some detailed requirements that were included in the proposed rule. AMS expects these changes to modestly reduce the total recordkeeping requirements or time cost of the information collection for LPDs, but AMS is unable to estimate these effects with certainty. To limit the potential for underestimating costs, AMS did not reduce hours and accordingly these changes did not affect the estimation of costs or benefits in the final rule relative to the proposed rule.

The proposed rule included § 201.110(b)(2), “Compliance review,” which required LPDs to conduct a required bi-annual review process. AMS removed this requirement in response to comments that self-audits would be burdensome for LPDs, and that elimination of this requirement would not substantially diminish compliance with § 201.110. Compliance will be enforced through regular AMS review of the policies and procedures poultry dealers are required to establish and maintain under § 201.110(b). Removing the compliance reviews reduced costs in the final rule relative to the proposed rule.

Based on comments received, AMS added a provision at § 201.112(c) to require that the LPD make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Capital Improvement Disclosure Document. Reasonable efforts include, but are not limited to, providing current contact information for professional translation service providers, trade associations with translator resources, relevant community groups, or any other person or organization that provides translation services in the poultry grower’s geographic area. Reasonable efforts, depending on the facts and circumstances (such as convenience, expense, and timeliness of the translation), may also include allowing the grower access to a computer-generated translation of the Disclosure Document and additional time to review any translated Disclosure Document.

A similar requirement was established for LPDs in § 201.102 of the “Transparency in Poultry Grower Contracting and Tournaments” final rule.¹²⁰ As LPDs already have all necessary information to make reasonable efforts to assist growers in translating disclosure documents and have made it available to growers who request the information. Similarly, AMS did not increase grower review time for the addition of § 201.112 as growers who require translation assistance already should be connected with the resources from § 201.102.

Small Businesses Affected

The Small Business Administration (SBA) defines small businesses by their North American Industry Classification System Codes (NAICS).¹²¹ SBA considers broiler producers small if sales are less than \$3.5 million per year. LPDs, classified under NAICS 311615, are considered small businesses if they have fewer than 1,250 employees.

AMS maintains data on LPDs from the Annual Reports these firms file with PSD.¹²² Currently, 42 LPDs would be subject to the regulation. Of these, 21 LPDs would be small businesses according to the SBA standard. In their fiscal year 2023, LPDs reported that they had 18,806 production contracts with

broiler growers. Small LPDs accounted for 1,208 contracts (6.0 percent).

Annual Reports from LPDs indicate they had 20,014 contracts, but a poultry grower can have more than one contract. The 2022 Census of Agriculture indicated that there were 14,144 contract broiler growers in the United States.¹²³ AMS does not regulate poultry growers and has no record of the number of poultry growers that qualify as small businesses but expects that nearly all of them are small businesses.

The typical size of broiler grow-out operations has trended larger from the early 2000s—when a typical broiler farm consisted of a 80,000–100,000 square foot operation—to a typical new farm today which “may have eight or more barns of over 30,000 square feet each on one site.”¹²⁴ Projected gross revenue for a newer farm receiving relatively high performance-based pay rates is \$224,000 for two 36,000 square foot barns.¹²⁵ Extrapolating these projections on a per house basis, gross revenue for an eight barn 288,000 square foot operation would total just under \$900,000 and an operation with 30 barns could still remain within the \$3.5 million threshold for small business classification. However, this same study notes that, “still, 80,000 to 120,000 square feet of housing for most family farms is all a single farmer can successfully operate while limiting hired labor.”

Direct Costs of Final §§ 201.106, 110, and 112

Direct costs of final §§ 201.106, 110, and 112 to LPDs would primarily consist of the time required to modify existing contracts, develop and comply with new policies, and collect and distribute it among the growers. Final §§ 201.106, 110, and 112 would also cost poultry growers the value of the time they put into reviewing and acknowledging receipt of new contracts and disclosures.

Expected direct costs are estimated as the total value of the time required by LPDs to modify existing contracts, develop and comply with new policies,

¹²³ USDA, NASS. 2023 Census of Agriculture: United States Summary and State Data. Volume 1, Part 51. Issued February 2024 Table 42. *st99_1_042_044.pdf* ([usda.gov](https://www.usda.gov)).

¹²⁴ Brothers, D. Goeringer, P. Thompson, J. “U.S. Broiler Growers Face Increasing Challenges on the Family Farm,” *Choices Magazine*, December 2023. Available online at <<https://www.choicesmagazine.org/choices-magazine/submitted-articles/us-broiler-growers-face-increasing-challenges-on-the-family-farm>> last accessed 11/6/2024.

¹²⁵ Alabama A&M & Auburn University Extension ANR-2932, February 2024. Available online at <https://www.aces.edu/wp-content/uploads/2022/10/ANR-2932_FarmTypesandEstimatedBusinessReturns_021924L-G.pdf> last accessed 11/6/2024.

¹²⁰ 88 FR 83210, 83301 (Nov. 28, 2023).

¹²¹ 13 CFR 121.201.

¹²² All LPDs are required to annually file PSD form 3002 “Annual Report of Live Poultry Dealers,” OMB control number 0581–0308. The Annual Report form is available to the public at <https://www.ams.usda.gov/sites/default/files/media/PSP3002.pdf>.

and collect and distribute required disclosures that would be required by final §§ 201.106, 110, and 112 as well as the time to create and maintain any necessary additional records. Estimates of the amount of time required to create and distribute the disclosure documents were provided by AMS subject matter experts. These experts were auditors and supervisors with many years of experience in auditing LPDs for compliance with the Packers and Stockyards Act. Estimates for the value of the time are U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics estimate released May 2023.¹²⁶ AMS marked up the wages 41.79 percent to account for benefits.

AMS estimated one-time first-year investment to LPDs of updating grower contracts and developing new grower payment systems, including modifying information systems to include new calculations as well as filing, and reporting to comply with § 201.106 would require 2,448 legal hours at \$139.96 per hour costing \$342,000, 5,670 hours of management time at \$96.40 per hour costing \$547,000, 1,440 hours of administrative time at \$49.36 per hour costing \$71,000, and 2,160 hours of information technology staff time at \$95.58 per hour costing \$206,000. Aggregate total first-year setup costs are expected to be \$1,167,000¹²⁷ for final § 201.106.¹²⁸

AMS expects that ongoing aggregate costs of implementation, maintenance, monitoring, and compliance with final § 201.106 would annually require an additional 144 legal hours at \$139.96 per hour costing \$20,000, 540 hours of management time at \$96.40 per hour costing \$52,000, 144 hours of administrative time at \$49.36 per hour costing \$7,000, and 288 hours of information technology staff time at \$95.58 per hour costing \$28,000. Total aggregate ongoing costs to small LPDs for final § 201.110 are expected to be \$107,000 annually.¹²⁹

AMS estimated the total costs of developing new policies and procedures, communications plans, and

compliance review systems to comply with final § 201.110 would require a one-time first-year aggregate investment of 480 legal hours at \$139.96 per hour costing \$67,000, 3,894 hours of management time at \$96.40 per hour costing \$375,000, 228 hours of administrative time at \$49.36 per hour costing \$11,000, and 270 hours of information technology staff time at \$95.58 per hour costing \$26,000. Total aggregate first-year setup costs are expected to be \$480,000¹³⁰ for final § 201.110.

AMS expects that ongoing aggregate costs of implementation, maintenance, monitoring, and compliance with final § 201.110 would annually require an additional 240 legal hours at \$139.96 per hour costing \$214,000, 2,856 hours of management time at \$96.40 per hour costing \$95,000, 114 hours of administrative time at \$49.36 per hour costing \$6,000, and 114 hours of information technology staff time at \$95.58 per hour costing \$11,000. Total aggregate ongoing costs to small LPDs for final § 201.110 are expected to be \$325,000 annually.¹³¹

Proposed § 201.112 would require LPDs to provide a Capital Improvement Disclosure Document any time the LPD requests existing broiler chicken growers to make an additional capital investment.¹³² AMS estimated ongoing annual costs of final § 201.112 to small LPDs would require on average an additional 7 legal hours at \$139.96 per hour costing \$1,000, 36 hours of management time at \$96.40 per hour costing \$3,000, 7 hours of administrative time at \$49.36 per hour costing \$400, and 9 hours of information technology staff time at \$95.58 per hour costing \$900. Total aggregate ongoing costs to small LPDs for final § 201.110 are expected to be \$6,000 annually.¹³³

Expected costs of final §§ 201.106, 110, and 112 are associated with developing, maintaining, updating, and complying with policies and procedures

that will be implemented at poultry growing complexes and communicating changes, and producing and distributing disclosure documents among contract growers. AMS expects that firms with fewer contract types and those that contract with few growers will have lower costs. Larger LPDs will tend to have larger numbers and types of contracts and will likely have more costs. Final §§ 201.106 and 201.110 only concern poultry grower ranking systems. Smaller LPDs that do not have grower ranking or tournament contracts will not have any of the costs associated with final §§ 201.106 and 201.110. Some LPDs have few contracts with poultry growers and raise poultry in their own facilities. Those dealers will have relatively lower costs.

AMS does not regulate poultry growers, and, with the exception of reviewing and signing contracts that have been updated by LPDs to meet requirements of § 201.106 and acknowledging receipt of Capital Improvement Disclosure Documents at the time of capital investment requests, the final rule imposes no requirements on poultry growers. To benefit from the disclosures and to understand the updated contracts, growers would need to review the new contracts and disclosure information provided. Growers that do not expect a benefit from reviewing the disclosure information likely would not review it.

AMS estimates aggregate growers' costs for reviewing updated contracts and disclosures associated with final §§ 201.106 and 201.112 combined to be \$315,000 in the initial year. After an updated contract has been reviewed and signed in the first year, AMS expects the annual aggregate cost for reviewing disclosures by growers making additional capital investments would be \$15,000 each year. This amounts to \$400 per grower in the first year. The table below summarizes costs of final §§ 201.106, 110, and 112 to small LPDs and small poultry growers.

Indirect Costs Associated With Final §§ 201.106, 110, and 112

Final § 201.106 will require all LPDs involved in broiler production with tournament or grower ranking contracts to redesign the way they pay broiler growers. It is likely that all LPDs will be required to change their contracts to make all performance base adjustments positive adjustments to the base prices. AMS does not have sufficient data to determine how many LPDs will need to change contracts to comply with the provision capping performance payments at 25 percent of total payments at a complex. AMS is aware

¹²⁶ See U.S. Bureau of Labor Statistics, *May 2023 National Occupational Employment and Wage Estimates*, May 2023 <https://www.bls.gov/oes/special.requests/oesm23all.zip>.

¹²⁷ 2,448 legal hours × \$139.96 per hour + 5,670 management hours × \$96.40 per hour + 1,440 administrative hours × \$49.36 per hour + 2,160 information technology hours × \$95.58 per hour = \$1,166,741.

¹²⁸ Please note throughout the document that components may not sum exactly to aggregate amounts due to rounding.

¹²⁹ 144 legal hours × \$139.96 per hour + 540 management hours × \$96.40 per hour + 144 administrative hours × \$49.36 per hour + 288 information technology hours × \$95.58 per hour = \$106,845.

¹³⁰ 480 legal hours × \$139.96 per hour + 3,894 management hours × \$96.40 per hour + 228 administrative hours × \$49.36 per hour + 270 information technology hours × \$95.58 per hour = \$479,623.

¹³¹ 240 legal hours × \$139.96 per hour + 2,856 management hours × \$96.40 per hour + 114 administrative hours × \$49.36 per hour + 114 information technology hours × \$95.58 per hour = \$325,432.

¹³² Based on information provided by subject matter experts, AMS estimates that capital upgrades would be required at 5% of complexes each year, triggering creation of a new disclosure document for approximately 5% of growers annually.

¹³³ 7 legal hours × \$139.96 per hour + 36 management hours × \$96.40 per hour + 7 administrative hours × \$49.36 per hour + 9 information technology hours × \$95.58 per hour = \$5,694.

that some firms would currently be in compliance with a 25 percent cap, and at least some firms will not.

Any firms that modify existing grower compensation structures at a complex in response to this rule could experience increased production costs if reductions in performance-based payments relative to total payments adversely affect grower performance incentives and cause growers to produce broilers less efficiently. In general, the “tournament” system of broiler grower compensation bases payments to individual growers on their performance relative to other growers. Performance payments provide an incentive for growers to optimize factors under their control, such as effort and management, and to some extent investment (subject to the concerns highlighted by this rule), to improve their own relative performance efficiency and increase income.

Tournament systems have been described in economic literature as “particularly economical means to provide incentive.” The strength of individual performance incentives is directly related to the size of expected grower performance payments, which will be limited by the total amount of performance-based pay distributed among all growers. Any firms that modify existing grower compensation structures at a complex in response to this rule by decreasing the relative size of performance payments available to growers at a complex might therefore weaken performance incentives and could result in reduced grower efficiency in broiler production.

Given the range of possible outcomes, AMS is unable to predict effects with any degree of certainty. For example, if production efficiency is reduced, economic principles suggest that cost of

production would increase at the impacted broiler complex, causing an inward shift of a firm’s marginal cost curve and an associated decrease in broiler production at the impacted complex. A decrease in production for a broiler complex would also be likely to reduce demand for broiler growing services in the area and could result in LPDs lowering overall rates of grower compensation and possibly terminating some marginal growers.

AMS is not able quantify indirect costs related to capping performance payments. However, if the cap has any significant effect on grower productivity, it is likely that indirect costs of capping performance payments will be considerably larger than the direct costs that AMS has been able to estimate.

TABLE 4—ESTIMATED DIRECT COSTS TO SMALL BUSINESSES OF FINAL §§ 201.106, 110, AND 112

Type of cost	Regulated live poultry dealers	Unregulated growers	Total *
Final § 201.106:			
First-year Cost	\$1,167,000	\$300,000	\$1,467,000
First-year Cost per Firm	56,000	351	NA
PV of Ten-year Cost Discounted at 2%	1,722,000	294,000	2,017,000
Ten-year Cost Annualized at 2%	192,000	33,000	225,000
Average Ten-Year Cost per Firm Annualized at 2%	9,000	38	N/A
Final § 201.110:			
First-year Cost	480,000	0	480,000
First-year Cost per Firm	23,000	0	NA
PV of Ten-year Cost Discounted at 2%	3,074,000	0	3,074,000
Ten-year Cost Annualized at 2%	342,000	0	342,000
Average Ten-Year Cost per Firm Annualized at 2%	16,000	0	NA
Final § 201.112:			
First-year Cost	6,000	15,000	21,000
First-year Cost per Firm	271	18	NA
PV of Ten-year Cost Discounted at 2%	51,000	135,000	186,000
Ten-year Cost Annualized at 2%	6,000	15,000	21,000
Average Ten-Year Cost per Firm Annualized at 2%	286	18	NA
Proposed §§ 201.106, 110, and 112:			
First-year Cost	1,652,000	315,000	1,967,000
First-year Cost per Firm	79,000	369	NA
PV of Ten-year Cost Discounted at 2%	4,848,000	429,000	5,277,000
Ten-year Cost Annualized at 2%	540,000	48,000	587,000
Average Ten-Year Cost per Firm Annualized at 2%	26,000	56	NA

* Rows may not sum to Total Costs due to rounding.

** Totals do not include indirect costs to associated with possible changes in supply or demand. AMS was not able to estimate indirect costs, but it is possible that they are larger than the direct costs in the table.

LPDs report net sales in Annual Reports to AMS. Table 5 below groups small LPDs’ net sales into quartiles, reports the average net sales in each quartile, and compares average net sales to average expected first-year direct costs per firm for each of final §§ 201.106, 110, and 112 and total first-year direct costs.¹³⁴ Estimated first-year

direct costs are higher than 10-year annualized costs, and for the threshold analysis, first-year costs will be higher than annualized costs as a percentage of net sales. Correspondingly, the ratio of ten-year annualized direct costs to net sales is lower than their corresponding first-year cost ratios listed in Table 5. If estimated costs meet the threshold in the first year, they will in the following

years as well. AMS is able to perform a threshold analysis on based on direct costs. However, AMS was unable to estimate indirect costs associated with the final rule include indirect costs.

Estimated first-year direct costs per firm are less than 1 percent of average net sales in the three largest quartiles. Total first-year direct costs as a percent of net sales are estimated to be about 0.8 percent for the smallest quartile. However, average first-year cost per entity in Table 5 is the average cost of

¹³⁴ AMS expects that recordkeeping costs will be correlated with the size of the firms. AMS ranked

live poultry dealers by size and grouped them into quartiles.

all of the small businesses. Costs for the LPDs in smallest quartile will likely be less than the average for small businesses.

LPDs do not report to AMS whether any of their contracts are tournament-style contracts but evaluating the number contracts that LPDs listed in their Annual Reports to AMS, few of the LPDs in smallest quartile contracted with a sufficient number of growers to implement tournament contracts. It is unlikely that any of the LPDs in the

smallest quartiles had any tournament contracts. It is unlikely that several of the smaller LPDs in the second quartile had any tournament contracts either.

Since final §§ 201.106 and 201.110 only apply to tournament contracts, none of the LPDs in the smallest quartile are likely to incur any costs from final §§ 201.106 and 201.110. Their costs are likely only costs associated with final § 201.112, which, as percentage of net sales would be 0.003 percent. Because the smallest LPDs have fewer contracts

than the other small LPDs, their costs associated with final § 201.112 are also likely less than average.

Costs in the threshold analysis do not include indirect costs, which AMS was not able to quantify. The size of the indirect costs is not known, and AMS cannot state with any confidence that the total costs associated with final §§ 201.106, 110, and 112 will be insignificant for any LPD.

TABLE 5—COMPARISON OF SMALL LIVE POULTRY DEALERS' NET SALES TO EXPECTED ANNUALIZED DIRECT COSTS OF FINAL §§ 201.106, 110, AND 112 *

Quartile (%)	Average net sales	First-year costs related to § 201.106 as a percent of net sales (%)	First-year costs related to § 201.110 as a percent of net sales (%)	First-year costs related to § 201.112 as a percent of net sales (%)	Total first-year costs as a percent of net sales (%)
0 to 25%	\$10,017,311	0.559	0.230	0.003	0.789
25 to 50%	34,567,539	0.162	0.067	0.001	0.229
50 to 75%	92,380,634	0.061	0.025	0.000	0.086
75 to 100%	226,958,521	0.025	0.010	0.000	0.035

*Numbers in the table may not sum to one due to rounding.

**Costs do not include indirect costs to associated with possible changes in supply or demand. AMS was not able to estimate indirect costs, but it is possible that they are larger than the direct costs in the table.

Direct Cost Associated With an Alternative §§ 201.106, 110, and 112

AMS also estimated costs of the original proposed rule as an alternative. Section 201.106(b) and (c) in the final rule were not include in the proposed rule. AMS estimated that alternative § 201.106 would require a one-time first-year investment of 1,728 legal hours at \$139.96 per hour costing \$242,000, 2,970 hours of management time at \$96.40 per hour costing \$286,000, 720 hours of administrative time at \$49.36 per hour costing \$36,000, and 720 hours of information technology staff time at \$95.58 per hour costing \$69,000. Aggregate total first-year setup costs are expected to be \$633,000. AMS does not expect additional ongoing costs of implementing final § 201.106 under the proposed rule alternative.

Under the proposed rule alternative, § 201.110(b) includes a section dealing with compliance reviews. AMS estimated that alternative § 201.110 would require a one-time first-year aggregate investment of 696 legal hours

at \$139.96 per hour costing \$97,000, 5,334 hours of management time at \$96.40 per hour costing \$514,000, 300 hours of administrative time at \$49.36 per hour costing \$15,000, and 504 hours of information technology staff time at \$95.58 per hour costing \$48,000. Total aggregate first-year setup costs for small LPDs under the alternative are expected to be \$675,000.

AMS expects alternative § 201.110 would annually require an additional 312 legal hours at \$139.96 per hour costing \$44,000, 3,576 hours of management time at \$96.40 per hour costing \$345,000, 150 hours of administrative time at \$49.36 per hour costing \$7,000, and 204 hours of information technology staff time at \$95.58 per hour costing \$19,000. Total aggregate ongoing costs to small LPDs for final § 201.110 are expected to be \$415,000 annually.

All sections of § 201.112 were included under the proposed rule alternative. AMS estimated that first-year and ongoing annual costs of final

§ 201.112 to small LPDs would require on average an additional 7 legal hours at \$139.96 per hour costing \$1,000, 36 hours of management time at \$96.40 per hour costing \$3,000, 7 hours of administrative time at \$49.36 per hour costing \$400, and 9 hours of information technology staff time at \$95.58 per hour costing \$900. Total aggregate ongoing costs to small LPDs for final § 201.110 are expected to be \$6,000 annually.

The alternative would have a relatively small effect on costs to poultry growers on a per grower basis, and growers will only review the disclosures if they perceive that they are beneficial. AMS estimates growers' aggregate costs for reviewing updated contracts and disclosures associated with final §§ 201.106 and 201.112 combined to be \$315,000 in the initial year. AMS expects the annual aggregate cost to growers making additional capital investments to be \$15,000 each year. Table 6 below summarizes costs of alternative §§ 201.106, 110, and 112 to small LPDs and small poultry growers.

TABLE 6—ESTIMATED COSTS TO SMALL BUSINESSES OF ALTERNATIVE §§ 201.106, 110, AND 112

Type of cost	Regulated live poultry dealers	Unregulated growers	Total *
Final § 201.106:			
First-year Cost	\$633,000	\$300,000	\$933,000
First-year Cost per Firm	30,000	351	NA
PV of Ten-year Cost Discounted at 2%	620,000	294,000	914,000
Ten-year Cost Annualized at 2%	69,000	33,000	102,000
Average Ten-Year Cost per Firm Annualized at 2%	3,000	38	N/A

TABLE 6—ESTIMATED COSTS TO SMALL BUSINESSES OF ALTERNATIVE §§ 201.106, 110, AND 112—Continued

Type of cost	Regulated live poultry dealers	Unregulated growers	Total *
Final § 201.110:			
First-year Cost	675,000	0	675,000
First-year Cost per Firm	32,000	0	NA
PV of Ten-year Cost Discounted at 2%	3,266,000	0	3,266,000
Ten-year Cost Annualized at 2%	364,000	0	364,000
Average Ten-Year Cost per Firm Annualized at 2%	17,000	0	NA
Final § 201.112:			
First-year Cost	6,000	15,000	21,000
First-year Cost per Firm	271	18	NA
PV of Ten-year Cost Discounted at 2%	51,000	135,000	186,000
Ten-year Cost Annualized at 2%	6,000	15,000	21,000
Average Ten-Year Cost per Firm Annualized at 2%	286	18	NA
Final §§ 201.106, 110, and 112:			
First-year Cost	1,313,000	315,000	1,628,000
First-year Cost per Firm	63,000	369	NA
PV of Ten-year Cost Discounted at 2%	3,937,000	429,000	4,366,000
Ten-year Cost Annualized at 2%	438,000	48,000	486,000
Average Ten-Year Cost per Firm Annualized at 2%	21,000	56	NA

* Rows may not sum to Total Costs due to rounding.

Net sales for small LPDs that would be required to make disclosure under alternative §§ 201.106, 110, and 112 averaged \$91 million for their fiscal year 2023. Expected first-year cost per LPD would be well below 0.1 percent.¹³⁵

TABLE 7—COMPARISON OF SMALL LIVE POULTRY DEALERS' NET SALES TO EXPECTED ANNUALIZED COSTS OF ALTERNATIVE §§ 201.106, 110, AND 112

Quartile	Average net sales	First-year costs related to § 201.106 as a percent of net sales (%)	First-year costs related to § 201.110 as a percent of net sales (%)	First-year costs related to § 201.112 as a percent of net sales (%)	Total first-year costs as a percent of net sales (%)
0 to 25%	\$10,017,311	0.299	0.319	0.003	0.629
25 to 50%	34,567,539	0.087	0.093	0.001	0.182
50 to 75%	92,380,634	0.032	0.035	0.000	0.068
75 to 100%	226,958,521	0.013	0.014	0.000	0.028

Clearly, excluding § 201.110(b)(1)(vi) and (b)(2) would reduce cost to small LPDs. AMS prefers final §§ 201.106, 110, and 112 because it reduces the amount of variation in payments that broiler growers might receive and provides protection against lower contract prices during the transition period of the first three years following implementation of the final rule.

If direct costs were the only consideration, it is likely that final §§ 201.106, 110, and 112 would not have a significant economic impact on a substantial number of small business LPDs. AMS does not have sufficient information to make a quantified estimate of the indirect costs associated with §§ 201.106, 110, and 112, but the indirect costs have the potential to be much larger than the direct costs that AMS was able to quantify. If indirect costs are equal to direct costs, total costs would be about 1.26 percent for LPDs in

the smallest quartile. It is possible that the indirect costs are considerably larger than direct costs, in which case larger LPDs would face significant costs. It is likely that costs will be significant for a substantial number of small business LPDs.

Costs to growers will be limited to the time required to review and acknowledge receipt of updated grower contracts and disclosures. AMS expects that final §§ 201.106, 110, and 112 will have effects on a substantial number of growers. However, the costs will not be significant for any of them. Because AMS does not regulate poultry growers, AMS does not have information regarding the business sizes of poultry growers similar to the information it has concerning LPDs.

Based on the above analyses, it is unlikely that final §§ 201.106, 110, and 112 will create significant costs for a substantial number of small business

broiler growers. AMS was not able to quantify indirect costs associated with final §§ 201.106, 110, and 112 but the rulemaking could cause significant costs for a substantial number of small LPDs.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), AMS requested OMB approval of the new information collection and recordkeeping requirements related to this final rule when it was proposed in the **Federal Register** on June 10, 2024 (89 FR 49002). The proposed information collection was for a total of 59,182 hours for the first year, and 42,682 hours per year thereafter. The comment period was open for 60 days and closed on August 9, 2024. Below is a summary of the final rule's information collection requirements, the comments AMS received relating to the information

¹³⁵ The first-year cost per small live poultry dealer of \$63,000 divided by the average net sales

for all small live poultry dealers of \$91 million is equal to 0.069 percent.

collection requirements of the proposed rule, and any changes AMS made in response to the comments. Additional detail can be found in the Regulatory Impact Analysis (RIA).

Title: Poultry Growing Tournament Systems: Fairness and Related Concerns.

OMB Number: 0581–0346.

Expiration Date of Approval: This is a NEW collection.

Type of Request: Approval of a New Information Collection.

Abstract: The information collection requirements in this request are essential to improve transparency and forestall deception and unfairness in the use of broiler growing arrangements, in accordance with the purposes of the Packers and Stockyards Act, 1921. The revisions to the Packers and Stockyards regulations would require that live poultry dealers (LPDs) establish, maintain, and review written documentation regarding their processes for the design and operation of a poultry grower ranking system that is consistent with the LPD duty of fair comparison, provide information through disclosures to growers when requesting that growers make additional capital investments, and submit contract and disclosure documentation to USDA when contract modifications result in reduced annual grower compensation during a transition period.

Under this final rule, LPDs must develop and document policies and procedures for the design and operation of their tournament system consistent with the duty of fair grower comparison. All LPD documentation will be provided to USDA on request, maintained for no less than five years, and used for ongoing internal compliance activities. The final rulemaking requires that LPDs provide a Capital Improvement Disclosure Document to growers when LPDs request that growers make additional capital investments. In addition, for each of the three years following the effective date, LPDs will be required to provide the prior and modified contracts as well as all related LPD Disclosure Documents to USDA if any contract modification or renewal results in less than the prior annual-calendar year's complex-wide average gross payment to the grower. The estimates provided below apply only to LPDs when they are required to provide the information to growers or create documentation for internal use and review. Poultry growers would not be required to provide information but would be able to use the information provided by LPDs to analyze additional capital investment decisions.

Broiler Grower Compensation Design Under § 201.106(c)

Estimate of Burden: Public burden for this collection of information is estimated to average 0.01 hours per response (years two through four), 0 hours per year thereafter.

Respondents: Live poultry dealers.

Estimated Number of Respondents: 42.

Estimated Number of Responses: 20,014.

Estimated Number of Responses per Respondent: 477.

Estimated Total Annual Burden on Respondents: 0 hours in the first year, and 194 hours per year thereafter for years two through four.

Operation of Broiler Grower Ranking Systems Under § 201.110(a) and (b)(1)(i) Through (v)

Estimate of Burden: Public burden for this collection of information is estimated to average 193.33 hours per response (first year), 169.61 hours per year thereafter.

Respondents: Live poultry dealers.

Estimated Number of Respondents: 42.

Estimated Number of Responses: 184.

Estimated Number of Responses per Respondent: 4.

Estimated Total Annual Burden on Respondents: 35,572 hours in the first year, and 31,208 hours per year thereafter.

Communication and Cooperation Under § 201.110(b)(1)(vi)

Estimate of Burden: Public burden for this collection of information is estimated to average 45.00 hours per response (first year), 16.00 hours per year thereafter.

Respondents: Live poultry dealers.

Estimated Number of Respondents: 42.

Estimated Number of Responses: 42.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1,890 hours in the first year, and 672 hours per year thereafter.

Broiler Grower Capital Improvement Disclosure Document Under § 201.112

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.61 hours per response (first year), 0.61 hours per year thereafter.

Respondents: Live poultry dealers.

Estimated Number of Respondents: 42.

Estimated Number of Responses: 1,001.

Estimated Number of Responses per Respondent: 24.

Estimated Total Annual Burden on Respondents: 607 hours in the first year, and 607 hours per year thereafter.

AMS estimates that 42 LPDs would each submit the prior and modified contracts as well as any LPD Disclosure Documents prepared with respect to those contracts to AMS as required under final § 201.106(c). AMS arrived at its estimate that 477 responses would be produced per LPD during each of years two, three, and four following the rule effective date in complying with the new requirements during a transition period following modification and renewal of broiler growing contracts by dividing the 20,014 grower contracts with broiler growers that were reported by 42 LPDs that filed fiscal year 2023 Annual Reports with AMS. AMS does not have access to sufficient data and cannot predict the number of complexes for which the annual calendar year's complex-wide average gross payment to the grower will be less than the prior year. Based on information provided by subject matter experts, AMS estimates that LPDs would be able to submit the required documentation for all contracts to USDA electronically once per year for a fixed annual time cost per complex. As a result, the estimate that all LPDs will provide 477 responses per year in years two through four therefore likely overestimates the burden by a substantial amount given that average grower payments may not be less than the prior year at most complexes. AMS estimates the annual cost of collecting and submitting required contract documents in years two through four, including management, legal, administrative, and information technology time, will require an average 0.01 hours each. AMS arrived at the estimates of the number of hours on an annual basis to submit required contract documentation by dividing the number of hours to collect and submit the required documents (184 hours in each of years two through four) by the annual number of responses for all LPDs (20,014).

AMS estimates that 42 LPDs would each establish, maintain, and review documentation of written processes for the design and operation of a poultry grower ranking system that is consistent with a duty of fair comparison as required under final § 201.110.¹³⁶ AMS arrived at its estimate that four (4) responses would be produced per LPD in complying with new requirements for

¹³⁶ Responses and costs related to final § 201.110(b)(1)(vi), "Communication and cooperation," are discussed below separately from the other paragraphs of § 201.110. Costs associated with final § 201.110(b)(2), "Record retention," are included in cost estimates for § 201.110(b)(1).

poultry grower ranking system fairness policies and procedures by dividing the 184 broiler plants (or complexes) indicated in the fiscal year 2023 Annual Report filed by 42 LPDs with broiler production.¹³⁷ AMS estimates first-year development and production of § 201.110 policies and procedures, including legal, management, administrative, and information technology time, would require an average of 193.33 hours for each response, while ongoing annual maintenance, compliance monitoring, production, and distribution would take 169.61 hours. AMS estimates first-year development and production of § 201.110 policies and procedures, including legal, management, administrative, and information technology time, would require an average of 193.33 hours for each response, while ongoing annual maintenance, compliance monitoring, production, and distribution would take 169.61 hours. AMS arrived at the estimates of the number of hours per response on an annual basis to set up, produce, distribute, monitor, review, and maintain § 201.110 policies and procedures by dividing the total number of hours required (35,572 first-year hours and 31,208 ongoing hours) by the annual number of responses for all LPDs (184).

AMS estimates that 42 LPDs would each develop and document one set of processes that address communication and cooperation when resolving grower concerns as required under final § 201.110(b)(1)(vi). AMS estimates first-year set-up and implementation of the plan, including management, legal, administrative, and information technology time, would require approximately 45.00 hours. AMS estimates ongoing annual implementation of communication, cooperation, and dispute resolution processes would require an average of 16.00 hours.

AMS estimates each of 42 LPDs would create and distribute an average of 24 Broiler Grower Capital Improvement Disclosure Documents each year for poultry growers relating to additional capital investments, as required under final § 201.112. AMS arrived at its estimate of 24 developed disclosure documents per LPD per year from AMS records which show 42 LPDs filed fiscal year 2023 Annual Reports with AMS, and their reports indicate

that they had 20,014 growing contracts with broiler growers during fiscal year 2023. Based on information provided by subject matter experts, AMS estimates that capital upgrades would be required at 5 percent of complexes each year, triggering creation of a new disclosure document for approximately 5 percent of growers annually. AMS multiplied the 20,014 growing contracts by 5 percent and divided by the 42 LPDs to arrive at 24 disclosure documents per LPD. LPDs would only be required to provide the Broiler Grower Capital Improvement Disclosure Document to growers when requesting or requiring the grower to make an additional capital investment. AMS estimates first-year and ongoing development, production, and distribution of the disclosure documents, including management, legal, administrative, and information technology time, would require an average 0.61 hours each. AMS arrived at the estimates of the number of hours on an annual basis to set up, produce, and distribute the Broiler Grower Capital Improvement Disclosure Documents by dividing the number of hours to set up, produce, and distribute the disclosures (607 first-year and annual ongoing hours) by the annual number of responses for all LPDs (1,001).

Under § 201.106(c) LPDs are required for a period for three years following the effective date to submit to USDA copies of the prior and modified contracts and any LPD Disclosure Documents prepared under § 201.102 if the annual-calendar year's complex-wide average gross payments to growers at a complex of an LPD is less than the prior annual-calendar year's complex-wide average gross payments to growers at the complex.

Final § 201.110 would require LPDs to provide a fair comparison among growers when basing compensation on a grouping or ranking of growers delivering during a specified period of time and would also require LPDs to document how they comply with that duty of fair comparison. The policies and procedures documentation required under final § 201.110 must describe the LPD's processes for the design and operation of a poultry grower ranking system for broiler growers that is consistent with the duty of fair comparison. The documentation of processes under final § 201.110, must also include a plan for communication and cooperation between the LPD and growers. LPDs are required to document, maintain, and comply with all policies and procedures required under final § 201.110 on an ongoing basis and provide them to USDA upon request. LPDs must retain all written

records relevant to compliance with § 201.110(b) for no less than 5 years from the date of record creation.

Final § 201.112 would require LPDs to provide a Broiler Grower Capital Improvement Disclosure Document any time the LPD requests existing broiler chicken growers to make an additional capital investment (\$12,500 or more per structure excluding maintenance or repair). The Broiler Grower Capital Improvement Disclosure Document must include information about the goal or purpose of the investment, financial incentives and compensation for the grower associated with the additional capital investment, all schedules and deadlines for the investment, a description of changes to housing specifications, and analysis of projected returns.

Costs of Final §§ 201.106, 110, and 112

The combined costs to LPDs for compliance with the recordkeeping and disclosure requirements of final §§ 201.106, 110, and 112 are expected to be \$3,807,000 in the first year, \$3,181,000 in years two through four, and \$3,168,000 in subsequent years. The total hours estimated for the LPDs to create, produce, distribute, and maintain these documents are 38,069 in the first year, 32,671 in years two through four, and 32,487 in subsequent years. As stated previously, the estimates provided apply only to LPDs who would be required to provide the information to growers.

The amount of time required for recordkeeping and disclosure was estimated by AMS subject matter experts. These experts were auditors and supervisors with many years of experience in AMS's Packers and Stockyards Division (PSD) conducting investigations and compliance reviews of regulated entities.

AMS used the May 2023 U.S. Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics for the time values in this analysis.¹³⁸ BLS estimated an average hourly wage for general and operations managers in animal slaughtering and processing to be \$67.99 per hour; \$34.81 per hour for administrative assistants; \$67.41 per hour for IT system managers; and \$98.71 per hour for lawyers in food manufacturing. In applying the cost estimates, AMS marked-up the wages by 41.79 percent to account for fringe

¹³⁷ All live poultry dealers are required to annually file PSD form 3002 "Annual Report of Live Poultry Dealers," OMB control number 0581-0308. The Annual Report form is available to the public at <https://www.ams.usda.gov/sites/default/files/media/PSP3002.pdf>.

¹³⁸ Estimates are available at U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, available at <https://www.bls.gov/oes/special-requests/oesm23all.zip> (accessed 9/14/2024). Featured OES Searchable Databases: U.S. Bureau of Labor Statistics (bls.gov) (accessed September 2024).

benefits. The average hourly wage rates, adjusted to include the 41.79 percent markup for benefits, are as follows: \$96.40 for managers, \$49.36 for administrative assistants; \$95.58 for IT system managers, and \$139.96 for lawyers.

Comments From the Proposed Rule and Changes to the Final Rule

After consideration of public comments, AMS determined to adopt the proposed rule as a final rule with several modifications. This section provides an overview of the comments made specifically on the costs and benefits and how the final rule differs from the proposed rule in that analysis.

Industry trade associations and LPDs commented that the full cost of implementing the proposed rule would be far greater than estimated by AMS. The commenters asserted that AMS greatly underestimated the costs that will be required for employing teams with highly specialized legal and technical expertise to implement the proposed rule by modifying or replacing grower contracts and communicating changes to growers. Commenters suggested that AMS did not adequately consider the total number of hours needed, but none provided quantified estimates. LPDs also commented that hourly rates paid to specialized industry professionals such as attorneys should be much higher. Commenters also suggested that implementation of the rule would require LPDs to hire and train additional staff and pull resources away from other important activities.

AMS consulted auditors and supervisors as subject matter experts who are familiar with LPDs, integrators, and broiler complex operations from many years of experience with AMS in auditing LPDs for compliance with the Act. The final rule provides an extended period of approximately 18 months following publication in the **Federal Register** before the effective date, to permit sufficient time for implementation. Hourly rates used in cost analysis for the proposed rule were based on averages for legal, management, administrative, and information technology labor categories specifically within the agricultural sector as published and annually updated by the U.S. Bureau of Labor Statistics. Although the largest corporations likely employ lawyers and other specialists at hourly rates much higher than the national average, contract development and review efforts at those companies are spread across many complexes. AMS expects that average hourly rates provide an appropriate benchmark for estimating

industry average costs. After further discussion with subject matter experts, AMS added a modest amount of time to account for the cost of information technology work in preparing § 201.112 disclosures. AMS subject matter experts confirmed that all other costs from the proposed rule are accurate estimates and accordingly, AMS made no other changes to the information collection requirements of the rule based on this comment.

AMS also received comments on the proposed rule in support of adding measures to protect growers against the risk that LPDs might unfairly reduce broiler grower total compensation during a transition period after implementation of the final rule. Based on comments received, AMS added § 201.106(c), which will require LPDs to submit copies of the prior and modified contracts and disclosures to AMS if average gross grower payments at a complex show year-over-year decline following a contract modification during the three calendar years commencing with and including the effective date of the rule. AMS will review the information provided by LPDs to identify any potentially unfair practices related to broiler grower compensation. AMS consulted with its internal subject matter experts and added direct information collection costs for LPDs to comply with this provision during the three-year period.

AMS also received comments suggesting that some of the detailed documentation requirements of proposed § 201.110(b) were similar to existing P&S documentation and disclosure requirements and might create unnecessarily burdensome and complex paperwork that could burden service technicians at broiler complexes and keep them from other important responsibilities such as assisting growers. In response to these comments, AMS made several changes to § 201.110(b) in the final rule that included consolidating and streamlining the documentation requirements and removing some detailed requirements delineated under subparagraphs in the proposed rule. AMS expects that these changes in final § 201.110(b) will add clarity and minimize potential confusion about the documentation requirements, thereby making them more effective. AMS expects these changes will somewhat reduce total recordkeeping requirements for LPDs. Based on consultation with internal subject matter experts, AMS determined that the precise amount of time savings is difficult to estimate. AMS therefore chose a cautious approach to avoid underestimating costs and did not

reduce the total recordkeeping requirements or the time cost of the information collection for LPDs. Accordingly, these changes did not affect the estimation of costs or benefits in the final rule.

The proposed rule included § 201.110(b)(2), “Compliance review,” which required LPDs to conduct a required bi-annual review of the processes set out in § 201.110(b)(1). AMS removed this requirement from the final rule in response to comments that self-audits would be burdensome for LPDs, and that elimination of this requirement would not substantially diminish effective compliance with § 201.110. Compliance will be enforced through regular AMS review of the policies and procedures LPDs are required to establish and maintain under § 201.110(b). Accordingly, removal of § 201.110(b)(2) eliminated the burden of compliance review on LPDs and reduced costs from the proposed to the final rule by the cost estimate in the proposed rule for that provision.

Based on comments received, AMS added a provision at § 201.112(c) to require that the LPD make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Broiler Grower Capital Improvement Disclosure Document. Reasonable efforts include, but are not limited to, providing current contact information for professional translation service providers, trade associations with translator resources, relevant community groups, or any other person or organization that provides translation services in the poultry grower’s geographic area. Reasonable efforts, depending on the facts and circumstances (such as convenience, expense, and timeliness of the translation), may also include allowing the grower access to a computer-generated translation of the Disclosure Document and additional time to review any translated Disclosure Document. A similar requirement was established for LPDs in § 201.102(g)(4). As LPDs already have all necessary information to make reasonable efforts to assist growers in translating disclosure documents and have made it available to growers who request the information, AMS did not add any time to its information collection cost estimates for LPDs to comply with this new requirement.

E. Executive Order 12988—Civil Justice Reform

Executive Order 12988 instructs each executive agency to adhere to certain

requirements in the development of new and revised regulations to avoid unduly burdening the court system. This rule has been reviewed under Executive Order 12988 and complies with these requirements. This rule is not intended to have retroactive effect. This rule would not preempt state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rulemaking. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule. Nothing in this rule is intended to interfere with a person's right to enforce liability against any person subject to the Act under authority granted in section 308 of the Act.

F. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 requires Federal agencies to consult with Indian Tribes on a government-to-government basis on policies that have Tribal implications. This includes regulations, legislative comments or proposed legislation, and other policy statements or actions. Consultation is required when such policies have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes. The following is a summary of activity to date.

AMS engaged in a Tribal Consultation in conjunction with a previous rulemaking also under the Act (*Inclusive Competition and Market Integrity Under the Packers and Stockyards Act* (87 FR 60010, October 3, 2022)) on January 19, 2023, in person in Tulsa, Oklahoma, and virtually. AMS received multiple Tribal comments from that Consultation, many of which were specific to and considered in that rulemaking. In that consultation, Tribes raised legal concerns with respect to the jurisdiction of the AMS enforcement of the P&S Act. Tribes commented that the P&S Act does not apply to Tribes and Tribal entities. Those comments raise a legal issue of statutory interpretation, but these concerns are not directly implicated by this final rule. This final rule provides additional standards for individual LPDs or growers, and AMS does not find that this rule carries substantial direct effects on one or more Indian Tribes beyond the purely legal issue raised during consultation.

AMS recognizes and supports the Secretary's desire to incorporate Tribal and Indigenous perspectives, remove

barriers, and encourage Tribal self-determination principles in USDA programs, including hearing and understanding Tribal views on legal authorities and cost implications as facts and circumstances develop. If a Tribe requests additional consultation, AMS will work with USDA's Office of Tribal Relations to ensure meaningful consultation is provided in accordance with Executive Order 13175.

G. Civil Rights Impact Analysis Statement

AMS has considered the potential civil rights implications of this final rule on members of protected groups to ensure that no person or group would be adversely or disproportionately at risk or discriminated against on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA. This final rule does not contain any requirements related to eligibility, benefits, or services that would have the purpose or effect of excluding, limiting, or otherwise disadvantaging any individual, group, or class of persons on one or more prohibited bases.

In its review, AMS conducted a disparate impact analysis, using the required calculations, which resulted in a finding that Asians and Native Hawaiian or Other Pacific Islanders could be disproportionately impacted by the rule, insofar as fewer farmers in those groups participate in poultry production than would be expected by their representation among U.S. farmers in general and therefore are less likely to benefit, as a whole, from the protections provided by this rule.¹³⁹ However, the regulations would provide benefits equally to all individual poultry growers across demographic characteristics, with some demographic groups being more or less represented among poultry growers. AMS will enhance efforts to notify the groups found to be more significantly impacted of the regulations and their implications. AMS will conduct mitigation and monitoring strategies and

¹³⁹ Among Asian and Native Hawaiian or Other Pacific Islander growers, a smaller percent participates in livestock or poultry agriculture (animal agriculture) than in other types of agriculture. A larger percent of American Indian or Alaskan Native growers participates in animal agriculture than in other types of agriculture. The other demographic groups' participation in animal agriculture tended to fall within 10 percentage points of their participation in agriculture overall.

reach out to several organizations that represent the interests of the impacted groups.

H. E-Government Act

USDA is committed to complying with the E-Government Act by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

I. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions of State, local, and Tribal governments, or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of \$100 million or more (adjusted for inflation) in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule will not compel the expenditure in any one year of \$100 million or more (adjusted for inflation) by State, local, and Tribal governments, in the aggregate, or by the private sector. Therefore, a statement under 2 U.S.C. 1532 is not required.

J. Congressional Review Act

Pursuant to subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 9 CFR Part 201

Confidential business information, Reporting and recordkeeping requirements, Stockyards, Surety bonds, Trade practices.

For the reasons stated in the preamble, AMS amends 9 CFR part 201 as follows:

PART 201—ADMINISTERING THE PACKERS AND STOCKYARDS ACT

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 7 U.S.C. 181–229c.

■ 2. Add § 201.106 to subpart N to read as follows:

§ 201.106 Broiler grower compensation design.

(a) *Rate transparency.* When a broiler growing arrangement between the live poultry dealer and the broiler grower compensates the grower based upon a grouping, ranking, or comparison of growers delivering poultry during a specified period, the live poultry dealer may not use the grower's grouping, ranking, or comparison to others to reduce any rate of compensation under the broiler growing arrangement.

(b) *Excessive variability.* The Secretary presumes that a live poultry dealer violates the Act when aggregate gross annual payments based upon a grouping, ranking, or comparison of growers exceed 25 percent of total gross payments to growers in a complex on an annual-calendar year basis.

(c) *Transition.* For modified or renewed broiler growing arrangements subject to paragraph (a) of this section, for each of the three calendar years commencing with and including the year this section becomes effective, if the annual-calendar year's complex-wide average gross payments to growers at a complex of a live poultry dealer is less than the prior annual-calendar year's complex-wide average gross payments to growers at the complex, the live poultry dealer must submit to the Secretary the following:

(1) A copy of the prior broiler growing arrangement and the modified or renewed growing arrangement; and

(2) Any Live Poultry Dealer Disclosure Document prepared under § 201.102 with respect to the prior broiler growing arrangement and the modified or renewed broiler growing arrangement for the growers at the complex.

■ 3. Add § 201.110 to subpart N to read as follows:

§ 201.110 Operation of broiler grower ranking systems.

(a) *Fair comparison.*—(1) *Duty of fair comparison.* Live poultry dealers providing compensation to broiler growers based upon a grouping, ranking, or comparison of growers delivering poultry must design and operate their poultry grower ranking system to provide a fair comparison among growers.

(2) *Fair comparison factors.* In determining whether the live poultry dealer reasonably designed or operated its poultry grower ranking system to deliver a fair comparison among growers or whether the live poultry dealer must utilize a non-comparison compensation method, the Secretary shall consider the following:

(i) Whether the distribution of inputs by the live poultry dealer causes material differences in performance, and whether appropriate adjustments to grower compensation will be made.

(ii) Whether the assignment of flock production practices by the live poultry dealer causes material differences in performance, and whether appropriate adjustments to grower compensation will be made.

(iii) Whether the designated time period used in the live poultry dealer's comparison is appropriate, including whether the live poultry dealer uses one or more groupings, rankings, or comparisons of growers to mitigate the effects of any differences in inputs over the designated time period.

(iv) Whether conditions and circumstances outside the control of the live poultry dealer render comparison impractical or inappropriate.

(v) Whether the live poultry dealer has made reasonable efforts to timely resolve concerns a grower raises regarding the live poultry dealer's design and operation of its poultry grower ranking system to deliver a fair comparison among growers.

(vi) Any other factor relevant to a fair comparison.

(3) *Non-comparison compensation method.* When a live poultry dealer uses a poultry grower ranking system and cannot conduct a fair comparison for one or more growers, the live poultry dealer must compensate those growers through a non-comparison method specified in the contract that reflects reasonable compensation to the grower for its services.

(b) *Documentation.*—(1) *Policies and procedures.* A live poultry dealer must establish and maintain written documentation of its processes for the design and operation of a poultry grower ranking system for broiler growers that is consistent with the duty of fair comparison. The written documentation must include the following:

(i) *Inputs under live poultry dealer control.* How and when the live poultry dealer assigns, adjusts, or otherwise accounts for similarities and differences of quality and quantity in the delivery of inputs to growers.

(ii) *Flock production practices.* How and when the live poultry dealer assigns, adjusts, or otherwise accounts for differences in production practices.

(iii) *League composition.* How the dealer determines groupings of growers for settlement.

(iv) *Evaluation period.* A reasonable time period over which the dealer evaluates the duty of fair comparison.

(v) *Non-comparison.* When a live poultry dealer may remove growers from a ranking group, and how the live poultry dealer compensates the growers to satisfy the non-comparison compensation method under paragraph (a)(3) of this section.

(vi) *Communication and cooperation.* How the live poultry dealer resolves a grower's concerns with the design or operation of a poultry grower ranking system for broiler growers that is consistent with the duty of fair comparison, including the timeliness of the resolution.

(2) *Record retention.* The live poultry dealer must retain all written records relevant to its compliance with this paragraph (b) for no less than 5 years from the date of record creation.

■ 4. Add § 201.112 to subpart N to read as follows:

§ 201.112 Broiler grower Capital Improvement Disclosure Document.

(a) *Disclosure requirement.* When a live poultry dealer requests that a broiler grower make an additional capital investment, the live poultry dealer must provide the broiler grower with a Capital Improvement Disclosure Document, as described in paragraph (b) of this section.

(b) *Disclosure contents.* The Capital Improvement Disclosure Document must disclose the following in a clear, concise, and understandable manner:

(1) The purpose of the additional capital investment for both the live poultry dealer and the grower, and a summary of all research and other supporting material that the live poultry dealer has relied upon in justifying the additional capital investment.

(2) All financial incentives and compensation for the grower associated with the additional capital investment.

(3) All construction schedules related to the request for additional capital investment.

(4) The housing specifications associated with the additional capital investment.

(5) Any required or approved manufacturers or vendors, and all financial benefits, if any, that the live poultry dealer or any officer, director, decision-making employee, or close family member of any such person, receives from the use of the required or approved manufacturer or vendor.

(6) An analysis of projected returns the grower can expect related to the additional capital investment, including any assumptions, risks, or uncertainties, sufficient to allow the grower to make their own projections.

(7) This statement that "USDA has not verified the information contained in

this document. If this disclosure by the live poultry dealer contains any false or misleading statement or a material omission, a violation of Federal and/or State law may have occurred. Violations of Federal and State laws may be determined to be unfair, unjustly discriminatory, or deceptive and unlawful under the Packers and Stockyards Act, as amended. You may file a complaint at *farmerfairness.gov* or call 1-833-DIAL-PSD (1-833-342-5773) if you suspect a violation of the Packers and Stockyards Act or any other Federal law governing fair and competitive marketing, including contract growing, of livestock and

poultry. Additional information on rights and responsibilities under the Packers and Stockyards Act may be found at *www.ams.usda.gov*.”

(c) *Translation*. Upon delivery to the grower, the live poultry dealer must make reasonable efforts to ensure that growers are aware of their right to request translation assistance and to assist the grower in translating the Capital Improvement Disclosure Document.

■ 5. Add § 201.290 to subpart N to read as follows:

§ 201.290 Severability.

If any provision of this subpart or any component of any provision is declared

invalid, or the applicability thereof to any person or circumstances is held invalid, it is the Agricultural Marketing Service’s intention that the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby with the remaining provision, or component of any provision, to continue in effect.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

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Part VII

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Guidance Regarding Certain Matters Relating to Nonrecognition of Gain or Loss in Corporate Separations, Incorporations, and Reorganizations;
Proposed Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[REG-112261-24]

RIN 1545-BR32

Guidance Regarding Certain Matters Relating to Nonrecognition of Gain or Loss in Corporate Separations, Incorporations, and Reorganizations**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations regarding certain matters relating to corporate separations, incorporations, and reorganizations qualifying, in whole or in part, for nonrecognition of gain or loss. These matters include distributions and retentions of controlled corporation stock, assumptions of liabilities by controlled corporations, exchanges of property between distributing corporations and controlled corporations, and distributions and transfers of consideration to distributing corporation shareholders and creditors. The proposed regulations would affect corporations and their shareholders and security holders. Proposed regulations modifying the reporting requirements for corporate separations are published elsewhere in the Proposed Rules section of this issue of the **Federal Register**.

DATES: Written or electronic comments and requests for a public hearing must be received by March 17, 2025.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> (indicate IRS and REG-112261-24) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Requests for a Public Hearing” section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments to the IRS’s public docket. Send paper submissions to CC:PA:01:PR (REG-112261-24), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Justin R. Du Mouchel at (202) 317-6975

(not a toll-free number); concerning submissions of comments and requests for a hearing, contact the Publications and Regulations branch at (202) 317-6901 (not a toll-free number) or by email to publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:**Authority**

This document contains proposed regulations under sections 355, 357, 361, and 368 of the Internal Revenue Code (Code) that would amend 26 CFR part 1 (Income Tax Regulations) by providing guidance regarding certain matters relating to corporate separations, reorganizations, and incorporations qualifying, in whole or in part, for nonrecognition of gain or loss. The proposed additions and amendments to the Income Tax Regulations are issued pursuant to the express delegations of authority to the Secretary of the Treasury or her delegate (Secretary) provided under sections 337(d), 361(b)(3), and 7805(a) of the Code.

Section 337(d) states, in part, that “[t]he Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of the amendments made by subtitle D of title VI of the Tax Reform Act of 1986,” including regulations “to ensure that such purposes may not be circumvented through the use of any provision of law or regulations (including the consolidated return regulations and part III of this subchapter).” Relating to the treatment of transfers to creditors, the second sentence of section 361(b)(3) states that “[t]he Secretary may prescribe such regulations as may be necessary to prevent avoidance of tax through abuse of the preceding sentence or [section 361](c)(3).” Finally, section 7805(a) authorizes the Secretary to “prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.”

Background**I. Overview of Section 355****A. Section 355 Transactions****1. In General**

If a transaction satisfies the requirements of section 355 (section 355 transaction) and other relevant provisions of the Code and Income Tax Regulations, the transaction may occur without recognition of any gain or loss to the distributing corporation (within the meaning of section 355(a)(1)(A)) and without recognition of any gain or loss

to, or the inclusion of any amount in the income of, the shareholders or security holders of the distributing corporation. A section 355 transaction may take one of the following forms: (i) a spin-off, which is a pro rata distribution of stock of the controlled corporation (within the meaning of section 355(a)(1)(A)) to shareholders of the distributing corporation; (ii) a split-off, which is a distribution of stock of the controlled corporation to some (but not all) shareholders of the distributing corporation in exchange for some or all of their stock of the distributing corporation; or (iii) a split-up, which is a liquidating distribution in which the distributing corporation distributes to its shareholders, either pro rata or non-pro rata, the stock of more than one controlled corporation. As discussed in parts I.A.3 and I.A.4 of this Background, a section 355 transaction may occur either as a “section 355(c) distribution” or as part of a “divisive reorganization.”

2. General Utilities Repeal

In *General Utilities & Operating Co. v. Helvering*, 296 U.S. 200 (1935), the Supreme Court of the United States (Supreme Court) held that corporations generally could distribute appreciated property to their shareholders without the recognition of any corporate-level gain (*General Utilities* doctrine). Congress repealed the *General Utilities* doctrine beginning with legislation in 1969 and culminating with the Tax Reform Act of 1986 (Public Law 99-514, 100 Stat. 2085), which, among other changes, amended sections 311, 336, and 337 of the Code (originally enacted in the Internal Revenue Code of 1954 (1954 Code) (Public Law 83-591, 68A Stat. 3) to apply gain and loss recognition to non-liquidating and liquidating distributions, respectively.

Notwithstanding the repeal of the *General Utilities* doctrine, section 355 allows a distributing corporation to distribute the stock and securities of a subsidiary (that is, a controlled corporation) to its shareholders without imposing a corporate-level tax on the distribution. Accordingly, as observed by the United States Tax Court (Tax Court), “more attention has been directed toward [s]ection 355 today than was ever the case in the past [because] it is one of the few (some might say the only) viable opportunity to escape the repeal of the *General Utilities* doctrine.” *McLaulin v. Comm’r*, 115 T.C. 255, 266 (2000).

In connection with the repeal of the *General Utilities* doctrine, Congress authorized the Treasury Department to promulgate regulations to carry out the purposes of that repeal, including by

preventing its avoidance. Specifically, section 337(d) directs the Secretary to prescribe regulations that are necessary or appropriate to carry out the purposes of *General Utilities* repeal, including “regulations to ensure that such purposes may not be circumvented through the use of any provision of law or regulations (including . . . part III of this subchapter).” Section 355, among other corporate organization and reorganization provisions, is included in part III of subchapter C of chapter 1 of the Code (subchapter C).

3. Section 355(c) Distributions

The general rule set forth in section 355(c)(1) provides that no gain or loss is recognized to a distributing corporation upon any distribution to which section 355 (or so much of section 356 of the Code as relates to section 355) applies and that is not made pursuant to a plan of reorganization (section 355(c) distribution). However, if the distributing corporation distributes any property other than stock or securities of a controlled corporation (that is, any property other than qualified property, as defined in section 355(c)(2)(B)) in a section 355(c) distribution, and if the fair market value of that property exceeds the distributing corporation’s adjusted basis in that property, then section 355(c)(2)(A) requires the distributing corporation to recognize gain as if the property were sold to the distributee at its fair market value. This Federal income tax treatment reflects the status of section 355 as a narrow exception to *General Utilities* repeal. *Compare* section 311(b).

Because a section 355(c) distribution is not made pursuant to a plan of reorganization, a section 355(c) distribution (unlike a divisive reorganization) does not permit the distributing corporation to satisfy distributing corporation debt constituting securities with property other than qualified property. In other words, because a section 355(c) distribution does not qualify as a reorganization under the definitional provisions of section 368(a)(1), the operative provision set forth in section 361(b)(3) is not applicable. Therefore, in a section 355(c) distribution, a distributing corporation cannot transfer any property other than qualified property to its creditors (including its security holders) without recognizing gain or loss on that transfer.

4. Divisive Reorganizations

A distributing corporation may carry out a section 355 transaction as part of a transaction that qualifies as a reorganization under section

368(a)(1)(D) or (G) and to which section 354 of the Code (or so much of section 356 as relates to section 354) does not apply (divisive reorganization). Section 368(a)(1)(D) provides, in part, that a reorganization includes a transfer by the distributing corporation of all or a part of its assets to a controlled corporation if, immediately after the transfer, the distributing corporation or one or more of its shareholders (including persons who were shareholders immediately before the transfer) are in control (within the meaning of section 368(c)) of the controlled corporation; but only if, pursuant to the plan of reorganization, stock or securities of the controlled corporation are distributed in a transaction that qualifies under section 355 or 356.

Under section 368(a)(1)(G), a transfer by a distributing corporation of all or a part of its assets to a controlled corporation in a case under title 11 of the United States Code or a similar case described in section 368(a)(3)(A)(ii) (title 11 or similar case) also is a divisive reorganization if, pursuant to the plan of reorganization, stock or securities of the controlled corporation are distributed in a transaction that qualifies under section 355 (or so much of section 356 as relates to section 355). Section 368(a)(3)(C) provides an ordering rule under which a transaction that would qualify both under section 368(a)(1)(G) and, among other provisions, under section 368(a)(1)(D) or section 351 of the Code, is treated as qualifying solely under section 368(a)(1)(G) for all purposes of subchapter C other than section 357(c)(1).

If a transaction satisfies the definitional requirements of section 368(a)(1)(D) or (G), the distributing corporation may qualify for nonrecognition treatment for (i) its exchange of property with the controlled corporation, (ii) its distribution of certain property to its shareholders, and (iii) its transfer of certain property to its creditors. Under section 357(a), the controlled corporation generally may assume distributing corporation liabilities without the distributing corporation recognizing gain or loss, except as provided in (i) section 357(b) (if the principal purpose for the liability assumption is to avoid Federal income tax or is not a bona fide business purpose), and (ii) section 357(c) (if the sum of the amount of liabilities assumed by the controlled corporation is greater than the total adjusted basis of assets transferred in the exchange).

Under section 361(a), the distributing corporation recognizes no gain or loss if

it exchanges property pursuant to the plan of reorganization solely for stock and securities in the controlled corporation. Under section 361(b)(1)(A), if section 361(a) would apply to an exchange but for the fact that the property received by the distributing corporation also includes money or other property, no gain will be recognized by the distributing corporation if it distributes the money or other property pursuant to the plan of reorganization. Under section 361(b)(3), the distributing corporation also generally may transfer that money or other property in connection with the reorganization to its creditors in satisfaction of distributing corporation debt held by those creditors, without recognition of gain or loss under section 361(b)(1)(A) to the extent the sum of the money and the fair market value of the other property transferred to such creditors does not exceed the adjusted bases of such assets transferred (reduced by the amount of liabilities assumed within the meaning of section 357(c)).

Under section 361(c)(1), the distributing corporation recognizes neither gain nor loss on its distribution of qualified property to its shareholders pursuant to the plan of reorganization. For this purpose, section 361(c)(2)(B) defines “qualified property” as any stock in, right to acquire stock in, or obligation of (i) the distributing corporation, or (ii) another corporation that is a party to the reorganization (for example, the controlled corporation) if such stock, stock right, or obligation is received by the distributing corporation in the exchange. In connection with the reorganization, the distributing corporation also generally may transfer that qualified property to its creditors in satisfaction of distributing corporation debt held by those creditors, without recognition of gain or loss under section 361(c).

For purposes of this preamble, the term “section 361 consideration” means, as described in section 361(a) and (b), the consideration received by a target corporation from an acquiring corporation in exchange for property transferred by the target corporation to the acquiring corporation pursuant to a plan of reorganization. Accordingly, in the context of a divisive reorganization, the term “section 361 consideration” means, for purposes of this preamble, the consideration received by the distributing corporation from the controlled corporation in exchange for property transferred by the distributing corporation to the controlled corporation pursuant to the plan of reorganization.

B. General Federal Income Tax Consequences to Distributing Corporation Shareholders

Section 355(a)(1) provides that, if a distributing corporation distributes to its shareholders with respect to its stock, or distributes to its security holders in exchange for their securities, solely stock or securities of a controlled corporation, and if certain other requirements are satisfied, then no gain or loss is recognized by, and no amount is included in the income of, the distributing corporation's shareholders or security holders upon the receipt of stock or securities of the controlled corporation. However, if any property is received that is not permitted to be received under section 355(a)(1), then section 356 (and not section 355) applies to the receipt of such property as provided in sections 355(a)(4)(A) and 356.

C. General Requirements for Qualification Under Section 355

To qualify as a section 355 transaction under section 355(a)(1), a transaction must satisfy the following requirements. First, under section 355(a)(1)(A), the distributing corporation must distribute stock or securities of a controlled corporation to a shareholder with respect to distributing corporation stock, or to a security holder in exchange for its securities. Second, under section 355(a)(1)(B), the transaction may not be used principally as a device for the distribution of the earnings and profits of the distributing corporation, the controlled corporation, or both. Third, under section 355(a)(1)(C), the distributing corporation and each controlled corporation must satisfy the active trade or business requirements of section 355(b).

With particular regard to these proposed regulations, section 355(a)(1) imposes a fourth requirement regarding distributions of controlled corporation stock and securities. Specifically, section 355(a)(1)(D) requires that, "as part of the distribution," the distributing corporation must distribute either (i) all stock and securities in the controlled corporation held by the distributing corporation immediately before the distribution, or (ii) an amount of stock in the controlled corporation constituting "control" within the meaning of section 368(c) (control distribution). In the case of distributions of less than 100 percent of stock in the controlled corporation, it must be established to the satisfaction of the Secretary that the retention by the distributing corporation of stock (or stock and securities) of the controlled

corporation was not pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax. For purposes of this preamble, such a retention of controlled corporation stock (or stock and securities) by the distributing corporation is referred to as a "retention," and the requirements in section 355(a)(1)(D) are referred to collectively as the "distribution requirement."

D. The Distribution Requirement and Retentions

1. Overview

As described in part I.C of this Background, the distribution requirement consists of two alternative rules. Under section 355(a)(1)(D)(i), the distributing corporation will satisfy the distribution requirement if it distributes all stock and securities in the controlled corporation held by the distributing corporation immediately before the distribution. Alternatively, under section 355(a)(1)(D)(ii), the distributing corporation will satisfy the distribution requirement if it satisfies the following two discrete requirements: (i) the distributing corporation distributes an amount of controlled corporation stock sufficient to qualify as a control distribution; and (ii) the distributing corporation establishes to the satisfaction of the Secretary that the retention of any controlled corporation stock or securities was not pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax.

2. Requirements for Control Distribution; *Commissioner v. Gordon*

Section 355(a)(1)(D) provides that, if a distributing corporation does not distribute all its stock and securities in the controlled corporation, the distributing corporation must make a control distribution as "part of the distribution." However, section 355(a)(1)(D) does not expressly impose a temporal requirement for making a control distribution. Accordingly, section 355(a)(1)(D) could be read as permitting a control distribution to occur over multiple taxable years of the distributing corporation.

In *Commissioner v. Gordon*, 391 U.S. 83 (1968), the Supreme Court considered the application of the distribution requirement to distributions by Pacific Telephone and Telegraph Company (Pacific) of stock of a newly formed, wholly owned subsidiary (Northwest) over multiple taxable years of Pacific. American Telephone and Telegraph Company (AT&T), which owned approximately 90 percent of the

stock of Pacific, decided to separate Pacific into two separate companies and, to effectuate that separation, caused Pacific to engage in the following transactions. First, pursuant to a plan of reorganization submitted to its shareholders, Pacific issued to its shareholders (including the taxpayer) transferable rights to acquire approximately 57 percent of the stock of Northwest on September 29, 1961. That plan of reorganization also provided that Pacific had an "expectation" that the remaining 43 percent of Northwest stock would be offered to Pacific's shareholders. Among other reasons for not distributing 100 percent of its Northwest stock, Pacific desired to achieve an appropriate capital structure and avoid potential State regulatory issues. On June 12, 1963, Pacific issued to its shareholders transferable rights to acquire the remaining 43 percent of Northwest stock. The taxpayer contended that the 1961 and 1963 distributions collectively qualified under section 355.

The Court concluded that neither distribution qualified under section 355, notwithstanding Pacific's "expectation" regarding the second distribution and its purposes for making multiple distributions. *Gordon*, 391 U.S. at 98. In its analysis, the Court expressed a general principle of Federal income tax that, "[a]bsent other specific directions from Congress, Code provisions must be interpreted so as to conform to the basic premise of annual tax accounting." *Id.* at 96. With regard to the distribution requirement, the Court noted that, if an initial transfer of less than a controlling interest in the controlled corporation is to be treated for Federal income tax purposes as a mere first step in the divestiture of control, "it must at least be identifiable as such at the time it is made." *Id.* The Court further stated that the requirement that the character of a transaction be determinable "does not mean that the entire divestiture must necessarily occur within a single tax year," but it does mean that, if one transaction is to be characterized as a "first step," then "there must be a binding commitment to take the later steps." *Id.* Of particular relevance to both the IRS's administrative function and the objective of these proposed regulations to provide increased certainty (see part IV of this Background), the Court expressed that it would be wholly inconsistent with the annual accounting premise to hold that the essential character of a transaction, and its Federal income tax impact, should remain "not only undeterminable but unfixed for an

indefinite and unlimited period in the future, awaiting events that might or might not happen.” *Id.*

The Court found that the facts and circumstances of Pacific’s staggered distributions of Northwest stock, as reflected in Pacific’s plan of reorganization, failed the binding-commitment standard set forth by the Court. *Id.* at 97. Although Pacific’s plan of reorganization evidenced an expectation to distribute its remaining Northwest stock within a three-year period following its initial 57-percent distribution, the Court emphasized that “there is obviously no promise to sell any particular amount of stock, at any particular time, at any particular price” set forth in that document. *Id.* Instead, Pacific’s plan of reorganization merely stated that such subsequent distributions would occur “[a]t a time or times related to its (Pacific’s) need for new capital.” *Id.* Consequently, the Court reasoned that, “[i]f the 1961 distribution played a part in what later proved to be a total divestiture of the Northwest stock, it was not, in 1961, either a total divestiture or a step in a plan of total divestiture.” *Id.* at 97–98.

3. Retentions

Section 1.355–2(e), which reiterates the distribution requirement, provides that the corporate business purpose or purposes for the distribution ordinarily will require the distribution of all stock and securities of the controlled corporation. If the distributing corporation retains any controlled corporation stock or securities, and if it is not established to the satisfaction of the Commissioner that the retention was not pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax, section 355 does not apply to the entire distribution (that is, the entire distribution fails to qualify as a section 355 transaction).

In Rev. Rul. 75–321, 1975–2 C.B. 123, the IRS addressed whether the retention by a widely held and publicly traded corporation (Distributing) of stock in its banking subsidiary (Controlled) complied with section 355(a)(1)(D)(ii) (that is, whether the retention was pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax). In this revenue ruling, Distributing distributed 95 percent of the stock of Controlled to Distributing’s shareholders to comply with Federal banking laws in a transaction that otherwise satisfied the requirements of section 355. Distributing retained 5 percent of Controlled’s stock to meet collateral requirements for short-term financing. The IRS concluded that the retention

was not pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax, because (i) a genuine separation of the corporate entities was effectuated, (ii) retention of a 5-percent stock interest in Controlled would not enable Distributing to maintain practical control over Controlled following the distribution, and (iii) a sufficient corporate business purpose existed for Distributing’s retention of the 5-percent interest in Controlled. *See also* Rev. Rul. 75–469, 1975–2 C.B. 126 (similar ruling with respect to a distributing corporation’s retention of controlled corporation securities to serve as collateral for a bank loan to the distributing corporation).

Similarly, in G.C.M. 32136 (Oct. 23, 1961), the IRS considered whether the retention by a distributing corporation (Distributing) of stock in a newly formed controlled corporation (Controlled) was pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax. Under the facts described in that memorandum, Distributing distributed 80 percent of Controlled stock to Distributing’s shareholders to comply with State banking laws in a transaction that otherwise satisfied the requirements of section 355, and Distributing retained 20 percent of Controlled stock. The avowed purpose for the retention was to permit a controlling group of Distributing’s shareholders to maintain effective control over Controlled. In concluding that Distributing had a Federal income tax avoidance purpose for the retention, the IRS determined that the requirement that a retention be specially justified “seems most likely to be intended to insure a genuine separation.” *See also* G.C.M. 32380 (Aug. 24, 1962) (reiterating that view).

II. Definitional and Operative Provisions Regarding Reorganizations

A. Overview

Subchapter C generally includes (i) definitional provisions, including under section 368, and (ii) operative provisions, including under sections 354, 356, 357, and 361. *See, for example, Microdot, Inc. v. United States*, 728 F.2d 593, 598 (2d Cir. 1984) (“Section 368(a)(1) is a definitional section, wholly distinct from [section] 354.”). As described in greater detail in part II.B of this Background, section 368(a)(1) defines the term “reorganization” as seven specifically described types of transactions under subparagraphs (A) through (G). Qualification of a transaction (or series of transactions) for a definitional

provision under section 368(a)(1) is the sole manner by which the application of an operative provision relating to a reorganization can occur. This statutory structure ensures that the tax-advantaged treatment provided by such operative provisions applies exclusively to those transactions that satisfy all statutory, regulatory, and judicial requirements for a particular definitional provision (for example, the continuity of interest and continuity of business enterprise requirements). As discussed in greater detail in part III of this Background, a primary purpose of the “plan of reorganization” requirement is to ensure that a transaction to which an operative provision is purported to apply is sufficiently connected to a reorganization defined in section 368(a)(1).

B. Section 368: Definitions Relating to Corporate Reorganizations

Section 368(a)(1) is the primary definitional provision of subchapter C with regard to reorganizations. For purposes of parts I through III of subchapter C, section 368(a)(1) defines the term “reorganization” to mean any of the seven types of transactions described in section 368(a)(1)(A) through (G), including triangular reorganizations (as defined in § 1.358–6(b)(2)) that are variants of such transactions and divisive reorganizations described in section 368(a)(1)(D) and (G). Section 368(a)(2) provides special rules that support the definitional provisions set forth in section 368(a)(1), and section 368(a)(3) similarly provides additional rules relating to title 11 or similar cases.

Section 368(b) and (c) also contains definitional provisions. For purposes of part III of subchapter C, section 368(b) generally defines the term “a party to a reorganization” to include (i) a corporation resulting from a reorganization, and (ii) both corporations, in the case of a reorganization resulting from the acquisition by one corporation of stock or properties of another. Section 368(b) defines other corporations as parties to a transaction depending on the type of transaction. *See also* § 1.368–2(f).

For purposes of subchapter C (other than sections 304 and 385 of the Code), section 368(c) defines the term “control” to mean the ownership of (i) stock possessing at least 80 percent of the total combined voting power of all classes of stock entitled to vote, and (ii) at least 80 percent of the total number of shares of all other classes of stock of the corporation. *See also* Rev. Rul. 59–259, 1959–2 C.B. 115 (requiring

ownership of (i) stock possessing at least 80 percent of the total combined voting power of all classes of voting stock, and (ii) at least 80 percent of the total number of shares of each class of outstanding non-voting stock).

C. Section 357: Assumptions of Liabilities by Transferee Corporations

1. Overview

Section 357 is an operative provision that facilitates exchanges involving the assumption of liabilities by generally preventing such assumptions from (i) being treated as the receipt of money or other property in an exchange, and (ii) disqualifying the exchange for nonrecognition treatment. *See* section 357(a); *see also* the anti-abuse rule in section 357(b) and the adjusted basis limitation in section 357(c). Section 357 reflects Congress's view that, "[i]n typical transactions changing the form or entity of a business it is not customary to liquidate the liabilities of the business and such liabilities are almost invariably assumed by the corporation which continues the business," but that nonrecognition treatment in section 357 should be limited solely to "bona fide transactions of this type." H.R. Rep. No. 76-855, at 19 (1939) (Conf. Rep.).

2. Response to *United States v. Hendler*

The original predecessor to current section 357, section 112(k) of the Internal Revenue Code of 1939 (1939 Code), was enacted by Congress as section 213(a) of the Revenue Act of 1939 (Public Law 76-155, 53 Stat. 862, 870) to address the adverse consequences of judicial and taxpayer interpretations of the Supreme Court's decision in *United States v. Hendler*, 303 U.S. 564 (1938). *See* S. Rep. No. 76-648, at 3 (1939) (referencing the *Hendler* opinion by name). In *Hendler*, the Court examined the Federal income tax consequences of a transaction that qualified as a reorganization under section 112 of the Revenue Act of 1928 (Public Law 70-562, 45 Stat. 791). As part of the reorganization, the transferee corporation (Borden Company) assumed and paid the indebtedness of the transferor (Hendler Company). The Court regarded the assumption and payment in substance as though the Borden Company had made the payment directly to the Hendler Company. *Hendler*, 303 U.S. at 566. Based on that treatment, the Court viewed the Hendler Company in substance as receiving money or other property that it failed to distribute to its shareholders (because that payment was made to a Hendler Company creditor,

albeit in form by the Borden Company). *Id.* Accordingly, the Court held that the Hendler Company recognized gain in the amount of that payment. *Id.* at 567.

Following the *Hendler* decision, Congress observed that the Court's analysis had "been broadly interpreted to require that, if a taxpayer's liabilities are assumed by another party in what is otherwise a tax-free reorganization, gain is recognized to the extent of the assumption." H.R. Rep. No. 76-855, at 19 (emphasis added). In other words, as successfully argued by the IRS in cases following *Hendler*, a transferee corporation's lack of payment of the liabilities was immaterial for the *Hendler* analysis to apply to treat the transferee corporation's assumption of a transferor's liabilities as a cash payment to the transferor. *See Haass v. Comm'r*, 37 B.T.A. 948, 955 (1938). The IRS advocated for this broad interpretation in response to an aggressive position taken by taxpayers, who relied on the *Hendler* decision to argue that the basis of stock they had received in prior exchanges should be increased by the amount of gain that *should have been recognized and taxed* by reason of the transferee corporation's assumption of liabilities, even though that gain had not actually been taxed by the IRS (and that tax had not been paid).

However, this broad interpretation jeopardized the nonrecognition treatment of bona fide assumptions carried out as part of reorganizations that Congress originally had intended to facilitate through the enactment of the reorganization provisions. *See* H.R. Rep. No. 76-855, at 19 ("Your committee therefore believes that such a broad interpretation as is indicated above will largely nullify the provisions of existing law which postpone the recognition of gain in such cases.").

3. Enactment of Section 357(a) and (b)

Congress enacted section 112(k) of the 1939 Code to balance (i) the need to facilitate the bona fide assumption of liabilities in transactions that satisfy the definitional requirements of a reorganization, with (ii) the need to minimize abusive tax planning through such assumptions (including through transitory transactions). Accordingly, section 112(k) of the 1939 Code provided for both (i) the general nonrecognition treatment adopted by section 357(a) of the 1954 Code and set forth in current section 357(a), and (ii) a supporting anti-abuse provision adopted by section 357(b) of the 1954 Code and set forth in current section 357(b).

Under section 357(b)(1), the total amount of liabilities assumed in an

assumption described in section 357(a) is treated for purposes of section 351 or 361 (as applicable) as money received by the transferor in the exchange if it *appears* that the principal purpose of the transferor with respect to the assumption was (i) to avoid Federal income tax on the exchange, or (ii) not a bona fide business purpose. In effect, section 357(b) can apply to a transaction to preserve the treatment required by *Hendler* for such abusive assumptions.

In making the determination required by section 357(b)(1), the nature of the liabilities and the circumstances under which the arrangement for the assumption was made are taken into account. In addition, section 357(b)(2) provides that, in any suit or proceeding in which the burden is on the transferor to prove that the liability assumption should not be treated as money received in the exchange, the transferor must meet that burden by a clear preponderance of the evidence.

4. Application of Section 357(b) to Divisive Reorganizations

In Rev. Rul. 79-258, 1979-2 C.B. 143, the IRS considered the application of section 357(b) to the assumption by a newly formed transferee corporation (Controlled) of a liability incurred by the transferor (Distributing) in close temporal proximity to, and in anticipation of, a transaction that qualified as a divisive reorganization under sections 355 and 368(a)(1)(D). One of the Distributing liabilities that Distributing desired Controlled to assume was a \$4,000x portion of a \$25,000x long-term debt owed to an insurance company that Distributing had incurred in connection with the business transferred to Controlled, and that had been outstanding for several years before the divisive reorganization (historical Distributing debt). However, Distributing could not apportion the historical Distributing debt between it and Controlled because the insurance company refused to relieve Distributing of its primary liability for repayment.

Therefore, in exchange for \$4,000x in loan proceeds, Distributing issued a new long-term note for which Distributing was primarily liable to a bank (new Distributing debt). Distributing then caused Controlled to assume the new Distributing debt in the divisive reorganization, and Distributing was relieved of its primary repayment liability (Controlled assumption). The proceeds of the new Distributing debt were used by Distributing to pay off \$4,000x of the historical Distributing debt. Distributing then distributed the Controlled stock to Distributing's shareholders.

From Distributing's standpoint, having Controlled assume the new Distributing debt was desirable because, absent Controlled's assumption of this debt, Distributing's assets would be reduced by the value of the Controlled stock (which was distributed to Distributing's shareholders), but Distributing's liabilities would not be reduced by the \$4,000x liability attributable to the business transferred to Controlled. As a result, Distributing's ability to borrow (and its ability to pay off the portion of the historical Distributing debt attributable to the business transferred to Controlled) could be adversely affected if Controlled did not assume the new Distributing debt.

To determine the potential application of section 357(b), the IRS engaged in a detailed analysis of the facts and circumstances relating to the issuance of the new Distributing debt and the Controlled assumption. First, the IRS observed that Distributing used the proceeds of the new Distributing debt to satisfy \$4,000x of the historical Distributing debt, thereby placing Distributing and Controlled in the same net economic position after the Controlled assumption as each corporation would have been in had Controlled been able to assume \$4,000x of the historical Distributing debt. Second, the IRS observed that the incurrence of the new Distributing debt and the Controlled assumption not only were necessary to effectuate the divisive reorganization, but also were a normal adjunct to the divisive reorganization given the non-assumable nature of part of the historical Distributing debt. Third, the IRS observed that Distributing's incurrence of the new Distributing debt and the Controlled assumption merely were in substitution for Controlled's assumption of a pro rata portion of the historical Distributing debt that Controlled could not assume. In that regard, because the divisive reorganization resulted in Controlled assuming a liability in an amount that properly related to its business operations and would be satisfied from earnings generated by those operations, the IRS viewed the incurrence of the new Distributing debt and the Controlled assumption as consistent with sound business practice. Accordingly, the IRS concluded that tax avoidance was not a principal purpose of the transaction and, therefore, that section 357(b) did not apply to the Controlled assumption.

Additionally, the IRS determined that the acquisition of the new Distributing debt and the Controlled assumption would not be viewed for Federal income

tax purposes as if Controlled had obtained the new Distributing debt and transferred the proceeds to Distributing. In this regard, the IRS found it immaterial that Distributing and Controlled may have been able to arrange their affairs in another manner, because the taxpayer satisfied its burden of proof as required under section 357(b). See *Simpson v. Comm'r*, 43 T.C. 900, 916 (1965) (stating that the application of section 357(b) is limited to transactions "arranged primarily so that the assumption of the [transferor]'s liability in the transaction itself results in tax avoidance for the transferor, or has no bona fide business purpose," and that section 357(b) was not intended to require recognition of gain on bona fide transactions designed to rearrange one's business affairs in such a manner as to minimize taxes in the future, consistent with existing provisions of the law); *ISC Industries, Inc. v. Comm'r*, T.C. Memo. 1971-283 (concluding that petitioner's principal purpose in having a new subsidiary assume liabilities placed upon the assets transferred to the subsidiary was not to avoid Federal income taxes on the transfer, but rather was to protect lines of credit for petitioner's finance business, and finding it immaterial that petitioner may have been able to arrange its affairs in another manner, or in a manner that produced more tax revenue, because section 357(b) clearly looks to the taxpayer's motives for doing what actually occurred).

5. Application of Section 357(c)

In the case of an exchange to which section 351 applies (section 351 exchange) or to which section 361 applies by reason of a divisive reorganization that qualifies under sections 355 and 368(a)(1)(D), section 357(c)(1) generally provides that, if the sum of the amount of the transferor's liabilities assumed by the transferee corporation exceeds the total adjusted basis of the assets transferred by the transferor to the transferee corporation in the exchange, then such excess is considered as a gain from the sale or exchange of a capital asset or of property that is not a capital asset, as the case may be. See also section 368(a)(3)(C) (providing that a reorganization that would qualify under both section 368(a)(1)(D) and (G) is treated as qualifying under section 368(a)(1)(D) for purposes of section 357(c)(1)).

However, section 357(c)(2) provides that the general rule in section 357(c)(1) does not apply to any exchange (i) to which section 357(b) applies, or (ii) that is pursuant to a plan of reorganization

within the meaning of section 368(a)(1)(G) in which no former shareholder of the transferor receives any consideration for its stock. Rev. Rul. 2007-8, 2007-1 C.B. 469, holds that the general rule in section 357(c)(1) does not apply to a section 351 exchange if that transaction also qualifies as a reorganization described in section 368(a)(1)(A), (C), (D) (provided the requirements of section 354(b)(1) are satisfied), or (G) (provided the requirements of section 354(b)(1) are satisfied).

Furthermore, under section 357(c)(3), if the transferor transfers in a section 351 exchange (including a divisive reorganization that overlaps with a section 351 exchange; see section 357(c)(3) (referencing an exchange to which section 357(c)(1) applies)) a liability the payment of which either would give rise to a deduction or would be described in section 736(a) of the Code (concerning payments made in liquidation of the partnership interest of a retiring or deceased partner), the amount of such liability is excluded in determining the amount of liabilities assumed under section 357(c)(1) unless the incurrence of the liability resulted in the creation of (or an increase in) the basis of any property. In addition, liabilities the payment of which would give rise to a capital expenditure are not included for purposes of section 357(c)(1) unless the incurrence of the liability resulted in the creation of (or an increase in) the basis of any property. See Rev. Rul. 95-74, 1995-2 C.B. 36.

D. Section 361: Distributions to Shareholders of Target Corporation

1. Overview

Section 361 is an operative provision applicable to certain exchanges and distributions of property in a transaction that satisfies the definitional requirements for qualification as a reorganization under section 368(a)(1). Section 361(a) and (b) provides the Federal income tax consequences to a target corporation (such as a distributing corporation in a divisive reorganization) that (i) is a party to a reorganization, and (ii) pursuant to the plan of reorganization, exchanges property with an acquiring corporation (such as a controlled corporation in a divisive reorganization) that also is a party to the reorganization. Section 361(c) provides the Federal income tax consequences to the target corporation (such as a distributing corporation in a divisive reorganization) of the distribution by the target corporation to its shareholders, or transfer to its creditors, of certain property in pursuance of or in

connection with the plan of reorganization that includes the exchange of property with an acquiring corporation (such as a controlled corporation in a divisive reorganization) that also is a party to the reorganization. See the discussion in part III.A of this Background (noting that the phrases “in pursuance of” and “in connection with” in section 361 convey the same meaning).

2. Enactment of Section 361(a): Purely Paper Transactions

The original predecessor to current section 361(a) was enacted by Congress as part of section 202(b) of the Revenue Act of 1918 (Pub. L. 65–254, 40 Stat. 1057, 1060 (1919)). The applicable part of section 202(b) of the Revenue Act of 1918 was subsequently incorporated in section 112 of the 1939 Code before being adopted as section 361(a) of the 1954 Code and thereafter as current section 361(a).

Congress enacted the applicable part of section 202(b) of the Revenue Act of 1918 “to establish the rule for determining taxable gains in the case of exchanges of property and to negate the assertion of tax in the case of certain purely paper transactions.” S. Rep. No. 65–617, at 5 (1918). As stated in the legislative history, the substance of the original predecessor to section 361(a) is that (i) when property is exchanged for other property, the property received in the exchange should be treated as the equivalent of cash in the amount of its fair market value, but (ii) when, in connection with the reorganization or consolidation of a corporation, a person receives, in place of stock or securities, new stock or securities of no greater aggregate par value, or when a person receives, in place of property, stock of a corporation formed to take over such property, no gain or loss should be deemed to occur from the exchange. See *id.* at 5–6.

More than a century after the enactment of its original predecessor, section 361(a) continues to provide generally that a corporation (that is, the target corporation) that is a party to a reorganization (such as the distributing corporation in a divisive reorganization) recognizes no gain or loss if it exchanges property pursuant to the plan of reorganization solely for stock and securities in another corporation (that is, the acquiring corporation) that is a party to the reorganization (such as a controlled corporation in a divisive reorganization).

3. Enactment of Section 361(b): Conduit for Distribution to Shareholders

The original predecessor to current section 361(b) was enacted by Congress as section 203(e) of the Revenue Act of 1924 (Pub. L. 68–176, 43 Stat. 253, 256). Section 203(e) of the Revenue Act of 1924 was subsequently incorporated in section 112 of the 1939 Code before being adopted as section 361(b) of the 1954 Code and thereafter as current section 361(b).

Congress enacted section 203(e) of the Revenue Act of 1924 to provide that (i) if the corporation that sells its assets in connection with the reorganization “acts merely as a conduit” in passing the sale proceeds on to its shareholders, no gain to the corporation is to be recognized, but (ii) if the corporation “retains the entire amount of proceeds with the result that the transaction is in substance a real sale, then the gain shall be recognized.” S. Rep. No. 68–398, at 16 (1924). This stated policy is reflected in current section 361(b)(1).

Section 361(b)(1)(A) provides that, if section 361(a) would apply to an exchange but for the fact that the property received by the target corporation also includes money or other property, no gain will be recognized by the target corporation if it distributes the money or other property pursuant to the plan of reorganization. Congress has enacted no limitation on the aggregate amount of cash and the fair market value of other property that a target corporation can distribute to its shareholders (as opposed to creditors) under section 361(b)(1)(A) (although section 368 limits the amount of money or other property that may be received in certain corporate reorganizations).

Section 361(b)(1)(B), which reflects congressional intent with respect to a target corporation’s failure to act solely as a conduit in distributing the sale proceeds (that is, money or other property) to its shareholders, provides that the target corporation (such as the distributing corporation in a divisive reorganization) recognizes gain in an amount that does not exceed the sum of the money and fair market value of the other property that the corporation fails to distribute pursuant to the plan of reorganization.

4. Section 361(c): Distributions of Appreciated Property to Target Corporation Shareholders

Section 361(c) originally was enacted by Congress as section 1804(g)(1) of the Tax Reform Act of 1986. As part of a wholesale rewrite of section 361, Congress amended section 361(c) by enacting section 1018(d)(5)(A) of the

Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647, 102 Stat. 3342, 3578) so that the statute “conforms the treatment of distributions of property by a corporation to its shareholders in pursuance of a plan of reorganization to the treatment of nonliquidating distributions (under section 311).” S. Rep. No. 100–445, at 393 (1988).

Section 311(a) generally provides that, except as provided in section 311(b) (concerning distributions of appreciated property), no gain or loss is recognized by a corporation on the distribution (not in complete liquidation) with respect to its stock of (i) its stock (or rights to acquire its stock), or (ii) property. Accordingly, section 361(c)(1) generally provides that, except as provided in section 361(c)(2) (concerning distributions of appreciated property), no gain or loss is recognized by a target corporation that is a party to a reorganization upon a distribution of property to its shareholders pursuant to a plan of reorganization.

Consistent with section 311(b), section 361(c)(2)(A) provides that, if the target corporation distributes property other than qualified property in a distribution described in section 361(c)(1), and if the fair market value of that other property exceeds the corporation’s adjusted basis in that other property, then gain is recognized by the target corporation as if the property were sold to the distributee at its fair market value. The term “qualified property” is defined in section 361(c)(2)(B) to mean (i) any stock, right to acquire stock, or obligation (including a security) of the corporation, and (ii) any stock, right to acquire stock, or obligation (including a security) of another corporation that is a party to the reorganization received by the target corporation in the exchange.

Therefore, although a target corporation would recognize no gain on an exchange described in section 361(a) (section 361(a) exchange) if that corporation received appreciated non-qualified property and distributed that property to its shareholders pursuant to section 361(b)(1)(A), that corporation nonetheless would recognize gain on the distribution to its shareholders under section 361(c)(2)(A). If any such property is subject to a liability, or if the shareholder assumes a liability of the target corporation in connection with the distribution, section 361(c)(2)(C) provides that the fair market value of that property is treated as not less than the amount of that liability for purposes of section 361(c)(2)(A).

5. Safe Harbors for Transfers to Creditors of the Distributing Corporation

Congress added section 361(b)(3) and (c)(3) as part of the wholesale rewrite of section 361 in the Technical and Miscellaneous Revenue Act of 1988. Section 361(b)(3) provides that, for purposes of section 361(b)(1), any transfer of the money or other property received in the exchange by the target corporation to its creditors in connection with the reorganization is treated as a distribution pursuant to the plan of reorganization. Similarly, section 361(c)(3) provides that, for purposes of section 361(c), any transfer of qualified property by the target corporation to its creditors in connection with the reorganization is treated as a distribution to its shareholders pursuant to the plan of reorganization.

6. Response to Supreme Court's Decision in *Minnesota Tea Company*

In *Minnesota Tea Co. v. Helvering*, 302 U.S. 609 (1938), the Supreme Court held that a distribution by a target corporation to its shareholders of cash received from an acquiring corporation in a reorganization was not a qualifying “distribution” for purposes of the predecessor to section 361(b)(1)(A), because the shareholders immediately used that distributed cash to pay the target corporation’s creditors as part of a prearranged plan. Citing *Gregory v. Helvering*, 293 U.S. 465, 469 (1935), as providing the “controlling principle” for its decision, the Court determined that the payment of indebtedness, and not the distribution of dividends, “was, from the beginning, the aim of the understanding with the stockholders and was the end accomplished by carrying that understanding into effect.” *Minnesota Tea*, 302 U.S. at 613–14. Because the *Minnesota Tea Company* “received the same benefit as though it had retained that amount from [the] distribution and applied it to the payment of such indebtedness,” the Court concluded that the company failed to satisfy the predecessor to section 361(b)(1)(A). *See id.* at 613 (emphasis added).

In describing the rationale for enacting section 361(b)(3) and (c)(3), the legislative history explains that each provision “overrules the holding in *Minnesota Tea Company v. Helvering*.” S. Rep. No. 100–445, at 393 n.102 (1988); *see also* H.R. Rep. 100–795, at 372 (1988). The legislative history described the substance of the safe harbor in section 361(b)(3) as providing that “transfers of property to creditors in satisfaction of the corporation’s

indebtedness in connection with the reorganization are treated as distributions pursuant to the plan of reorganization for this purpose.” S. Rep. No. 100–445, at 393 (1988) (emphasis added). Likewise, the legislative history described the corresponding safe harbor in section 361(c)(3) as providing that “the transfer of qualified property by a corporation to its creditors in satisfaction of indebtedness is treated as a distribution pursuant to the plan of reorganization.” *Id.* (emphasis added). By treating transfers of property to creditors in satisfaction of indebtedness as distributions pursuant to the plan of reorganization, Congress balanced the dual policy objectives of (i) preserving consistency with the fundamental requirement of section 361 that property be distributed, and (ii) enacting a provision to address transfers to creditors in satisfaction of indebtedness that overruled the holding in *Minnesota Tea*.

7. Adjusted Basis Limitation for Purposes of Section 361(b)(3)

In the case of a divisive reorganization described in sections 355 and 368(a)(1)(D), the third sentence in section 361(b)(3) (adjusted basis limitation) limits the extent to which a transfer of money or other property to a creditor is treated as a distribution pursuant to the plan of reorganization for the purposes of section 361. Specifically, section 361(b)(3) applies solely to the extent the sum of the money and the fair market value of the other property transferred to creditors of the distributing corporation does not exceed the aggregate adjusted bases of the assets transferred to the controlled corporation in the section 361(a) exchange, reduced by the amount of the distributing corporation’s liabilities that the controlled corporation actually assumes within the meaning of section 357(c).

Congress enacted the adjusted basis limitation in section 361(b)(3) as part of the American Jobs Creation Act of 2004 (Pub. L. 108–357, 118 Stat. 1418) based on the concern stated in the legislative history that taxpayers had developed tax-planning strategies to circumvent the adjusted basis limitation in section 357(c) on actual assumptions by controlled corporations in divisive reorganizations. *See* S. Rep. No. 108–192, at 185 (2003). Specifically, the committee report observed that a distributing corporation (i) could cause the controlled corporation to borrow money from a financial institution and transfer that money to the distributing corporation in the section 361(a) exchange, and then (ii) could use that

money to pay its creditors. *Id.* The committee report concluded that, although this series of transactions does not involve an actual assumption by the controlled corporation within the meaning of section 357, it is “economically similar to the actual assumption” because, at the end of the series of transactions, the distributing corporation has reduced its indebtedness to its creditor and the controlled corporation has become indebted to a creditor (albeit a different creditor) for an equal amount. *See id.* Accordingly, “because section 361(b) [did] not contain a limitation on the amount that can be distributed to creditors,” Congress limited the scope of the section 361(b)(3) safe harbor to “the amount of the basis of the assets contributed to a controlled corporation in a divisive reorganization.” *Id.*

8. Express Grant of Authority

As stated previously in the Authority section of this preamble, the second sentence of section 361(b)(3) provides the Secretary with an express grant of authority to prescribe such regulations as may be necessary to prevent avoidance of Federal income tax through abuse of the safe harbors in section 361(b)(3) and (c)(3). Congress included this grant of authority in section 361(b)(3) when Congress enacted both provisions as part of the Technical and Miscellaneous Revenue Act of 1988.

III. Plan of Reorganization; Party to a Reorganization

A. Overview

For more than a century, the “plan of reorganization” requirement has served to limit the application of the operative provisions in subchapter C solely to those transactions with a sufficiently proximate relationship to transactions that satisfy the definitional requirements in subchapter C for a reorganization (proximate relationship requirement). For example, *see* section 202(b) of the Revenue Act of 1918 (providing that an exchange did not qualify for nonrecognition treatment unless the transaction was “in connection with” a reorganization). In other words, Congress has long viewed the proximate relationship requirement as an integral tool for preventing the nonrecognition provisions in subchapter C from applying to transactions to which general gain or loss provisions of the Code (for example, section 1001 of the Code) should apply.

This long-standing congressional purpose is illustrated by the evolution of section 202(c)(1) of the Revenue Act

of 1921 (Pub. L. 67–98, 42 Stat. 227). That provision originally provided nonrecognition treatment for an exchange of property held for investment or for productive use in a trade or business, with no exception for stock or securities, and with no proximate relationship requirement. Tax advisors took advantage of this provision by structuring exchanges of portfolio investment securities for other securities in transactions that resulted in no recognition of Federal income tax. After receiving a request from the Treasury Department to address this abuse, Congress amended section 202(c)(1) by removing exchanges of stock and securities from nonrecognition treatment except for exchanges occurring in the context of a reorganization. *See An Act to Amend the Revenue Act of 1921 in Respect to Exchanges of Property*, Public Law 67–545, 42 Stat. 1560 (1923); J. Seidman, *Legislative History of Federal Income Tax Laws: 1938–1861*, at 798 (1938); *see also* Letter from A. W. Mellon, Secretary of the Treasury, to Congressman William R. Green, Acting Chairman of the Committee on Ways and Means (Jan. 13, 1923).

Since first establishing the proximate relationship requirement, Congress has implemented that requirement through various linguistic formulations over time. However, Congress has indicated that such variations in language were not intended to reflect substantive differences. For example, Congress replaced “in connection with” in section 202(b) of the Revenue Act of 1918 with “in the reorganization” in section 202(c) of the Revenue Act of 1921. When describing section 202(c) of the Revenue Act of 1921, a congressional committee print explicitly referred to the proximate relationship under that section as requiring an “in connection with” relationship. *See S. Comm. on Finance*, 68th Cong., *Statement of the Changes Made in the Revenue Act of 1921 by H.R. 6715 and the Reasons Therefor*, at 5–6 (Comm. Print 1924).

In section 203(c) of the Revenue Act of 1924, Congress restated the proximate relationship requirement as requiring an “in pursuance of a plan of reorganization” relationship. This requirement, like the “in connection with” requirement, exists in the current definitional and operative provisions of subchapter C. The legislative history underlying section 203 of the Revenue Act of 1924 explicitly refers to the “in pursuance of the plan of reorganization” formulation in several instances as “in connection with the reorganization.” *See H.R. Rep. No. 68–179*, at 13–16

(1924). In particular, at one point, the Committee on Ways and Means described the change in formulation of the proximate relationship requirement as a result of “minor changes in phraseology.” *See id.* at 13.

B. Definition of “Plan of Reorganization”

The term “plan of reorganization” is not defined in subchapter C. Instead, the sole authoritative guidance defining this term is set forth in the Income Tax Regulations. Specifically, § 1.368–2(g) provides that the term “plan of reorganization” refers to a “consummated transaction specifically defined as a reorganization under section 368(a),” and that “[s]ection 368(a) contemplates genuine corporate reorganizations which are designed to effect a readjustment of continuing interests under modified corporate forms.” Section 1.368–2(g) further provides that the term “plan of reorganization” “is not to be construed as broadening the definition of reorganization as set forth in section 368(a),” but rather “is to be taken as limiting the nonrecognition of gain or loss to such exchanges or distributions as are directly a part of the transaction specifically described as a reorganization in section 368(a).” Section 1.368–2(g) further provides that the transaction (or series of transactions) “embraced in a plan of reorganization must not only come within the specific language of section 368(a),” but also that “the readjustments involved in the exchanges or distributions effected in the consummation [of the plan of reorganization] must be undertaken for reasons germane to the continuance of the business of a corporation a party to the reorganization.”

However, significant uncertainty and confusion have arisen regarding the scope, purpose, and application of § 1.368–2(g). As expressed by the Tax Court in an observation often referenced by courts and commentators, “the above definition is imbued with qualities of flexibility and vagueness, with the result that it does not present precise self-executing guidelines.” *Int’l Telephone & Telegraph Corp. v. Comm’r*, 77 T.C. 60, 75 (1981); *see also J.E. Seagram Corp. v. Comm’r*, 104 T.C. 75, 96 (1995) (relying on the quote in *Int’l Telephone* in observing that § 1.368–2(g) provides “substantial elasticity”). As a result, § 1.368–2(g) (including its proximate relationship requirement) has created significant uncertainty and confusion for taxpayers and the IRS in determining the scope of transactions that properly should be taken into account for purposes of

applying the definitional and operative provisions of subchapter C.

Section 1.368–1(c) further describes the “plan of reorganization” concept and provides important context regarding the application of this concept and its embedded proximate relationship requirement. Specifically, § 1.368–1(c) provides, in part, that “[t]he provisions of [part III of subchapter C] referred to in this paragraph *are inapplicable unless there is a plan of reorganization*” (emphasis added). Section 1.368–1(c) further provides that “[a] plan of reorganization must contemplate the bona fide execution of one of the transactions specifically described as a reorganization in section 368(a) and for the bona fide consummation of each of the requisite acts under which nonrecognition of gain is claimed.” That transaction, and those acts, must be an “ordinary and necessary incident of the conduct of the enterprise and must provide for a continuation of the enterprise.” *Id.* Finally, § 1.368–1(c) provides that a scheme involving “an abrupt departure from normal reorganization procedure in connection with a transaction on which the imposition of tax is imminent, such as a mere device that puts on the form of a corporate reorganization as a disguise for concealing its real character, and the object and accomplishment of which is the consummation of a preconceived plan having no business or corporate purpose, is not a plan of reorganization.”

Consistent with the discussion in part III.A of this Background, § 1.368–1(c) reflects the function of the “plan of reorganization” concept and its embedded proximate relationship requirement—namely, to limit the application of the definitional and operative provisions of subchapter C to those transactions included in the plan of reorganization. Section 1.368–1(c) also requires all transactions properly included in the plan of reorganization to be consistent with, and to facilitate satisfaction of, a principal requirement for nonrecognition treatment under the reorganization provisions of subchapter C (that is, the continuation of an enterprise). Finally, § 1.368–1(c) reflects that devices and sham transactions cannot properly be included in a plan of reorganization.

C. Party to a Reorganization

Section 368(b) generally provides that the term “a party to a reorganization” includes (i) a corporation resulting from a reorganization, and (ii) both corporations, in the case of a reorganization resulting from the

acquisition by one corporation of stock or properties of another. Consistent with section 368(b), § 1.368–2(f) defines the term “party to a reorganization” as including “a corporation resulting from a reorganization, and both corporations in a transaction qualifying as a reorganization where one corporation acquires stock or properties of another corporation.” Section 1.368–2(f) further articulates which entities are parties to a reorganization in various types of reorganizations defined in section 368(a)(1). However, the uncertainty regarding the meaning of “plan of reorganization,” described in part III.B of this Background, has resulted in confusion regarding the proper identification of parties to a reorganization.

D. Reporting and Recordkeeping Requirements for Corporate Reorganizations

Section 1.368–3 sets forth reporting and recordkeeping requirements for corporate reorganizations. Section 1.368–3(a) requires a plan of reorganization to be adopted by each corporation that is a party to the reorganization, and it requires each such corporation to include a statement with its Federal income tax return that includes certain limited information about the reorganization. However, § 1.368–3(a) provides no additional detail on the manner in which the plan of reorganization must be adopted, and it does not require the plan of reorganization to be reflected in any documentation or records of the parties to the reorganization.

Current § 1.368–3(a) contrasts starkly with a prior version of § 1.368–3(a), which provided that the plan of reorganization “must be adopted by each of the corporations parties thereto; and the adoption must be shown by the acts of its duly constituted responsible officers, and appear upon the official records of the corporation.” See § 1.368–3(a) (effective from November 26, 1960, to May 29, 2006) (prior § 1.368–3(a)).

Prior § 1.368–3(a) also imposed additional requirements to facilitate the IRS’s administration of the reorganization provisions in part III of subchapter C. In particular, prior § 1.368–3(a) required the parties to a reorganization to file with the IRS a “copy of the plan of reorganization, together with a statement, executed under the penalties of perjury, showing in full the purposes thereof and in detail all transactions incident to, or pursuant to, the plan.” In contrast, taxpayers currently are not required by § 1.368–3 to provide as part of their Federal income tax return a plan of

reorganization that describes the transactions to which taxpayers intend to apply the nonrecognition provisions of subchapter C.

In addition, prior § 1.368–3(a) required taxpayers to file with the IRS “a complete statement of all facts pertinent to the nonrecognition of gain or loss in connection with the reorganization.” Current § 1.368–3(a) contains no such requirement. Therefore, the IRS currently does not receive as part of a taxpayer’s Federal income tax return a statement of facts necessary to determine the proper application of the nonrecognition provisions of subchapter C to the transactions comprising a corporate reorganization.

Instead, current § 1.368–3(a) merely requires each corporate party to a reorganization to include a statement, on or with its return for the taxable year of the exchange, that includes: (i) the names and employer identification numbers (if any) of all such parties; (ii) the date of the reorganization; (iii) the value and basis of the assets, stock, or securities of the target corporation transferred in the transaction, determined immediately before the transfer in the manner described in § 1.368–3(a); and (iv) the date and control number of any one or more private letter rulings issued by the IRS in connection with the reorganization. Current § 1.368–3(b) imposes similar requirements on significant holders of stock or securities of the target corporation.

Like prior § 1.368–3(c), current § 1.368–3(d) requires taxpayers to retain their permanent records with respect to a corporate reorganization.

IV. TIGTA Report To Improve Enforcement of Corporate M&A Transactions

In 2019, the Treasury Inspector General for Tax Administration (TIGTA) published a report titled “A Strategy Is Needed to Assess the Compliance of Corporate Mergers and Acquisitions With Federal Tax Requirements,” Ref. No. 2019–30–050 (Sept. 5, 2019) (TIGTA Report). In that report, TIGTA considered the scope of information required to be provided under § 1.368–3(a) and expressed that “the forms previously detailed represent only a small portion of the information that may be filed, and certain forms used to report merger and acquisition (M&A) transactions may not be providing sufficient information to identify noncompliance.” *Id.* at 14–15.

Accordingly, TIGTA recommended that, if the IRS finds that the current forms do not contain information

sufficient for identifying potential noncompliance in M&A transactions, the IRS “should consider amending the filing criteria and information required in the forms to develop useful compliance tools.” *Id.* at 14. The IRS agreed with this recommendation, stating that it will continue to consider how to use M&A transaction information in its compliance efforts.

V. Reporting Requirements for Section 355 Transactions

In a notice of proposed rulemaking (REG–116085–23) published elsewhere in the Proposed Rules section of this issue of the **Federal Register**, the Treasury Department and the IRS are issuing proposed regulations to revise current § 1.355–5 (proposed § 1.355–5) to enhance the IRS’s ability to administer and enforce the requirements of section 355. Similar to current § 1.368–3 (previously discussed in part III.D of this Background), current § 1.355–5 requires the distributing corporation and each significant distributee (as defined in current § 1.355–5(c)(1)) to include a statement with its tax return that includes certain limited information about the section 355 transaction. To implement the recommendation in the TIGTA Report described in part IV of this Background, proposed § 1.355–5 would require taxpayers to submit new IRS Form 7216, *Multi-Year Reporting Related to Section 355 Transactions* (or any successor form), to provide the IRS with additional information to help the IRS identify potential noncompliance in section 355 transactions.

VI. Revenue Procedure 2024–24 and Notice 2024–38

On May 2, 2024, the Treasury Department and the IRS released Rev. Proc. 2024–24, 2024–21 I.R.B. 1214, to provide procedures for requesting private letter rulings from the IRS regarding certain matters relating to section 355 transactions. Rev. Proc. 2024–24 superseded Rev. Proc. 2018–53, 2018–43 I.R.B. 667, and made several significant changes to the requirements of that revenue procedure and to Rev. Proc. 2017–52, 2017–41 I.R.B. 283.

Also on May 2, 2024, the Treasury Department and the IRS released Notice 2024–38, 2024–21 I.R.B. 1211, to describe their views and concerns relating to certain matters addressed in Rev. Proc. 2024–24, and to solicit feedback on the provisions set forth in Rev. Proc. 2024–24. In section 2.01 of Notice 2024–38, the Treasury Department and the IRS requested that such feedback take into account the

following three objectives for potential future guidance: (i) the guidance will be consistent with all relevant provisions of the Code (compliance objective); (ii) the guidance will provide certainty to taxpayers and the IRS regarding the application of all relevant provisions of the Code to purported section 355 transactions (increased certainty objective); and (iii) the guidance will be responsive to the manner in which section 355 transactions are engaged in by taxpayers and reflect current market practices and preferences (transaction facilitation objective), to the extent that such approach does not conflict with the first two objectives.

Explanation of Provisions

The purpose of these proposed regulations is to establish a comprehensive set of rules to implement certain core definitional and operative provisions of subchapter C that address corporate separations, incorporations, and reorganizations. The current regulatory framework underlying these provisions is incomplete, outdated, and not reflective of their importance to the Federal corporate income tax system, given the trillions of dollars of corporate transactions governed by these statutory provisions. Due to the lack of up-to-date regulatory guidance, taxpayers and the IRS must rely on a patchwork of caselaw, IRS revenue rulings and revenue procedures, and non-authoritative IRS documents to discern the current state of the law with respect to these core provisions of subchapter C.

Accordingly, providing comprehensive regulatory guidance to facilitate the implementation of these core definitional and operative provisions of subchapter C would promote taxpayer certainty and sound tax administration. Although Notice 2024–38 focused on Federal income tax issues regarding section 355 transactions, these core definitional and operative provisions also address incorporations and acquisitive reorganizations. Therefore, the proposed regulations would implement those statutory provisions for all corporate M&A transactions, in a manner that reflects the three objectives described in section 2.01 of Notice 2024–38 (that is, the compliance objective, the increased certainty objective, and the transaction facilitation objective) in accordance with their respective priorities as set forth therein.

A principal objective of the Treasury Department and the IRS in issuing these proposed regulations is to significantly improve horizontal equities among taxpayers and tax advisors. In other

words, based on feedback from tax advisors, the lack of authoritative guidance in this area effectively has transformed a taxpayer's option to request a private letter ruling on the application of certain definitional and operative provisions into a requirement. Indeed, tax advisors have directly reached out to the Treasury Department and the IRS to emphasize the mandatory nature of private letter rulings on certain topics in this area because, based on the current state of authoritative guidance, those tax advisors could not provide tax opinions at a sufficient level of comfort in the absence of a private letter ruling. Therefore, these tax advisors have stressed the importance of engaging in bar association panels and other professional speaking engagements to access the perspectives of Treasury Department and IRS officials regarding the government's current views on certain fundamental corporate tax issues.

These proposed regulations would provide, through publicly accessible authoritative guidance, core definitional and operative provisions. This guidance is intended to facilitate the ability for taxpayers to achieve increased comfort on the Federal income tax treatment of their corporate M&A transactions without the need for a private letter ruling. Just as importantly, this guidance is intended to encourage the submission of private letter ruling requests and facilitate the IRS private letter ruling process. In particular, these proposed regulations are intended to help direct the focus of tax advisors to those issues that raise significant Federal income tax compliance concerns, and consequently improve the organization and focus of their private letter ruling submissions. Similarly, these proposed regulations are intended to increase the efficiency of the private letter ruling program by allowing submission reviewers to focus primarily on such significant issues, rather than those issues that would be addressed directly by this guidance.

In explaining the provisions of these proposed regulations, this Explanation of Provisions discusses issues described in Notice 2024–38 and the feedback received in response to Notice 2024–38. Such feedback has informed the development of these proposed regulations. This Explanation of Provisions also references proposed regulations, published elsewhere in the Proposed Rules section of this issue of the **Federal Register**, that would implement enhanced reporting requirements for section 355 transactions. Those enhanced reporting requirements are integral to the

proposed substantive guidance set forth in these proposed regulations. Specifically, as described further in this Explanation of Provisions, this proposed substantive guidance reflects the long-standing reality that corporate transactions typically are carried out over multiple taxable years. The increased transactional flexibility that would be provided by these proposed regulations is conditioned on the IRS's ability to track the execution of these transactions throughout their lifecycle, and the enhanced reporting requirements for section 355 transactions would facilitate the IRS's ability to carry out its administrative function with respect to these transactions.

I. Distinction Between Delayed Distributions and Retentions; Rules for Qualifying Retentions

A. Notice 2024–38

Section 2.02(1) of Notice 2024–38 stated the view of the Treasury Department and the IRS that the Code provides separate and distinct treatment for three instances in which a distributing corporation temporarily continues to hold controlled corporation stock or securities following the date on which the distributing corporation has distributed an amount of controlled corporation stock constituting control (within the meaning of section 368(c)) (control distribution date). These three instances are: (i) a delayed distribution of controlled corporation stock or securities that is “part of the distribution” (within the meaning of section 355(a)(1)(D)); (ii) a delayed distribution of controlled corporation stock or securities that is “in pursuance of the plan of reorganization” (within the meaning of section 361); and (iii) a retention of controlled corporation stock or securities.

Section 2.02(2) of Notice 2024–38 stated the view of the Treasury Department and the IRS that section 355(a)(1)(D) effectively creates a rebuttable presumption that any retention evidences a plan to achieve a Federal income tax avoidance purpose. Section 2.02(2) of Notice 2024–38 also stated that the Treasury Department and the IRS are considering the degree to which connections between the distributing corporation and the controlled corporation (and, as appropriate, the DSAG and the CSAG) after the control distribution date would prevent a transaction from qualifying under section 355. (The terms “DSAG” and “CSAG” mean the separate affiliated group (as defined in section 355(b)(3)(B)) of which the distributing

corporation or the controlled corporation, respectively, is the common parent.)

Section 2.02(2) of Notice 2024–38 also stated the view of the Treasury Department and the IRS that overlapping directors, officers, or key employees and the existence of continuing contractual agreements between the distributing corporation (and other members of the DSAG) and the controlled corporation (and other members of the CSAG) that include provisions that are not arm’s-length weigh against a determination of qualification under section 355.

B. Stakeholder Input

1. Existence of Rebuttable Presumption Under Section 355(a)(1)(D)(ii)

As an initial matter, some stakeholders have contended that section 355(a)(1)(D)(ii) does not create a rebuttable presumption that a retention evidences a plan with a principal purpose of avoiding Federal income tax, notwithstanding the explicit statutory requirement that the Secretary must be satisfied that such a purpose does not exist. Instead, these stakeholders have asserted that Congress’s intent in including the “no tax avoidance purpose” language in section 355(a)(1)(D)(ii) is unclear, and that the legislative history of section 355 does not give further details about the meaning of this language.

Accordingly, these stakeholders have suggested that, rather than include a rebuttable presumption, the proposed regulations should place greater emphasis on (i) an examination of the corporate business purpose for the section 355 transaction, and (ii) a determination of whether the retained controlled corporation stock is disposed of as “part of the distribution” (see section 355(a)(1)(D)) or “in pursuance of the plan of reorganization” (see section 361(c)). These stakeholders contend that their view is supported by sections 354, 355, and 361, as well as by § 1.368–2(g), which requires readjustments involved in the exchanges or distributions effected in consummating a plan of reorganization to be “undertaken for reasons germane to the continuance of the business of a corporation a party to the reorganization.”

2. Application of Plan of Reorganization With Regard to Section 355(a)(1)(D)(ii)

Stakeholders also have requested clarification in the proposed regulations that all delayed distributions, whether before or after the control distribution date, are treated as part of the distribution (within the meaning of

section 355(a)(1)(D)) if they are effectuated pursuant to the plan of reorganization. Relatedly, stakeholders have recommended that the proposed regulations employ the same standard (that is, the same level of proximate relationship) in considering whether a transaction is “part of the distribution” and “in pursuance of a plan of reorganization.” Stakeholders have further requested confirmation in the proposed regulations that the “no tax avoidance purpose” requirement in section 355(a)(1)(D)(ii) applies only to the extent a delayed distribution fails to qualify under the operative provisions.

Based on their analogy to their view of the “plan of reorganization” concept, these stakeholders have contended that the “as part of the distribution” requirement in section 355(a)(1)(D) provides substantial flexibility to the distributing corporation regarding the timing and manner of dispositions of controlled corporation stock (for example, in a delayed distribution of controlled corporation stock to shareholders of the distributing corporation). In this regard, stakeholders have recommended that the phrase “as part of the distribution” be interpreted to provide section 355 qualification for situations in which the distributing corporation contemplates—but provides no further level of commitment to—a spectrum of potential dispositions of controlled corporation stock, so long as the distributing corporation eventually achieves one or more of those contemplated possibilities or related variants. As described by such stakeholders, the distributing corporation need not identify the timing of those dispositions (regardless of whether they span multiple taxable years of the distributing corporation), the potential recipients of controlled corporation stock (for example, creditors of the distributing corporation), or the method of disposing of that stock.

The stakeholder input described in the foregoing paragraphs ultimately focuses on two aspects of the IRS private letter ruling program for section 355 transactions: (i) the requirement set forth in section 3.03(3)(a)(ii) of Rev. Proc. 2024–24 (the so-called “pick a lane” requirement); and (ii) the elimination under that revenue procedure of so-called “backstop retention rulings.”

With regard to the “pick a lane” requirement, these stakeholders read section 3.03(3)(a)(ii) of Rev. Proc. 2024–24 as providing that the IRS will entertain a request for rulings that: (i) a delayed distribution of controlled corporation stock or securities will be, as applicable, “part of the distribution”

(within the meaning of section 355(a)(1)(D)) or “in pursuance of the plan of reorganization” (within the meaning of section 361); and (ii) a retention of controlled corporation stock or securities that is not included in a ruling request described in clause (i) of this sentence will not be in pursuance of a plan having as one of its principal purposes the avoidance of Federal income tax (within the meaning of section 355(a)(1)(D)(ii)). Stakeholders have further stated that, to comply with the so-called “pick a lane” requirement, a taxpayer must specify the portions of controlled corporation stock remaining after the control distribution (i) to which the taxpayer intends section 361(c) to apply, and (ii) which the taxpayer intends to retain and not dispose of under section 361(c). See section 3.03(3)(d) of Rev. Proc. 2024–24.

In practice, the “pick a lane” requirement requires a taxpayer to identify to the IRS those transactions that the taxpayer intends to carry out as part of its plan of reorganization. However, stakeholders have contended that this requirement is problematic because Rev. Proc. 2024–24 also has eliminated the availability of “backstop retention rulings,” which stakeholders have described as “protective rulings” affording taxpayers a determination by the IRS, before the first step of a divisive reorganization, that a retention at no point will have failed to satisfy the “no tax avoidance purpose” requirement in section 355(a)(1)(D)(ii).

Stakeholders have contended that these changes in private letter ruling policy, combined with the requirement that all controlled corporation stock or securities be distributed within 12 months of the date of the first distribution (first distribution date) to receive a ruling that the distribution qualifies for nonrecognition treatment under section 355 (see section 3.03(2)(b)(ii) of Rev. Proc. 2024–24), have created an unnecessary risk for taxpayers that an intended divisive reorganization could fail to qualify under section 355 (section 355(a)(1)(D)(ii) risk). For purposes of these proposed regulations, the term “first distribution” means the earliest distribution in a series of distributions made pursuant to the plan of distribution or plan of reorganization, as appropriate.

Specifically, these stakeholders have asserted that, because transactions intended to qualify for nonrecognition treatment under section 361(c) often require most of a year to complete, tax advisors now are faced with three undesirable options. First, tax advisors could recommend the premature

termination of such transactions, which otherwise would have been effectuated for bona fide business purposes for corporate taxpayers. Second, tax advisors could attempt, in an unreasonably short timeframe, to receive from the IRS a supplemental private letter ruling that the “springing retention” (that is, a retention that arises unexpectedly during the 12-month period) satisfies the “no tax avoidance purpose” requirement. Third, tax advisors could provide an opinion that the springing retention satisfies the “no tax avoidance purpose” requirement, notwithstanding the lack of authoritative guidance on that issue.

C. Proposed Regulations

Consistent with the statement in section 2.02(2) of Notice 2024–38, proposed § 1.355–10(c)(1) would reflect the presumption that a retention is pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax. However, the Treasury Department and the IRS appreciate the views of stakeholders regarding delayed distributions and retentions. In particular, the Treasury Department and the IRS are sensitive to the potential negative impacts of the “pick a lane” requirement and related requirements in Rev. Proc. 2024–24 on divisive reorganizations, and to the lack of clear, authoritative guidance regarding the “no tax avoidance purpose” requirement of section 355(a)(1)(D)(ii). Therefore, and consistent with the compliance, increased certainty, and transaction facilitation objectives of these proposed regulations, the Treasury Department and the IRS have proposed rules to address the uncertainty highlighted by stakeholders in a manner that facilitates the ability of (i) taxpayers to carry out bona fide section 355 transactions, and (ii) the IRS to ensure that such transactions comply with all requirements of the Code.

1. Proposed Safe Harbor To Address Section 355(a)(1)(D)(ii) Risk

a. Overview

In response to stakeholder concerns regarding the section 355(a)(1)(D)(ii) risk, these proposed regulations would provide a safe harbor that incorporates objectively verifiable conditions for retentions not to be treated as pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax (qualifying retentions). The Treasury Department and the IRS have proposed this safe harbor to enable taxpayers to satisfy the requirements of section 355(a)(1)(D)(ii) with greater

certainty even in the absence of a private letter ruling from the IRS—thereby achieving an increased certainty and transaction facilitation objectives. For taxpayers that do not satisfy the requirements of the proposed safe harbor, the proposed regulations would provide for a general facts-and-circumstances determination for whether a retention is a qualifying retention.

b. Section 355(a)(1)(D)(ii) Safe Harbor

Under the section 355(a)(1)(D)(ii) safe harbor in proposed § 1.355–10(c)(3), a distributing corporation would be treated as satisfying the general facts-and-circumstances test in proposed § 1.355–10(c)(2)(ii) for a qualifying retention if all six of the following conditions are satisfied. First, the distributing corporation must have a specific corporate business purpose for the retention as of the date of adoption of the plan of distribution or plan of reorganization, as appropriate, and at all times during the period of retention. Second, stock of the controlled corporation must be widely held during the period of retention after the first distribution date. Third, any overlap between the officers, directors, or key employees of the DSAG and of the CSAG must be limited in the manner described in proposed § 1.355–10(c)(3)(iv). Fourth, any continuing arrangements between the distributing corporation and the controlled corporation during the period of retention either (i) must be negotiated on and reflect arm’s-length terms, or (ii) within two years after the first distribution date, must be terminated or renegotiated to reflect arm’s-length terms. Fifth, the plan of distribution or plan of reorganization, as appropriate, must reflect a definite intent in the official records of the distributing corporation that the distributing corporation dispose of all retained controlled corporation stock (or securities) by the end of the five-year period beginning on the first distribution date. Sixth, the disposition of retained controlled corporation stock (or securities) must not result in less Federal income tax to the distributing corporation (determined based on the fair market value and adjusted basis of that stock (or securities) as of the first distribution date) than if that stock (or securities) had been distributed in the first distribution. The distributing corporation must include in its plan of distribution or plan of reorganization (as applicable) a description of each agreement and transaction that establishes the satisfaction of the foregoing six conditions.

c. Rationale for Section 355(a)(1)(D)(ii) Safe Harbor

The safe harbor in proposed § 1.355–10(c)(3) is intended to balance taxpayers’ need for certainty with the IRS’s need to ensure taxpayer compliance with section 355(a)(1)(D)(ii). As discussed in part IV of the Background, TIGTA recommended that the IRS consider amending the filing criteria and information required in current forms to develop useful compliance tools. The inclusion of objective requirements in the section 355(a)(1)(D)(ii) safe harbor is consistent with both TIGTA’s recommendation and the compliance, increased certainty, and transaction facilitation objectives for guidance described in section 2.01 of Notice 2024–38.

Moreover, under proposed § 1.355–5 and new IRS Form 7216 (*see* part V of the Background), and consistent with the recommendation in the TIGTA Report, a taxpayer would be required to report key information that would enable the IRS to ensure that the taxpayer, during each taxable year of the retention period, continues to comply with the requirements of the section 355(a)(1)(D)(ii) safe harbor. Thus, the section 355(a)(1)(D)(ii) safe harbor, coupled with the enhanced reporting requirements for section 355 transactions, would increase taxpayer certainty (by reducing the so-called section 355(a)(1)(D)(ii) risk) and would facilitate IRS administration of section 355(a)(1)(D)(ii). The Treasury Department and the IRS are of the view that these two proposals would significantly help achieve all three objectives of these proposed regulations.

The proposed regulations would not incorporate the stakeholders’ recommendation that the requirements of section 355(a)(1)(D)(ii) be treated as satisfied so long as the distributing corporation disposes of all controlled corporation stock pursuant to the plan of reorganization. Such an approach would conflict with long-standing § 1.355–2(e)(2), which requires the consideration of factors aside from the manner in which the distributing corporation disposes of its retained controlled corporation stock (for example, if the distribution would be treated to any extent as a distribution of “other property” under section 356). The stakeholders’ recommendation would not be consistent with section 355(a)(1)(D)(ii), because that recommendation, by itself, would not ensure a genuine separation.

In addition, the proposed regulations would not incorporate stakeholders’ recommendation that a strong corporate

business purpose for a section 355 transaction be treated as sufficient to satisfy the requirements under section 355(a)(1)(D)(ii). This suggestion is inconsistent with the plain reading of the statute, which requires a determination that the avoidance of Federal income tax was not a principal purpose of the retention. In other words, the distributing corporation could possess a strong corporate business purpose for the section 355 transaction in general and for the retention in particular, and yet also possess a principal purpose for the retention of avoiding Federal income tax.

Ultimately, the stakeholders' recommended approaches would conflict with the purpose of section 355(a)(1)(D), which is to ensure genuine separations between the distributing and controlled corporations—a policy reflected in the legislative history of section 355(a)(1)(D) and the long-standing view of the Treasury Department and the IRS regarding that purpose as fundamental to all section 355 transactions. The legislative history of section 355(a)(1)(D) indicates that Congress's initial preference was to provide no exception to the complete-distribution requirement under section 355(a)(1)(D)(i), and that the exception for retentions originated through a subsequent Senate amendment. *See* H.R. Rep. No. 83–1337, at A121 (1954); S. Rep. No. 83–1622, at 266 (1954). Indeed, Treasury regulations that predated the enactment of section 355(a)(1)(D), and that tax advisors have acknowledged as the basis for section 355(a)(1)(D), provided that the business reasons supporting a distribution of controlled corporation stock ordinarily required the distribution of *all* controlled corporation stock owned by the distributing corporation. *See* § 29.112(b)(11)–2(c) of Regulation 111 (issued under section 112(b)(11) of the 1939 Code, the predecessor to section 355 of the 1954 Code); *see also* § 1.355–2(e)(2), which continues to reflect this language). Long-standing revenue rulings and general counsel memoranda also reflect the view that, under the plain reading of section 355(a)(1)(D)(ii), Congress intended to subject retentions to heightened scrutiny to ensure that the section 355 transaction effectuates a genuine separation of the distributing corporation and the controlled corporation. *See* Rev. Rul. 75–469; Rev. Rul. 75–321; *see also* G.C.M. 32136 (Oct. 23, 1961).

2. Facts-and-Circumstances Test for Determining Compliance With Section 355(a)(1)(D)(ii)

If a taxpayer fails to satisfy the requirements of the section 355(a)(1)(D)(ii) safe harbor in proposed § 1.355–10(c)(3), the taxpayer may establish compliance with section 355(a)(1)(D)(ii) through satisfaction of the facts-and-circumstances test in proposed § 1.355–10(c)(2)(ii). As with qualification for the proposed section 355(a)(1)(D)(ii) safe harbor, satisfaction of the proposed facts-and-circumstances test would require a determination that the distributing corporation and the controlled corporation have genuinely separated, among other requirements. This proposed facts-and-circumstances approach combined with the proposed safe harbor would provide taxpayers and the IRS with increased certainty regarding the application of section 355(a)(1)(D)(ii).

Under the facts-and-circumstances approach of proposed § 1.355–10(c)(2)(ii), the distributing corporation first must establish that the distribution resulted in a genuine separation of the DSAG and the CSAG. Second, the distributing corporation must establish that the retention does not allow the DSAG to retain any practical control over the CSAG. Third, there must be a sufficient corporate business purpose for the retention as of the date the plan of distribution or the plan of reorganization (as applicable) is adopted. Fourth, there must be a sufficient corporate business purpose for the retention at all times during the period of retention. Fifth, the disposition of retained controlled corporation stock (or securities) must not result in less Federal income tax to the distributing corporation (determined based on the fair market value and adjusted basis of that stock (or securities) as of the first distribution date) than if that stock (or securities) had been distributed in the first distribution.

Consistent with the views set forth in section 2.02(2) of Notice 2024–38, the existence of (i) overlapping officers, directors, or key employees between the DSAG and the CSAG, and (ii) non-arm's-length continuing contractual agreements between the DSAG and the CSAG, would be facts and circumstances indicating that the retention fails the requirements under section 355(a)(1)(D)(ii). For purposes of proposed § 1.355–10(c)(2)(ii), the relative weight of those indicia would depend upon all facts and circumstances, including the corporate business purpose for the section 355

transaction. For example, such continuing relationships particularly would weigh against a determination that the retention satisfies the requirements under section 355(a)(1)(D)(ii) if the purported corporate business purpose for the section 355 transaction is so-called “fit and focus” (that is, a separation to enhance the success of the separated businesses by resolving management, systemic, or other problems that arise by virtue of the distributing corporation's operation of different businesses within a single corporation or affiliated group).

3. Consistent Voting Requirements

Regardless of whether a section 355 transaction qualifies for the section 355(a)(1)(D)(ii) safe harbor, if the section 355 transaction involves a retention, proposed § 1.355–10(c)(2)(iii) would require the DSAG to vote any retained controlled corporation stock in proportion to the votes cast by the controlled corporation's other shareholders (other than persons related to the distributing corporation). This proposed requirement is consistent with the long-standing position of the Treasury Department and the IRS with regard to section 355(a)(1)(D)(iii), as expressed through several revenue rulings, revenue procedures, and other sub-regulatory guidance.

4. Plan of Distribution

Consistent with long-standing guidance, the Treasury Department and the IRS continue to agree with stakeholders that the plan of reorganization is relevant for determining the applicability of the definitional and operative provisions under subchapter C to dispositions of controlled corporation stock. *Compare* Rev. Rul. 2002–85, 2002–2 C.B. 986 (concluding that an acquiring corporation's contribution of a target corporation's assets to a subsidiary corporation subsequent to a transaction otherwise qualifying as a reorganization under section 368(a)(1)(D) was “pursuant to the plan of reorganization”; therefore, the continuity of business enterprise (COBE) requirement was not violated); Rev. Rul. 69–142, 1969–1 C.B. 107 (concluding that an acquiring corporation's exchange of its debentures for those held by bondholders of the target corporation was not part of the reorganization exchange; therefore, the “solely for voting stock” requirement in section 368(a)(1)(B) was satisfied). In this regard, the “plan of reorganization” concept provides a useful analogy for distinguishing distributions to which section 355 should apply from those to

which other sections of the Code (such as section 311) should apply.

Accordingly, proposed § 1.355–4 would set forth a series of provisions pursuant to which a taxpayer would establish its plan of distribution for distributions to which section 355(c) is purported to apply. These proposed rules generally would parallel the proposed plan of reorganization provisions in proposed § 1.368–4, as discussed in more detail in part III.C of this Explanation of Provisions.

Specifically, under the proposed rules, section 355 would apply to those distributions that are properly included in the plan of distribution and, therefore, are treated as “part of the distribution” within the meaning of section 355(a)(1)(D). Thus, for example, proposed § 1.355–4(d)(2)(iii) would provide that distributions that are carried out in close temporal proximity with a section 355(c) distribution are not properly included in the plan of distribution and therefore would not qualify for nonrecognition treatment under section 355 unless Federal income tax principles (including the step transaction doctrine) would apply to determine that those distributions are in substance part of the plan of distribution for the section 355(c) distribution.

Additionally, a distribution that is merely one of several (if not more) contemplated possibilities would not be properly included in the plan of distribution. Instead, proposed § 1.355–4(d)(1) would require the distributing corporation to evidence a definite intent to carry out the distribution through a written commitment in one or more official records that substantiate the plan of distribution. As previously discussed in part I.B of this Explanation of Provisions, the Treasury Department and the IRS disagree with the stakeholders’ view that a plan of distribution should reflect mere transactional possibilities under a “wait and see” approach. Adoption of this stakeholder recommendation would conflict with the requirement of section 355(a)(1)(D)(ii) that the non-tax avoidance nature of a retention be “established to the satisfaction of the Secretary,” because it would not be possible for the Secretary to establish the actual nature of a hypothetical transaction. In addition, adopting this stakeholder recommendation would both significantly compromise the IRS’s ability to administer and enforce the requirements of section 355 and reduce certainty regarding section 355 qualification.

Under proposed § 1.355–4(a)(2)(i) and (b)(1), the term “plan of distribution”

generally would mean a plan of distribution established by a distributing corporation that satisfies all requirements set forth in proposed § 1.355–4(c) and that is filed with the IRS pursuant to proposed § 1.355–5. Proposed § 1.355–4(a)(2)(iii) and (b)(2) would provide that a plan of distribution also may be established based on corrections to the taxpayer-filed plan by the Commissioner based on all relevant facts and circumstances, all relevant provisions of the Code, and general principles of Federal income tax law (including the step transaction doctrine). If the taxpayer fails to file a plan of distribution under proposed § 1.355–5, proposed § 1.355–4(a)(2)(iv) and (b)(2) would provide that the Commissioner may identify a plan of distribution for the transaction.

Consistent with the objectives for guidance described in section 2.01 of Notice 2024–38, the proposed plan of distribution provisions are intended to facilitate taxpayer certainty in identifying distributions to which section 355 properly should be applied. *See, for example,* proposed § 1.355–4(c)(3)(i)(B) (providing a safe harbor presumption for timely prosecuting the plan of distribution) and (d) (providing rules for determining whether a distribution is properly included in the plan of distribution).

In addition, the plan of distribution would provide the IRS with a single, timely document that identifies all relevant distributions necessary to determine the appropriate Federal income tax treatment of the purported section 355(c) distribution. This proposal, combined with the enhanced reporting requirements for section 355 transactions under proposed § 1.355–5, would reestablish an appropriate line of sight for the IRS into taxpayer compliance under section 355, thereby helping to achieve the compliance and increased certainty objectives. *Compare* former § 1.355–5 (effective from November 26, 1960, to May 29, 2006) (requiring the taxpayer to “attach to its return for the year of the distribution a detailed statement setting forth such data as may be appropriate in order to show compliance with the provisions of [section 355]”).

5. Treatment of Delayed Distributions and Retentions

The Treasury Department and the IRS appreciate the feedback received from stakeholders regarding the similarities between delayed distributions and retentions. The Treasury Department and the IRS agree with stakeholders that, because a section 355 transaction requires the distribution of controlled

corporation stock by the distributing corporation, each of the following could apply to the same transaction: (i) the “part of the distribution” requirement in section 355(a)(1)(D); (ii) the “in pursuance of the plan of reorganization” requirement in section 361; and (iii) the retention requirements in section 355(a)(1)(D)(ii).

In particular, the Treasury Department and the IRS share the stakeholders’ view that, if the distributing corporation does not distribute all its controlled corporation stock in the first distribution, the “delayed distribution” and “retention” labels give rise to a distinction without a difference in determining the existence of a genuine separation between the distributing corporation and the controlled corporation. In this respect, proposed § 1.355–2(e)(2)(iii) would focus on whether a genuine separation has occurred, without regard to whether the controlled corporation stock not distributed as part of the first distribution is disposed of through a distribution or transfer under section 361(c) or a taxable sale under section 1001.

However, the Treasury Department and the IRS continue to view the “part of the distribution” requirement in section 355(a)(1)(D), the “in pursuance of the plan of reorganization” requirement in section 361, and the “no tax avoidance purpose” requirement in section 355(a)(1)(D)(ii) as discrete requirements that address discrete issues reflective of discrete policies. The “part of the distribution” requirement in section 355(a)(1)(D) serves as a scoping provision for the applicability of section 355(a)(1)(D)(i) and (ii) to distributions of controlled corporation stock. As discussed in parts I.C.4 and III.C of this Explanation of Provisions, the proposed plan of distribution and plan of reorganization rules would facilitate the determination of which distributions are “part of the distribution.”

As reflected in the legislative history of section 361, the “in pursuance of the plan of reorganization” requirement serves in large part to limit the application of the operative provisions in subchapter C to those transactions with a sufficiently proximate relationship with transactions that qualify under a definitional provision in subchapter C. *See* part II.A of the Background.

Lastly, the “no tax avoidance purpose” requirement in section 355(a)(1)(D)(ii) serves to ensure there is a genuine separation of the distributing corporation and the controlled corporation in situations in which the distributing corporation continues to

hold controlled corporation stock following the first distribution. This requirement applies regardless of whether that controlled corporation stock is disposed of pursuant to the plan of reorganization under section 361(c).

6. Timing Requirement for Control Distribution

Consistent with the Supreme Court's decision in *Gordon* (discussed in part I.D.2 of the Background), proposed § 1.355-2(e)(2) would require a distributing corporation, pursuant to a plan of distribution or plan of reorganization, as appropriate, to distribute an amount of stock of the controlled corporation constituting control (within the meaning of section 368(c)) either (i) within a single taxable year, or (ii) over two taxable years, but only if all distributions up to and including the control distribution are effectuated pursuant to a binding commitment that is described in the plan of distribution or plan of reorganization (as applicable). A two-year limitation for distributing control would provide taxpayers with additional transactional flexibility while facilitating the IRS's ability to administer and enforce the requirements of section 355. This approach would help achieve the increased certainty and transaction facilitation objectives of these proposed regulations.

7. Requirements for Nonrecognition Treatment

In accordance with the foregoing discussion in this part I.C, these proposed regulations would revise § 1.355-2(e) to provide that a distribution does not qualify for nonrecognition treatment under section 355(a)(1) unless the following requirements are satisfied. First, proposed § 1.355-2(e)(2)(i) and (ii) would provide that the distributing corporation must distribute an amount of stock of the controlled corporation constituting control (within the meaning of section 368(c)) either (i) within a single taxable year, or (ii) during two taxable years, subject to the "binding commitment" requirement described in part I.C.6 of this Explanation of Provisions. Second, proposed § 1.355-2(e)(2)(iii) would provide that any controlled corporation stock not distributed as part of the first distribution must satisfy the requirements for a qualifying retention in proposed § 1.355-10(c).

As previously discussed in parts I.C.1 through 3 of this Explanation of Provisions, to satisfy the requirements for a qualifying retention (and to thereby rebut the presumption of a tax

avoidance purpose for the retention), the distributing corporation must: (i) either qualify for the section 355(a)(1)(D)(ii) safe harbor in proposed § 1.355-10(c)(3) or satisfy the facts-and-circumstances test in proposed § 1.355-10(c)(2)(ii); and (ii) vote any retained controlled corporation stock in proportion to votes cast by the controlled corporation's other shareholders (other than distributing corporation related persons). See proposed § 1.355-10(c)(2)(iii).

II. Non-Substantive Modifications to Section 355 Regulations

These proposed regulations would make certain non-substantive revisions to current §§ 1.355-1 and 1.355-4. For example, these proposed regulations would modify current § 1.355-1 by adding general definitions that apply for purposes of the section 355 regulations, incorporating the rules in current § 1.355-4 as proposed § 1.355-1, and moving the applicability dates from current § 1.355-1(a) to proposed § 1.355-1(e). These revisions are not intended to make any substantive change.

III. Plan of Reorganization; Party to a Reorganization

A. Notice 2024-38

As stated in section 2.02(4) of Notice 2024-38, the Treasury Department and the IRS understand that confusion and disagreement exists regarding the application of the "plan of reorganization" requirement to divisive reorganizations. For example, some stakeholders view the applicability of the "plan of reorganization" requirement to be potentially obviated by the temporal requirements set forth in section 3.04(6) of Rev. Proc. 2018-53 (concerning delayed satisfaction of distributing corporation debt). It is the view of the Treasury Department and the IRS that this is incorrect.

Section 2.02(4) of Notice 2024-38 further states that, although the "plan of reorganization" requirement incorporates a degree of transactional flexibility, such flexibility is limited by current §§ 1.368-1(c) and 1.368-2(g), and the Treasury Department and the IRS view this requirement as helpful to ensure that delayed distributions are not used to avoid the repeal of the *General Utilities* doctrine (see part I.A.2 of the Background).

B. Stakeholder Input

The Treasury Department and the IRS have received a broad spectrum of feedback from stakeholders regarding the "plan of reorganization"

requirement. However, consistent with the view of the Treasury Department and the IRS set forth in Notice 2024-38, stakeholders uniformly have contended that this requirement should be applied in a flexible manner.

Certain stakeholders have described the guidance in current § 1.368-2(g) regarding the meaning and scope of the "plan of reorganization" requirement as circular and incomplete. Those stakeholders similarly have described § 1.368-1(c) as providing only conceptual guidance as to which transactions are properly included in a plan of reorganization. These stakeholders also have described § 1.368-3(a) as requiring each party to the reorganization to adopt that plan but then failing to provide any guidance on how such parties are to satisfy that requirement. Stakeholders have aptly noted that Notice 2024-38 provided little additional clarity regarding the "plan of reorganization" requirement.

Additionally, certain stakeholders have noted that few cases address the meaning and scope of the "plan of reorganization" concept, and that, even within such cases, courts often have applied the step transaction doctrine and the substance-over-form doctrine to determine the existence of a plan of reorganization. For example, one stakeholder highlighted *King Enterprises, Inc. v. United States*, 418 F.2d 511 (Ct. Cl. 1969), in which the U.S. Court of Federal Claims applied the step transaction doctrine to treat the acquisition of stock of a target corporation (Tenco), followed by the merger of the target corporation into the acquiring corporation (Minute Maid), as a reorganization qualifying under section 368(a)(1)(A). The court identified the threshold issue as "whether the transfer of Tenco stock to Minute Maid is to be treated for tax purposes as an independent transaction of sale, or as a transitory step in a transaction qualifying as a corporate reorganization," which dictated the resolution of the central issue of "whether the initial exchange of stock was a step in a unified transaction pursuant to a 'plan of reorganization'." *King Enterprises*, 418 F.2d at 514-15. Based on an analysis of the "operative facts in this case," the court applied the step transaction doctrine to conclude that the two transactions comprised a single, unified transaction. *Id.* at 515-16, 519. Even though no formal plan of reorganization existed, the court relied on those facts and that analysis to identify a plan of reorganization for that unified transaction. *Id.* at 519 n.11 (relying on *Redfield v. Commissioner*, 34 B.T.A. 967 (1936), for the proposition

that “[a] formal plan or reorganization is not necessary if the facts of the case show a plan to have existed”).

In *Seagram Corp. v. Commissioner*, 104 T.C. 75 (1995), the Tax Court considered whether to integrate (i) an acquisition of stock of a target corporation (Conoco) through a first-step tender offer made by a subsidiary of an acquiring corporation (DuPont Tenderor and DuPont, respectively), and (ii) a subsequent merger of Conoco into DuPont Tenderor. The court acknowledged that the tender offer and subsequent merger each possessed independent significance, and that the subsequent merger was subject to several contingencies. *Seagram*, 104 T.C. at 93–94. However, the court emphasized that DuPont and DuPont Tenderor “were under a binding and irrevocable commitment to complete the culminating merger—the second step—upon the successful completion of the DuPont tender offer—the first step.” *Id.* at 98. Based on all facts and circumstances of the tender offer and subsequent merger, including official records of DuPont and DuPont Tenderor, the court identified the existence of a plan of reorganization, reasoning that, “because DuPont was contractually committed to undertake and complete the second-step merger once it had undertaken and completed the first-step tender offer, these carefully integrated transactions together constituted a plan of reorganization within the contemplation of section 354(a).” *Id.* at 98–99 (relying principally on, and noting satisfaction of, the Supreme Court’s binding commitment standard in *Gordon*).

Stakeholders also have noted that the Tax Court in *Seagram* characterized the “plan of reorganization” concept expressed in § 1.368–2(g) as one of “substantial elasticity,” relying on the court’s prior observations on that concept in *Int’l Telephone*. *Seagram*, 104 T.C. at 96. (In *Int’l Telephone*, the Tax Court noted that § 1.368–2(g) “is imbued with qualities of flexibility and vagueness, with the result that it does not present precise self-executing guidelines.” 77 T.C. at 75.) The Tax Court in *Seagram* also relied on scholarly commentary for the proposition that, even though § 1.368–2(g) at that time required a plan of reorganization to be filed with the IRS, it was self-evident that the IRS and the courts could identify the existence of a plan of reorganization in the event the taxpayer either did not file one or filed one that was inaccurate. *See Seagram*, 104 T.C. at 96 (quoting Peter L. Faber, *The Use and Misuse of the Plan of*

Reorganization Concept, 38 Tax L. Rev. 515, 523 (1982–1983)).

Stakeholders also have commented on temporal considerations relating to plans of reorganization. Stakeholders have contended that the length of time between transactions effectuating a plan of reorganization should not prevent any particular transaction from being considered part of the plan. Conversely, these stakeholders have contended that the temporal proximity of one transaction to another transaction that is properly included in a plan of reorganization should not be determinative as to whether the other transaction is properly included in the plan. Stakeholders also have contended that imposing a time limitation for completing a plan of reorganization would be inappropriate.

Additionally, some stakeholders have recommended granting taxpayers the flexibility to either execute the steps identified in the plan of reorganization or change them at any time, based on each taxpayer’s judgment on how best to achieve the objectives of their transaction. However, other stakeholders have recommended clarifying that entering into a new transaction not contemplated by the plan, even in the alternative, is not treated as pursuant to the plan of reorganization.

In sum, stakeholders uniformly have described the current regulations addressing the “plan of reorganization” requirement as lacking sufficient clarity and comprehensiveness. Accordingly, some stakeholders have requested guidance regarding the metrics needed for a taxpayer to establish a plan of reorganization. Specifically, stakeholders have requested guidance regarding (i) the means by which parties to a reorganization can adopt a plan of reorganization (in particular, some stakeholders have recommended allowing actions of a corporation’s authorized representatives, and not just formal written actions of the board, to be taken into account for this purpose), (ii) transactions that may occur at a future time, are contingent, or are in the alternative, and (iii) transactions that may develop as a result of events arising after the plan of reorganization is adopted.

The stakeholder input received has highlighted not only the deficiencies in authoritative guidance regarding the meaning and scope of the “plan of reorganization” requirement, but also the importance of this requirement in determining whether the operative provisions of subchapter C apply to a particular transaction.

C. Proposed Regulations

1. Overview

The Treasury Department and the IRS agree with stakeholders that the current guidance regarding the “plan of reorganization” requirement is inadequate and creates significant confusion. Consistent with stakeholder recommendations, the proposed regulations would clarify, among other items, (i) the metrics needed for a taxpayer to establish a plan of reorganization, (ii) the manner whereby parties to a reorganization can adopt a plan of reorganization, and (iii) the requirements for prosecuting a plan of reorganization (including in the event of a change in circumstances following adoption of the plan). In proposing this guidance, the Treasury Department and the IRS have endeavored to balance the importance of providing taxpayers with transactional flexibility to effectuate bona fide business transactions with the need to facilitate IRS administration of the reorganization provisions of subchapter C. Accordingly, the Treasury Department and the IRS believe that this guidance would help achieve the compliance, increased certainty, and transaction facilitation objectives of these proposed regulations. (See the discussion of the objectives for guidance in part VI of the Background; *see also* the discussion of the TIGTA Report in part IV of the Background.)

2. Proposed Rules Regarding Plan of Reorganization

a. Purpose and Effect of Plan of Reorganization

The Treasury Department and the IRS view a plan of reorganization as serving two related purposes. First, a plan of reorganization serves to identify those transactions to which the definitional and operative provisions of subchapter C apply. Second, a plan of reorganization serves to distinguish transactions the Federal income tax treatment of which is governed by the reorganization provisions of subchapter C from transactions to which the general recognition provisions of the Code (such as section 1001) apply.

However, under the proposed regulations, a taxpayer’s failure to set forth a plan of reorganization in a single, comprehensive document neither would be determinative as to the existence or scope of a plan of reorganization for a transaction nor would govern the application of any definitional or operative provision to that transaction. *See* proposed § 1.368–4(a)(3).

b. Determination of Plan of Reorganization

The proposed regulations would permit a plan of reorganization to be determined in several different manners. Under the manner preferred by the Treasury Department and the IRS, a taxpayer would prepare a single, comprehensive document that satisfies all requirements set forth in proposed § 1.368–4(d) and file that document with the IRS as required by proposed § 1.368–3(a)(5) (taxpayer-filed plan of reorganization). See proposed § 1.368–4(b)(1). The taxpayer-filed plan of reorganization would contain the information required by prior and current § 1.368–3(a) and incorporate recommendations of the TIGTA Report.

Specifically, proposed § 1.368–4(d) would set forth the following requirements. First, the proposal would require the taxpayer-filed plan of reorganization to identify (i) all parties to the reorganization (as required by current § 1.368–3(a)), (ii) all transactions properly included in the plan of reorganization (as required by prior § 1.368–3(a)), and (iii) all liabilities (including debt) to be assumed by the acquiring corporation and the obligees (or creditors) of those liabilities, and (iv) all debt of the target corporation that will be satisfied with section 361 consideration and the creditors of that debt. Second, the proposal would require such plan to describe the intended Federal income tax treatment of those transactions (which would facilitate implementing the recommendations of the TIGTA Report). Third, the proposal would require such plan to describe the corporate business purpose for each transaction (consistent with current § 1.368–2(g)). Lastly, the proposal would require such plan to establish that each transaction facilitates the continuance of the business of a corporation a party to the reorganization (consistent with current § 1.368–2(g)). See proposed § 1.368–4(d)(1).

The proposed regulations would reflect a preference that taxpayers will timely file a complete and accurate plan of reorganization. See proposed § 1.368–4(c)(1). Accordingly, the Federal income tax consequences of the subject transactions generally would be determined in accordance with that plan. See proposed § 1.368–4(a)(2)(i). Throughout the duration of the transaction or series of transactions, which potentially could span several taxable years, the IRS would possess the ability to monitor the taxpayer's execution of that plan of reorganization (for example, through the taxpayer's annual filing of Form 7216 for divisive

transactions). The Treasury Department and the IRS intend the proposed approach (i) to increase taxpayer certainty regarding the Federal income tax treatment of transactions properly included in a plan of reorganization, and (ii) to facilitate IRS administration of the reorganization provisions of subchapter C.

However, if a taxpayer files a plan of reorganization with the IRS that fails to satisfy any requirement set forth in proposed § 1.368–4(d), or if the taxpayer fails to file a plan of reorganization with the IRS in accordance with proposed § 1.368–3(a)(5), proposed § 1.368–4(c)(2)(i) recognizes that the Commissioner may correct or identify a plan of reorganization. Under proposed § 1.368–4(c)(2)(ii), the Commissioner may determine that a transaction or series of transactions should be included in, or excluded from, a plan of reorganization based on (i) all facts and circumstances regarding the transaction or series of transactions, and (ii) all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine.

The proposed approach is consistent with long-standing caselaw indicating that the existence and proper scope of a plan of reorganization can be determined in the absence of formal documentation. See, for example, *Redfield*, 34 B.T.A. at 973 (“It is not necessary, however, that such a plan of reorganization be evidenced by a formal written document, such as a contract or corporate minutes. It is sufficient if the circumstances indicate that the various steps taken were pursuant to a definite plan of reorganization.”); *Fry v. Comm’r*, 5 T.C. 1058, 1070 (1945) (similar). The proposed regulations would reflect this long-standing position because conditioning the applicability of the definitional and operative provisions of subchapter C on whether a plan of reorganization formally was prepared and filed would, in particular and contrary to law, make the reorganization regime entirely elective.

Nonetheless, the Treasury Department and the IRS are of the view that formal documentation requirements for taxpayer-filed plans of reorganization are necessary to facilitate the IRS's administration of the reorganization provisions of subchapter C. See part III of the Background. Moreover, the preference for complete and accurate taxpayer-filed plans of reorganization under proposed § 1.368–4(c)(1) requires adequate substantiation with the IRS, which would be provided by objectively verifiable, official corporate documents. Accordingly, proposed § 1.368–4(d)

would enhance the current reporting requirements for plans of reorganization.

c. Agreement by Parties to Plan of Reorganization; Beginning of Plan of Reorganization

Proposed § 1.368–4(d)(2) would provide that, prior to the first step of a reorganization, the plan of reorganization or an original plan of reorganization that becomes the amended plan of reorganization, as applicable, must be finalized and adopted by the party to the reorganization. Taxpayers would demonstrate satisfaction of this requirement through (i) the acts of duly authorized officers and directors of the corporation, and (ii) the official records of the party to the reorganization.

The Treasury Department and the IRS are of the view that the proposed approach would provide greater taxpayer certainty regarding the means by which parties to a reorganization can adopt a plan of reorganization than current § 1.368–3(a), which provides only that “[t]he plan of reorganization must be adopted by each of the corporations that are parties thereto.” As previously discussed in part III.B of this Explanation of Provisions, the current regulations have created significant uncertainty due to the lack of guidance on what constitutes an “adoption” by the parties. The proposed regulations would address this uncertainty in a manner consistent with prior § 1.368–3(a) and statutory law. See section 806(g)(3) of the Tax Reform Act of 1976 (Public Law 94–455, 90 Stat. 1520, 1606) (describing how a corporation is considered to have adopted a plan of reorganization for purposes of determining the effective date of certain modifications to sections 382 and 383).

In addition, the proposed substantiation requirements would facilitate the IRS's administrative function by marking the beginning of the taxpayer's plan of reorganization—a feature that the Tax Court also views as important. See *Seagram*, 104 T.C. at 98 (emphasizing in its plan of reorganization analysis that the DuPont/Conoco Agreement “provides a discrete start and finish”).

d. Timing Requirement for Completion of Plan of Reorganization

i. General “Expedition Completion” Requirement

Proposed § 1.368–4(d)(3)(i)(A) and (ii)(A) would require that, taking into account all facts and circumstances (including the one or more corporate

business purposes for a reorganization), all parties to the reorganization must complete the plan of reorganization as expeditiously as practicable, and in the manner described in that plan. The proposed approach takes into account taxpayers' need for transactional flexibility and reflects the long-standing principle that the passage of time is not determinative of whether a transaction is part of a plan of reorganization. *See, for example, Wilson v. Comm'r*, T.C. Memo. 1961-135 ("The mere lapse of time is not decisive. The important thing is that the steps which are taken evidence a consistent performance of the reorganization plan and purpose.").

ii. Presumption of Satisfaction if Completion Within 24 Months

However, the Treasury Department and the IRS are concerned that the lack of a time limitation for completing a plan of reorganization raises administrability concerns for the IRS. Accordingly, the Treasury Department and the IRS are (i) issuing proposed § 1.355-5, and (ii) introducing new Form 7216, to provide the IRS with information regarding divisive transactions that span multiple tax years. *See* part V of the Background.

Additionally, temporal guidelines would provide greater certainty to taxpayers. In this regard, stakeholders have requested the inclusion of safe harbors in these proposed regulations to mitigate uncertainty arising from conceptual rules and facts-and-circumstances determinations. Based on this feedback, proposed § 1.368-4(d)(3)(i)(B) would provide that the "expeditious completion" requirement is presumed to be satisfied if all parties to a reorganization complete the plan of reorganization within the 24-month period beginning on the date of the first step of the plan of reorganization. This increased certainty would help achieve the transaction facilitation objective of these proposed regulations, and providing a 24-month safe harbor would help achieve the compliance objective of these proposed regulations.

e. Requirements for Transactions To Be Treated as Properly Included in Plan of Reorganization

i. Overview

Stakeholders have recommended various standards and approaches for determining whether a transaction is properly included in a plan of reorganization. As noted by stakeholders, neither current guidance nor the caselaw regarding the "plan of reorganization" requirement adequately addresses this issue. The proposed

regulations would synthesize the overarching principles of this caselaw into rules that could be applied by taxpayers and the IRS with significantly greater certainty than under current Treasury guidance and the caselaw.

ii. Definite Intent Requirement

As a threshold requirement, proposed § 1.368-4(e)(1)(i) would require that, prior to the first step of a plan of reorganization or an original plan of reorganization that becomes the amended plan of reorganization, one or more parties to the reorganization must evidence a definite intent to carry out the transaction. This definite intent must be evidenced through a written commitment in one or more official records of the party that substantiate the plan of reorganization. Under this proposal, the existence of contingencies or conditions would not be conclusive in determining whether a party to the reorganization satisfies this requirement.

The "definite intent" standard is intended to provide sufficient transactional flexibility to encourage bona fide business transactions in a manner consistent with long-standing caselaw. The origins of the "definite intent" standard can be traced back to judicial opinions of the Board of Tax Appeals (BTA), the predecessor to the Tax Court. For example, in *Fry v. Commissioner*, the BTA relied on this standard for determining the existence of a plan of reorganization from "what appear[ed] on the minutes of the meeting of the stockholders and the meeting of the board of directors of the old bank," which had articulated the business objectives and transaction steps for the reorganization. 5 T.C. at 1070; *see also Redfield*, 34 B.T.A. at 973 (noting that, although a formal written plan of reorganization is not necessary, the circumstances evidencing that a reorganization occurred need to indicate that the various steps taken in pursuance thereof were taken "pursuant to a definite plan of reorganization") (emphasis added); *Seagram*, 104 T.C. at 97 (observing that the DuPont/Conoco Agreement "definitively states the terms for 'the acquisition of [Conoco] by [DuPont Tenderor and]' sets out . . . the series of transactions which in their totality were intended to accomplish a section 368 reorganization").

In contrast, courts have determined that transactions subject to a lesser degree of intent or predominated by uncertainty are not properly included in a plan of reorganization. For example, in *National Bank of Commerce in Memphis v. United States*, 87 F. Supp. 302 (W.D. Tenn. 1949), the court

concluded that a transaction contemplated prior to the plan of reorganization was not properly included in that plan because the transaction was uncertain and indefinite as of the time of the first step of the plan of reorganization. 87 F. Supp. at 304. The court emphasized that "[a]n element in a plan of reorganization that cannot be legally enforced and, in addition is fraught with much uncertainty, is indefinite and not necessary to the reorganization, cannot be considered as one of the steps resulting in the completed transaction." *Id.* Accordingly, if the parties did not anticipate or otherwise contemplate a transaction prior to the adoption of the plan of reorganization, that transaction cannot be included in that plan. *See Atwood Grain & Supply Co. v. Comm'r*, 60 T.C. 412, 423 (1973) (observing that "[t]here [wa]s no evidence that issuance of the preferred stock was contemplated either in the merger negotiations or in the merger agreement," and reasoning that, "[i]n order to include events occurring after a merger in the plan of merger there must be some anticipation of the event in the merger").

Stakeholders have noted that a "plan of reorganization" concept that includes every possibility considered by any taxpayer in connection with a reorganization would be overbroad and meaningless. Indeed, a commenter relied upon by the Tax Court for its analysis in *Seagram* noted that "[t]he contemplated possibility standard is too broad. . . . A more appropriate standard would be to link the later transaction to the earlier one only if there is a firm commitment to consummate it." *Faber, The Use and Misuse of the Plan of Reorganization Concept*, 38 Tax L. Rev. at 547. The Treasury Department and the IRS agree that such a standard would not be appropriate for the proposed regulations. Accordingly, proposed § 1.368-4(e)(1)(iii)(A) would provide that mere contemplation that a transaction may be carried out would not be sufficient to satisfy the "definite intent" requirement, regardless of whether that contemplated transaction is included in an official record of the party.

However, the Treasury Department and the IRS recognize that the "contemplated possibility" standard is relevant for certain plan of reorganization determinations. Accordingly, proposed § 1.368-4(e)(1)(iii)(B) would provide that a party's mere contemplation of a transaction may be relevant for purposes of the correction or identification of a plan of reorganization by the

Commissioner. As previously discussed in part III.C.2.b. of this Explanation of Provisions, the Commissioner's determination under proposed § 1.368–4(c)(2)(ii) would be based on all facts and circumstances pertaining to the transaction and the application of all relevant Code provisions and Federal income tax principles, including the step transaction doctrine.

Permitting the IRS to determine the outer reaches of the scope of transactions potentially includable in a plan of reorganization through an analysis of all facts and circumstances and Federal income tax principles would be consistent with judicial authorities that have applied a “contemplated possibility” test. For example, in *Anheuser-Busch, Inc. v. Commissioner*, 40 B.T.A. 1100 (1939), the BTA relied on substance-over-form principles to determine the scope of transactions included in a plan of reorganization, based on its determination that a first-step transfer to a parent corporation was “transitory and without real substance.” 40 B.T.A. at 1106. As part of its analysis, the court observed that the parent had “contemplated,” but was not obligated to carry out, the immediate transfer of the property received to its subsidiary, and the court expanded the scope of the plan of reorganization to include that second-step transfer. *Id.* at 1106–07 (relying on the substance-over-form analysis of *Helvering v. Bashford*, 302 U.S. 454, 458 (1938)). Other judicial opinions similarly have used the existence of a contemplated possibility in this manner. *See, for example, Avco Mfg. Corp. v. Comm’r*, 25 T.C. 975, 984–85 (1956) (noting that a “subsequent transfer of the property . . . was a contemplated possibility under the plan that actually eventuated” and was properly included within the scope of the plan of reorganization under the mutual interdependence test); *Transport Products Corp. v. Comm’r*, 25 T.C. 853, 857–58 (1956).

Once a definite intent is established, the existence of contingencies and other conditions that could affect prosecution of the plan of reorganization are not treated as diminishing that level of intent. *See, for example, Seagram*, 104 T.C. at 96 (“DuPont had an indisputable legal obligation to complete the Merger with Conoco, notwithstanding the possibility of intervening legal impediments, or contingencies, which in fact, never materialized”). Accordingly, proposed § 1.368–4(e) would provide that, for purposes of determining whether a party to a reorganization satisfies the “definite intent” requirement, the existence of

contingencies or conditions is not conclusive.

Section 355 transactions would be subject to a special definite intent requirement under proposed §§ 1.355–4(d)(1)(ii) and 1.368–4(e)(1)(ii). Specifically, if a control distribution occurs in a later taxable year than the first distribution, the distributing corporation would not be treated as establishing a definite intent unless all distributions up to and including the control distribution are effectuated pursuant to a binding commitment. This proposed special “definite intent” requirement would reflect the Supreme Court’s decision in *Gordon*. *See also* the discussion in part I.D.2 of the Background.

iii. Proximate Relationship Requirement

(a) Overview

The proposed regulations would set forth standards for determining whether a transaction shares a sufficient relationship with other transactions to which a definitional or operative provision applies. To reflect the distinct purposes for, and requirements of, the definitional provisions and the operative provisions in subchapter C, the proposed regulations would set forth two different sets of proximate relationship requirements.

(b) Necessary or Integral Test for Qualification Under Definitional Provisions

Under proposed § 1.368–4(e)(2)(i)(A), a transaction would be treated as part of the plan of reorganization for a reorganization to which a definitional provision can apply only if, on its own or as part of a series of transactions, the transaction either (i) is necessary to satisfy one or more requirements of the definitional provision, or (ii) is an integral part of a series of transactions carried out to satisfy the requirements of the definitional provision. In practice, the “integral part” test generally would be relevant for transactions that are not “necessary to satisfy” one or more requirements of a definitional provision. The proposed regulations would require satisfaction of either condition to be evidenced by a written commitment in one or more official records of the party to the reorganization. *See* proposed § 1.368–4(e)(2)(i)(A).

The “necessary to satisfy” condition is intended to convey, with more precision, a requirement set forth in current § 1.368–2(g). Section 1.368–2(g) states, in part, that “[t]he term plan of reorganization has reference to a consummated transaction specifically defined as a reorganization under

section 368(a).” In addition, current § 1.368–2(g) provides that “[t]he term is not to be construed as broadening the definition of ‘reorganization’ as set forth in section 368(a).” The Treasury Department and the IRS view the “necessary to satisfy” condition as already clear (given that the definitional provisions in section 368(a)(1) describe the steps necessary for qualification) but have rearticulated this standard to eliminate the circularity and vagueness that courts and stakeholders have identified in current § 1.368–2(g). *See Int’l Telephone*, 77 T.C. at 75 (noting such vagueness); *Seagram*, 104 T.C. at 96 (highlighting the Tax Court’s observation in *Int’l Telephone*).

The “integral part” condition also is embedded in current § 1.368–2(g), which provides that the term “plan of reorganization” is to be taken as limiting the nonrecognition of gain or loss to “such exchanges or distributions as are *directly a part of the transaction specifically described as a reorganization in section 368(a)*” (emphasis added). The Treasury Department and the IRS view this “directly a part” standard as less stringent than the “necessary to satisfy” standard but nonetheless view it as mandating that a transaction must be essential to qualifying a series of transactions as a reorganization. Accordingly, the proposed regulations would replace the phrase “directly a part of the transaction” with an “integral part” standard.

The proposed “integral part” standard is intended to reflect the structure of section 368(a)(1) and the long-standing position of the IRS and the courts. For example, a distributing corporation that retains controlled corporation stock may qualify under section 355—and therefore ultimately may satisfy a condition in section 368(a)(1)(D)—through multiple types of dispositions of controlled corporation stock. In each instance, such disposition may be viewed as integral to section 368(a)(1)(D) qualification. (*See also* the requirements for qualifying retentions previously discussed in part I.C of this Explanation of Provisions.)

The foregoing principle is reflected in Rev. Rul. 57–518, 1957–2 C.B. 253, which addressed whether a transaction satisfied a prior version of section 368(a)(1)(C) that did not yet impose a liquidation requirement. In Rev. Rul. 57–518, a target corporation transferred 70 percent of its assets to an acquiring corporation for acquiring corporation voting stock. The target corporation then disposed of all its remaining assets in recognition transactions (that is, not under the operative nonrecognition

provisions of subchapter C) and liquidated. Although the liquidation was not described in, or required by, that prior version of section 368(a)(1)(C), the IRS concluded that the liquidation was part of the plan of reorganization. Like the disposition by a distributing corporation of retained controlled corporation stock in a transaction to which section 1001 applies, the target corporation liquidation was not necessary to achieve qualification under section 368(a)(1), but it was an integral part of a series of transactions carried out to satisfy the requirements of that definitional provision.

(c) But for, or Integral to, Test for Application of Operative Provision

Under proposed § 1.368–4(e)(2)(i)(B), a transaction would be treated as part of the plan of reorganization to which an operative provision can apply only if, on its own or as part of a series of transactions, the transaction either (i) would not have occurred but for the reorganization that is covered by the plan of reorganization, or (ii) is an integral part of a series of transactions carried out to satisfy the requirements of the definitional provision intended to apply to the reorganization. The proposed regulations would require satisfaction of either condition to be evidenced by a written commitment in one or more official records of the party to the reorganization. Both of these conditions are intended to replace the “directly a part of” standard set forth in current § 1.368–2(g) with standards that are clearer and more reflective of the purpose and requirements of the operative provisions in subchapter C.

The proposed “but for” condition is embedded within the “directly a part of” requirement in current § 1.368–2(g). Among other objectives, this proposed condition is intended to help clarify the determination of whether an operative provision applies to a distribution that occurs within close temporal proximity to one or more transactions that are properly included in a plan of reorganization. For example, in determining whether section 361(b) should apply to a distribution by a distributing corporation to its shareholders in close temporal proximity to a divisive reorganization, the proposed “but for” test would clarify that section 361(b) treatment would be applicable only if that distribution would not have occurred “but for” the divisive reorganization. See the examples in proposed § 1.361–3(f)(2) through (5).

An “integral part” standard also would increase taxpayer certainty as compared to the current “directly a part

of” standard, particularly because courts historically have applied an “integral part” standard. For example, in *Sheldon v. Commissioner*, 6 T.C. 510 (1946), the Tax Court found that a transaction was integral to a merger even though the transaction was not necessary for qualification for a definitional provision under section 368(a)(1). In *Sheldon*, the Tax Court considered whether a pre-merger distribution should be included in the plan of reorganization for the merger. 6 T.C. at 517–18. The court emphasized that the pre-merger distribution was made to equalize values of the target corporation and the acquiring corporation so that the merger could be one of equals, thereby satisfying a condition for executing the merger. *Id.* In its analysis, the court provided that “[t]he purpose of this distribution, its place in the sequence of events, and the surrounding circumstances, lead to but one conclusion. They all demonstrate that it was an integral part of the reorganization transaction as a whole and must be treated in connection with it.” *Id.* at 517. See also *Int’l Telephone*, 77 T.C. at 76 (noting the absence of “a binding agreement or other factors indicating that conversion [of debentures] was an integral part of the plans of reorganization”).

Additionally, the Treasury Department and the IRS are of the view that replacing the “directly a part of” standard in current § 1.368–2(g) with the standards in proposed § 1.368–4(e)(2)(i)(B) would improve taxpayer certainty in determining the applicability of an operative provision of subchapter C. Proposed § 1.368–4(e) would provide additional certainty by requiring the “but for” standard to be applied in tandem with the “definite intent” requirement set forth in proposed § 1.368–4(e)(1). In other words, a transaction would not be properly included in a plan of reorganization if the party to the reorganization failed to evidence a definite intent to carry out that transaction, regardless of whether the transaction would not have occurred “but for” the reorganization.

This implementation of the “but for” standard would be consistent with judicial authorities, including those cited by stakeholders. For example, in *International Telephone*, the Tax Court considered exchanges involving debentures that could not have occurred but for the execution of a reorganization that qualified under section 368(a)(1)(C). 77 T.C. at 72–78. Although the court observed the existence of that “but for” relationship, the court reasoned that “[t]he fact that [the acquiring

corporation] assumed the conversion obligation as part of the plans of reorganization does not mean . . . that the subsequent conversions and retirement of the debentures were also part of the reorganizations.” *Id.* at 76. Based on the lack of indicia indicating satisfaction of the proposed “direct intent” requirement, the Tax Court concluded that such exchanges were not properly included in the plan of reorganization. See *id.* at 76–77 (noting the lack of any binding agreement, any other type of obligation, or other facts that would indicate satisfaction of the “direct intent” requirement). See also *Becher v. Comm’r*, 22 T.C. 932 (1954) (treating a distribution as not part of the plan of reorganization under the predecessor to section 368(a)(1)(D), and therefore not “boot,” based on an examination of the facts and circumstances of the distribution and the transactions comprising the reorganization).

(d) Independent Legal Significance; Temporal Proximity

Proposed § 1.368–4(e)(2)(ii) would confirm that the independent significance of a transaction (for example, the fact that the transaction has a separate business motive apart from the reorganization) does not preclude satisfaction of the proximate relationship requirements in proposed § 1.368–4(e)(2)(i)(A) and (B). The Treasury Department and the IRS view this approach as consistent with established caselaw (see *Seagram*, 104 T.C. at 91–93) and reflective of the realities of bona fide business transactions. It has long been the understanding of the Treasury Department and the IRS that a transaction could be included in the plan of reorganization even though it may have separate business motives, or separate and permanent legal, economic, and business consequences, apart from the reorganization.

Additionally, proposed § 1.368–4(e)(2)(iii) would provide that a transaction occurring in close temporal proximity to one or more other transactions is not properly included in a plan of reorganization unless Federal income tax principles (including the step transaction doctrine) would apply to determine that the transaction was, in substance, part of the plan of reorganization.

iv. Business Purpose Consistency Requirement

Lastly, in order for a transaction to be treated as properly included in a plan of reorganization, proposed § 1.368–4(e)(3) would require the transaction (on its

own, or as part of a series of transactions) to be consistent with, and directly related to, one or more corporate business purposes for the reorganization (for example, the transaction directly furthers one or more corporate business purposes for the reorganization).

The Treasury Department and the IRS view the proposed corporate business purpose consistency requirement as reflective of established caselaw. *See Seagram*, 104 T.C. at 83, 97 (noting that the tender offer and the merger shared the same corporate business purpose of enabling DuPont to acquire all the stock of Conoco). In addition, the Treasury Department and the IRS view this proposed rule as conceptually grounded in current § 1.368–2(g), which provides that “the readjustments involved in the exchanges or distributions effected in the consummation [of the reorganization] must be undertaken for reasons germane to the continuance of the business of a corporation a party to the reorganization.”

f. Amended Plan of Reorganization

The Treasury Department and the IRS recognize that, in certain circumstances, taxpayers may need to amend their plans of reorganization. Accordingly, proposed § 1.368–4(f)(1) would provide that, if a taxpayer amends a plan of reorganization after the first step of the original plan (amended plan of reorganization), those amendments do not cause the taxpayer to fail to satisfy the “plan of reorganization” requirements set forth in proposed § 1.368–4(d) only if the following requirements are satisfied. First, the amendments to the plan must be in direct response to an identifiable, unexpected, and material change in market or business conditions that occurs after the date on which the original plan of reorganization is adopted by the party to the reorganization. Second, the amendments must be necessary to effectuate the reorganization. Third, the amended plan of reorganization must satisfy all requirements set forth in proposed § 1.368–4(d) to qualify as a plan of reorganization.

If the taxpayer satisfies the requirements in proposed § 1.368–4(f)(1), proposed § 1.368–4(f)(2)(i) would provide that the definitional and operative provisions described in proposed § 1.368–1(c)(2)(i) and (ii) would apply to the transactions identified in, and carried out pursuant to, the amended plan of reorganization. In other words, the proposed regulations would confirm that the Federal income tax consequences of all transactions

properly included in the amended plan of reorganization would be determined based on that plan of reorganization (and not on the original plan of reorganization). However, proposed § 1.368–4(f)(2)(ii) would provide that, if the amended plan of reorganization fails to satisfy the requirements in proposed § 1.368–4(f)(1), the Commissioner may correct or identify the amended plan of reorganization.

3. Proposed Rules Regarding Party to a Reorganization

In addition to providing rules regarding the determination, adoption, and prosecution of a plan of reorganization, the proposed regulations would revise current § 1.368–2(f) to further clarify (i) which persons are parties to a reorganization, and (ii) the consequences of determining that a person is (or is not) a party to a reorganization.

Proposed § 1.368–2(f)(1) generally would provide that the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii), respectively, apply solely to a transaction that is carried out by, between, or among one or more parties to a reorganization. For purposes of determining the scope of transactions to which those provisions apply, the term “party to a reorganization” would be limited under proposed § 1.368–2(f)(2) through (4) solely to a corporation that (i) engages in a transaction or series of transactions that satisfies a definitional provision set forth in section 368(a)(1), and (ii) is determined to be a party to a reorganization, as further described in the following paragraph.

In general, proposed § 1.368–2(f)(4)(i) would provide that a corporation’s status as a party to a reorganization is established solely by the inclusion and identification of the corporation as a party to the reorganization in a plan of reorganization filed with the IRS pursuant to proposed § 1.368–3(a)(5). However, proposed § 1.368–2(f)(4)(ii) would provide that the corporation’s status as a party to a reorganization may be determined by the Commissioner based on (i) all facts and circumstances regarding the transaction or series of transactions, and (ii) all relevant provisions of the Code and general principles of tax law, including the step transaction doctrine.

Proposed § 1.368–2(f)(3)(ii) would retain the rules in current § 1.368–2(f) regarding the impact of certain transfers of assets or stock in a reorganization on a person’s status as a party to the reorganization.

IV. Application of Substance-Over-Form, Agency, and Other Relevant Theories to Intermediated Exchanges and Direct Issuance Transactions

A. Notice 2024–38

In section 2.02(5) of Notice 2024–38, the Treasury Department and the IRS announced that they are continuing to study the application of the Code, as well as general principles of Federal income tax law (including substance-over-form, agency, or other relevant theories), to monetization transactions involving section 361 consideration. In particular, this study continues to focus on intermediated exchanges, which occur through (i) the acquisition by an intermediary (such as an investment bank) of historical distributing corporation debt from holders of that debt, and (ii) the subsequent satisfaction of that debt by the distributing corporation using section 361 consideration.

As capital market transactions have evolved, this study also has focused increasingly on direct issuance transactions, which typically occur through: (i) the issuance of new debt by a distributing corporation to an intermediary for cash in anticipation of a divisive reorganization; (ii) the use of that cash by the distributing corporation to satisfy historical distributing corporation debt, during a potentially indefinite period; and (iii) the satisfaction of that new debt by the distributing corporation through the transfer of section 361 consideration to the intermediary.

This study reflects the long-standing position of the Treasury Department and the IRS that general principles of Federal income tax law (including substance-over-form, agency, or other relevant theories) apply to determine the Federal income tax consequences of all transactions, including such monetization transactions. *See United States v. Fruehauf Corp.*, 577 F.2d 1038, 1068 (6th Cir. 1978) (“The incidence of federal taxation has always depended upon the substance of transactions . . .”). Indeed, this position is consistent with nearly a century of Supreme Court precedent beginning with the Court’s decision in *Gregory v. Helvering*, which established that the application of the Code to a transaction (or series of transactions) turns on the substance of the transaction. *See Gregory*, 293 U.S. at 467–70 (concluding that the “reorganization attempted was without substance and must be disregarded [and] [t]o hold otherwise would be to exalt artifice above reality and to deprive the statutory provision in question of all serious purpose”);

United States v. Iles, 906 F.2d 1122, 1127 (6th Cir. 1990) (“The Supreme Court has recognized, at least as far back as *Gregory v. Helvering* . . . that substance over form governs federal taxation.”) (citations omitted).

The application of substance-over-form and similar doctrines can affect qualification for nonrecognition treatment under section 361. Notice 2024–38 conveyed the long-standing view of the Treasury Department and the IRS that the application of agency principles to an intermediated exchange involving so-called “old and cold” distributing corporation debt could cause that transaction to be recharacterized for Federal income tax purposes such that the distributing corporation would not be treated as transferring section 361 consideration to a creditor in satisfaction of distributing corporation debt. In other words, if the intermediary were found to be acting on behalf of the distributing corporation under agency principles, transfers of section 361 consideration to the intermediary would not satisfy the requirements for nonrecognition under section 361. With respect to a direct issuance transaction in which the distributing corporation issues and redeems the new debt in close temporal proximity, the Treasury Department and the IRS are of the view that the transaction could be recast under general principles of Federal income tax law such that the nonrecognition requirements under section 361 are not satisfied.

B. Stakeholder Input

1. Intermediated Exchanges

Stakeholders have contended that intermediated exchanges should not be subject to recharacterization, provided that the distributing corporation establishes the intermediary’s status as a creditor acting for its own account under agency principles. Stakeholders have stated that this approach would be consistent with Rev. Rul. 2017–9, 2017–21 I.R.B. 1244, because intermediated exchanges (i) do not conflict with the underlying policy of section 361(c)(3), (ii) do not avoid the result intended by section 361(c)(3) (that is, the reallocation of historical distributing corporation liabilities to the controlled corporation), and (iii) do not produce results that are inconsistent with the underlying intent of section 361(c)(3). In other words, stakeholders have suggested that, in determining whether an intermediated exchange should be recharacterized, the relevant question is whether the distributing corporation debt acquired by the intermediary was

issued with a purpose of avoiding any requirement or limitation under section 361.

In this regard, one stakeholder has requested guidance providing that steps of an intermediated exchange will not be recast under Federal income tax principles if (i) the intermediary acts on its own account in acquiring distributing corporation debt from third parties (that is, the intermediary becomes the owner of such debt for Federal income tax purposes and the acquisition is not funded or guaranteed by the distributing corporation), (ii) the intermediary assumes the risk that the distributing corporation may default on its debt while such debt is held by the intermediary, and (iii) the distributing corporation debt acquired by the intermediary was not issued with a purpose of avoiding the requirements or limitations of section 361.

Another stakeholder has recommended that the Treasury Department and the IRS refrain from issuing substantive guidance given the fact-intensive nature of determining whether an intermediated exchange should be recast. The stakeholder has recommended that the IRS continue to issue private letter rulings on a case-by-case basis to taxpayers that are able to establish an intermediary’s status as a creditor acting for its own account by reference to the factors specified in a series of technical advice memoranda previously issued by the IRS. *See* T.A.M. 8815003 (Dec. 11, 1987); T.A.M. 8738003 (May 22, 1987); T.A.M. 8735007 (May 18, 1987); T.A.M. 8735006 (May 18, 1987).

2. Direct Issuances

Stakeholders have provided various recommendations to the Treasury Department and the IRS regarding the treatment of direct issuance transactions. Stakeholders uniformly have contended that the proposed regulations should recast or recharacterize a direct issuance transaction only if the transaction presents an abuse within the meaning of section 361(b)(3). In addition, stakeholders consistently have contended that the policy of section 361 confirms that direct issuance transactions satisfy the requirements for nonrecognition treatment under section 361. Although one stakeholder has acknowledged that, in some circumstances, the Treasury Department and the IRS may have a legitimate concern that a direct issuance transaction should be treated as a sale of controlled corporation stock to the intermediary, the stakeholder has noted that delineating the exact bounds of an

abusive transaction as it relates to section 361(b)(3) and (c)(3) would be difficult. Accordingly, stakeholders generally have recommended that the Treasury Department and the IRS continue to address the section 361 qualification of direct issuance transactions through the IRS’s private letter ruling program rather than through Treasury regulations.

Alternatively, stakeholders have recommended that the proposed regulations set forth specific safe harbors for direct issuance transactions that, after adequately taking into account commercial considerations (which one stakeholder has referred to as “commercially grounded carveouts”), clearly would not present evidence of abuse. One stakeholder has recommended that a direct issuance transaction be respected as a borrowing if: (i) the newly issued debt qualifies as debt for Federal income tax purposes; (ii) the new debt issuance and the exchange agreement with the intermediary (regarding satisfaction of the newly issued debt with controlled corporation stock or securities) are pursuant to two legally separate agreements; (iii) the distributing corporation is not under economic compulsion to satisfy the newly issued debt with controlled corporation stock or securities at the time of issuance because the distributing corporation has sufficient other resources to repay the debt; (iv) the newly issued debt is satisfied with controlled corporation stock or securities having a fair market value equal to the principal amount and unpaid interest on the debt; and (v) the distributing corporation retains tax ownership of the controlled corporation stock or securities until the time of repayment.

Another stakeholder has suggested additional factors to be considered, including (i) the number of days the newly issued debt is outstanding before the exchange of that debt for controlled corporation stock or securities, and (ii) whether the intermediary participating in the direct issuance transaction is a member of a syndicate of lenders that has historically provided debt financing to the distributing corporation. Additionally, a stakeholder has recommended (i) limiting permissible direct issuance transactions to situations in which the proceeds of the new debt are used to retire historical debt, and (ii) including a general anti-avoidance rule based on the distributing corporation’s business purpose for entering into the direct issuance transaction.

C. Proposed Regulations

1. Overview

The Treasury Department and the IRS continue to be of the view that, under certain circumstances, intermediated exchanges and direct issuance transactions can be recast or otherwise recharacterized under Federal income tax principles. Certain stakeholders have described the aforementioned concerns of the Treasury Department and the IRS with respect to such transactions as new or as deriving primarily from direct issuance transactions or refinancing transactions.

However, these concerns are neither new nor unique. As confirmed almost a century ago by the Supreme Court in *Gregory v. Helvering*, the application of substance over form and other general Federal income tax principles is inseparable from the application of the Code itself. *See also Newman v. Comm'r*, 894 F.2d 560, 562 (2d Cir. 1990) (emphasizing that, “in reviewing a transaction for tax consequences, the substance of the agreement takes precedence over its form”). Accordingly, one objective of these proposed regulations is to clarify that general Federal income tax principles apply with regard to the application of section 361 just as such principles would apply with regard to the application of other Code provisions.

With regard to the application of section 361 to intermediated exchanges, the Treasury Department and the IRS note that concerns regarding agency and substance over form date back decades to a series of technical advice memoranda that considered the application of a prior version of section 108 of the Code to conceptually similar intermediated exchanges of stock and securities. *See T.A.M. 8815003* (Dec. 11, 1987); *T.A.M. 8738003* (May 22, 1987); *T.A.M. 8735007* (May 18, 1987); *T.A.M. 8735006* (May 18, 1987). The so-called “5/14 standard” in corporate private letter rulings developed out of concerns similar to those discussed in those memoranda. (Under this standard, rulings generally would be issued by the IRS if: (i) the intermediary purchased distributing corporation debt; (ii) after at least five days, the intermediary and the distributing corporation entered into an agreement to exchange the purchased distributing corporation debt for section 361 consideration; and (iii) the exchange occurred at least 14 days after the intermediary purchased the distributing corporation debt.)

With regard to the application of section 361 to direct issuance transactions, the Treasury Department and the IRS have expressed similar

concerns for more than a decade. In particular, the Treasury Department and the IRS ceased considering certain private letter ruling requests under section 361 in part due to this type of section 361 monetization transaction. *See* section 5.01(10) of Rev. Proc. 2013–3, 2013–1 I.R.B. 113. As explained by Treasury Department and IRS officials at that time, these transactions raised issues concerning the application of general principles of Federal income tax, including the substance-over-form doctrine. Stakeholders also raised similar issues at that time.

In addition, certain stakeholders have mischaracterized the concerns of the Treasury Department and the IRS as focused principally on (i) whether the new debt should be respected as a debt instrument for Federal income tax purposes, or (ii) temporal proximity. With regard to the former point, certain stakeholders have provided feedback on Notice 2024–38 emphasizing debt-equity factors or have noted that, outside of Federal income tax (for example, under securities law), new debt issued by a distributing corporation in a direct issuance transaction would be treated as debt.

However, as previously discussed in this part IV.C.1, the Treasury Department and the IRS are concerned with the application of the Code and Federal income tax principles—not commercial law or other non-Federal income tax law—to intermediated exchanges and direct issuance transactions. In particular, as expressed in Notice 2024–38, the concern is not simply the status of the newly issued distributing corporation debt as debt for Federal income tax purposes, but also that the form of those debt-elimination transactions should be respected and not recharacterized under Federal income tax principles.

With regard to the latter point, the Treasury Department and the IRS replaced the 5/14 standard for private letter rulings in Rev. Proc. 2018–53 with a standard based on a facts-and-circumstances analysis. This change was made due to concerns that the 5/14 standard provided a temporal requirement that was indifferent to the particular facts and circumstances of the transaction, including the intermediary’s relationship with the distributing corporation. As a consequence, the Treasury Department and the IRS observed that the 5/14 standard created confusion for taxpayers as to whether temporal proximity is the sole consideration with regard to the application of agency or substance-over-form principles to intermediated

exchanges and direct issuance transactions.

The Treasury Department and the IRS also continue to be of the view that Rev. Rul. 2017–9 and other revenue rulings mentioned by stakeholders in their submitted feedback do not (and cannot) set forth broadly applicable principles that would dictate the positions set forth in these proposed regulations. One reason is that there are long-established limitations on the precedential value of revenue rulings. Specifically, “[r]evenue rulings published in the [Internal Revenue] Bulletin do not have the force and effect of Treasury Department regulations (including Treasury Decisions), but are published to provide precedents to be used in the disposition of other cases, and may be cited and relied upon for that purpose.” Section 601.601(d)(2)(v)(d) of the Statement of Procedural Rules (codifying section 7.01(4) of Rev. Proc. 89–14, 1989–8 I.R.B. 20). In addition, “[e]ach revenue ruling represents the conclusion of the Service as to the application of the law to the entire statement of facts involved,” as opposed to an application outside of that entire statement of relevant facts. Section 601.601(d)(2)(v)(d) (codifying section 7.01(6) of Rev. Proc. 89–14). Based on these limitations, “taxpayers, Service personnel, and others concerned are cautioned against reaching the same conclusion in other cases unless the facts and circumstances are substantially the same.” Section 601.601(d)(2)(v)(e).

Another reason is that, in almost all instances, the facts and circumstances set forth in the revenue rulings mentioned by stakeholders are not substantially the same as the transaction facts considered by the Treasury Department and the IRS in developing these proposed regulations. *See* Rev. Rul. 2017–9 (providing that “[t]his revenue ruling provides guidance regarding the federal tax treatment of certain transactions referred to as ‘north-south’ transactions,” rather than intermediated exchanges or direct issuance transactions); Rev. Rul. 59–197, 1959–1 C.B. 77 (considering the potential effect of a “cash sale to the key employee” of the distributing corporation on section 355 qualification, rather than an intermediated exchange or a direct issuance transaction). Accordingly, those revenue rulings address entirely different provisions of the Code. *See* Rev. Rul. 2017–9 (addressing the application of, and qualification under, sections 301, 351, 355, and 361(b)(1) and (2) (not section 361(b)(3) and (c)(3))); Rev. Rul. 59–197 (addressing the application of the device

and continuity of interest requirements under section 355, not section 361(b)(3) and (c)(3)).

However, the Treasury Department and the IRS are of the view that the facts and analysis set forth in Rev. Rul. 79–258 are relevant for purposes of developing proposed regulations under section 357(b). Accordingly, based on a de novo consideration of the analysis set forth in that revenue ruling, proposed § 1.357–3(d)(4)(ii)(B) would incorporate that analysis into proposed rules regarding the assumption by a controlled corporation of distributing corporation debt issued in close proximity to a divisive reorganization. See the discussion in part VIII.C.3.b of this Explanation of Provisions. For the reasons discussed in this part IV.C.1, the Treasury Department and the IRS do not view it as appropriate for these proposed regulations to extend the analysis of Rev. Rul. 79–258 to proposed rules addressing the application of section 361.

2. General Approach of Proposed Regulations

The Treasury Department and the IRS appreciate the feedback received from stakeholders on intermediated exchanges and direct issuance transactions. As emphasized in Notice 2024–38, and consistent with other aspects of these proposed regulations, the proposed rules addressing these topics are intended (i) to be consistent with all relevant provisions of the Code (that is, the compliance objective); (ii) to provide certainty to taxpayers and the IRS regarding the application of all relevant provisions of the Code to purported section 355 transactions (that is, the increased certainty objective); and (iii) to be responsive to the manner in which section 355 transactions are engaged in by taxpayers and reflect current market practices and preferences (that is, the transaction facilitation objective), to the extent that doing so does not conflict with the compliance and increased certainty objectives.

With regard to the increased certainty objective, the Treasury Department and the IRS have leveraged the expertise of IRS audit and examination personnel to develop proposed rules that, to the extent practicable, employ bright-line safe harbors, objectively verifiable conditions for qualification, and other similar architecture that can be readily reflected on Form 7216. These rules reflect the express delegation of authority to the Secretary to prevent avoidance of tax through abuse of section 361(b)(3) or (c)(3). The Treasury Department and the IRS have

endeavored to balance this increased certainty objective with the transaction facilitation objective.

3. Specific Aspects of Proposed Regulations

a. General Requirements for Deemed Distribution Treatment

Proposed § 1.361–5 would implement section 361(b)(3) and (c)(3) by setting forth requirements that, if satisfied, would cause a transfer of section 361 consideration by the distributing corporation to its creditor to be treated as a distribution by the distributing corporation to its shareholders pursuant to the plan of reorganization. First, the creditor of the distributing corporation must be a qualifying creditor, as determined under proposed § 1.361–5(b). Second, the distributing corporation debt that is satisfied with section 361 consideration must constitute eligible distributing corporation debt, as determined under proposed § 1.361–5(c)(2). Third, the amount of distributing corporation debt that can be eliminated under the safe harbors of section 361(b)(3) and (c)(3) cannot exceed a maximum amount, as determined under proposed § 1.361–5(d). Lastly, the transfer by the distributing corporation of section 361 consideration in exchange for eligible distributing corporation debt must be carried out as part of a qualifying debt elimination transaction, as determined under proposed § 1.361–5(e).

Notwithstanding the satisfaction of the foregoing requirements, proposed § 1.361–5(f)(1)(i) would provide that the amount of section 361 consideration treated as transferred by the distributing corporation to a creditor of the distributing corporation in a qualifying debt elimination transaction is reduced by the amount of distributing corporation debt that is transitorily eliminated. See the discussion in part VII.C of this Explanation of Provisions regarding transitorily eliminated distributing corporation debt.

b. Qualifying Creditors

Proposed § 1.361–5(b)(1) would require each creditor to which the distributing corporation transfers section 361 consideration in a divisive reorganization to be a creditor that holds eligible distributing corporation debt (as described in proposed § 1.361–5(c)). Additionally, proposed § 1.361–5(b)(1) and (b)(2)(i) generally would prohibit the distributing corporation from satisfying eligible distributing corporation debt held by a person related (within the meaning of section 267(b) or section 707(b)(1)) (see

proposed § 1.361–1(b)(47)) to the distributing corporation (distributing corporation related person), the controlled corporation (controlled corporation related person), or a related person with regard to a distributing corporation related person or a controlled corporation related person (collectively, non-qualifying creditors). Creditors that hold eligible distributing corporation debt, and that are not otherwise disqualified as non-qualifying creditors under proposed § 1.361–5(b)(2), are referred to as “qualifying creditors.”

Proposed § 1.361–5(b)(2)(ii) would provide an exception to the general related-creditor prohibition in proposed § 1.361–5(b)(2)(i) for a creditor that is a distributing corporation related person or a related person with regard to a distributing corporation related person if three requirements are satisfied. First, as part of the plan of reorganization, proposed § 1.361–5(b)(2)(ii)(A) would provide that the section 361 consideration must be transferred to a creditor that is neither a distributing corporation related person nor a related person with regard to a distributing corporation related person (unrelated ultimate creditor). Specifically, if the section 361 consideration is money or other property, proposed § 1.361–5(b)(2)(ii)(A)(1) would provide that it must be transferred to an unrelated ultimate creditor pursuant to the plan of reorganization no later than the end of the 12-month period beginning on the date the distributing corporation receives the money or other property (as appropriate). If the section 361 consideration is qualified property (as defined in proposed § 1.361–1(b)(43)), proposed § 1.361–5(b)(2)(ii)(A)(2) would provide that it must be transferred to an unrelated ultimate creditor in an expeditious manner pursuant to the plan of reorganization under proposed § 1.368–4(d)(3). Second, proposed § 1.361–5(b)(2)(ii)(B)(1) would provide a general provision that all debt for which section 361 consideration is exchanged must be in existence as of the earliest applicable date. Proposed § 1.361–5(b)(2)(ii)(B)(2) would provide that distributing corporation debt held directly by a distributing corporation related person or a related person with regard to a distributing corporation related person must qualify as historical distributing corporation debt described in proposed § 1.361–5(c)(2)(i). Third, proposed § 1.361–5(b)(2)(ii)(C) would provide that each transaction (including each intermediate and unrelated ultimate creditor transfer), creditor (including the unrelated ultimate

creditor), and debt satisfied with section 361 consideration must be identified and described in the plan of reorganization with regard to the divisive reorganization.

For purposes of the requirements in proposed § 1.361–5(b)(2)(ii)(A), proposed § 1.361–5(b)(2)(ii)(A)(3) would permit one or more intermediate transfers of section 361 consideration between or among distributing corporation related persons or related persons with regard to distributing corporation related persons to satisfy debts (including the initial distributing corporation debt) if those intermediate transfers culminate in a transfer of section 361 consideration to an unrelated ultimate creditor. Under proposed § 1.361–5(b)(2)(iii), a person's status as a distributing corporation related person or a controlled related person, or as a related person with regard to any distributing corporation related person or as a related person with respect to any controlled corporation related person, would be determined at the time of that person's receipt of the section 361 consideration in exchange for the satisfaction and retirement of debt in a transfer or series of transfers described in proposed § 1.361–5(b)(2)(ii)(A).

c. Eligible Distributing Corporation Debt

i. In General

Proposed § 1.361–5(c)(1) would provide that distributing corporation debt is not eligible to be satisfied with section 361 consideration under proposed § 1.361–5(a) unless that debt qualifies as eligible distributing corporation debt.

(a) Historical Distributing Corporation Debt

In general, proposed § 1.361–5(c)(2)(i) would provide that distributing corporation debt that qualifies as historical distributing corporation debt is eligible to be satisfied with section 361 consideration. In general, distributing corporation debt qualifies as historical distributing corporation debt if that debt was incurred before the “earliest applicable date,” and that debt has an original term that ends after the date of the exchange described in § 1.361–2(a) or 1.361–3(a) and is identified in the plan of reorganization or original plan of reorganization (if amended). The “earliest applicable date” is defined in proposed § 1.361–1(b)(27) as the earliest date of three specified events: (i) the date of the first public announcement (as defined in § 1.355–7(h)(10)) of the divisive reorganization or a similar transaction;

(ii) the date the distributing corporation entered into a written agreement to effectuate the divisive reorganization or a similar transaction; and (iii) the date the distributing corporation's board of directors approved the divisive reorganization or a similar transaction.

However, the Treasury Department and the IRS are of the view that a debt refinancing exception would be appropriate to help achieve the transaction facilitation objective. Specifically, proposed § 1.361–5(c)(2)(ii) would provide that distributing corporation debt incurred by the distributing corporation after the earliest applicable date is treated as historical distributing corporation debt only if the following four requirements are met. First, proposed § 1.361–5(c)(2)(ii)(A) would provide that the distributing corporation debt must be (i) a refinancing of historical distributing corporation debt, or (ii) a refinancing of refinanced historical distributing corporation debt (that is, the debt must be traced directly through one or more refinancings to debt that qualifies as historical distributing corporation debt). Second, proposed § 1.361–5(c)(2)(ii)(B) would provide that the refinanced historical distributing corporation debt must not have been incurred as part of a plan to incur debt in addition to historical distributing corporation debt determined under proposed § 1.361–5(c)(2)(i) (or an amount of debt in addition to the amount of historical distributing corporation debt determined under paragraph (d) of that section, without regard to proposed § 1.361–5(d)(2)(iv)) in anticipation of the divisive reorganization (for example, the incurrence of the refinanced historical distributing corporation debt would have occurred without regard to the divisive reorganization). Third, proposed § 1.361–5(c)(2)(ii)(C) would provide that the distributing corporation must engage in a qualifying debt elimination transaction solely under proposed § 1.361–5(e)(3) or (4) to eliminate that refinanced historical distributing corporation debt. Fourth, proposed § 1.361–5(c)(2)(ii)(D) would provide that the qualifying debt elimination transaction must be described and identified in the plan of reorganization or original plan of reorganization (if amended) for the divisive reorganization.

Proposed § 1.361–5(c)(2)(iii) would provide that a revolving credit agreement to which the distributing corporation is a debtor qualifies as historical distributing corporation debt only if the following requirements are met. First, the distributing corporation must have entered into the agreement

before the earliest applicable date. Second, the agreement does not expire until after the date of the exchange described in proposed § 1.361–2(a) or 1.361–3(a). Third, the agreement is identified in the plan of reorganization or original plan of reorganization (if amended). The Treasury Department and the IRS request comments regarding whether there are other arrangements similar to revolving credit agreements that, based on the same rationale employed by these proposed regulations, should be treated similarly.

(b) Qualifying Trade Payables

Proposed § 1.361–5(c)(2)(iv) would provide that qualifying trade payables are eligible to be satisfied with section 361 consideration. For purposes of that qualification, the following requirements must be met. First, the trade payables must be described in a plan of reorganization or original plan of reorganization (if amended). Second, the trade payables must have been incurred in the ordinary course of business of the distributing corporation. Third, the satisfaction of such trade payables is necessary (A) to ensure the allocation to the controlled corporation of all liabilities properly associated with the business assets transferred to that corporation and (B) to result in the controlled corporation being allocated liabilities in an amount that properly relates to its business operations, the earnings of which will be used to properly satisfy those liabilities.

(c) Direct Issuance Debt

These proposed regulations would also provide that direct issuance debt is eligible to be satisfied with section 361 consideration. Specifically, proposed § 1.361–5(c)(2)(v) would provide that direct issuance debt incurred as part of a direct issuance transaction (as defined in proposed § 1.361–1(b)(17)) satisfying the requirements of proposed § 1.361–5(e)(4) is eligible to be satisfied with section 361 consideration. See the discussion in part IV.C.3.d.iv regarding qualifying direct issuance transactions.

ii. Amount of Distributing Corporation Debt Repaid

Under proposed § 1.361–5(d)(1), the maximum amount of distributing corporation debt that can be satisfied with section 361 consideration under proposed § 1.361–5(a) would equal the amount obtained by subtracting the aggregate amount of distributing corporation debt that the controlled corporation assumes (in accordance with proposed §§ 1.357–2 through 1.357–4) pursuant to the plan of reorganization from the lesser of (i) the

aggregate amount of distributing corporation debt (as determined under proposed § 1.361–5(c)(3)), and (ii) the aggregate amount of distributing corporation debt determined under the eight-quarterly-average test set forth in proposed § 1.361–5(d)(2). The Treasury Department and the IRS are of the view that incorporating the IRS's long-standing, quarterly average test for advance ruling purposes (which was expanded to an eight-quarterly-average test in Rev. Proc. 2018–53 to provide a more accurate determination) into this computation would help achieve the increased certainty objective of these proposed regulations.

(a) Aggregate Amount of Distributing Corporation Debt

Under proposed § 1.361–5(c)(3)(ii), the aggregate amount of distributing corporation debt would include solely the amounts described in proposed § 1.361–5(c)(3)(ii)(A) through (E), as applicable, taking into account any reduction required by proposed proposed § 1.361–5(c)(3)(iii) (that is, offsetting debts). Specifically, proposed § 1.361–5(c)(3)(ii)(A) would provide that the aggregate amount of historical distributing corporation debt would equal the aggregate remaining principal amount, as of the earliest applicable date, of all historical distributing corporation debt other than historical distributing corporation debt that is eliminated as part of a qualifying direct issuance transaction. With regard to refinanced distributing corporation debt, proposed § 1.361–5(c)(3)(ii)(B) would provide that, if the distributing corporation relies on the refinancing exception for historical distributing corporation debt under proposed § 1.361–5(c)(2)(ii), then the amount of that debt distributing corporation debt would equal the lesser of (i) the original principal amount of the refinanced distributing corporation debt and (ii) the principal amount of the original historical distributing corporation debt (that is, the distributing corporation debt to which the refinanced distributing corporation debt is traced) as of the earliest applicable date. With regard to a revolving credit agreement that satisfies the requirements set forth in § 1.361–5(c)(2)(iii), proposed § 1.361–5(c)(3)(ii)(C) would provide that the amount of that debt would be the lesser of (i) the balance under that agreement as of the earliest applicable date (and not the maximum amount that could be incurred by the distributing corporation under that agreement), and (ii) the lowest balance under the agreement beginning on the earliest applicable date

and ending on the control distribution date.

Additionally, proposed § 1.361–5(c)(3)(ii)(D) would provide that the amount of qualifying trade payables would equal the aggregate amount of those payables on the date of the exchange described in proposed § 1.361–2(a) or 1.361–3(a). With regard to direct issuance debt, proposed § 1.361–5(c)(3)(ii)(E) would provide that the amount of that debt would equal the aggregate principal amount of that debt on the date exchange described in proposed § 1.361–2(a) or 1.361–3(a).

Lastly, proposed § 1.361–5(c)(3)(iii) would require the aggregate amount of distributing corporation debt be reduced to reflect certain offsetting debts. That is, if the distributing corporation is a creditor, and if the debtor with respect to that debt is a creditor with respect to distributing corporation debt, the distributing corporation would be required to reduce the aggregate principal amount of its distributing corporation debt by the aggregate principal amount of debt issued to that other person for purposes of the computation under proposed § 1.361–5(c)(3)(ii). This proposed rule also would include reductions to account for revolving credit agreements.

(b) Eight-Quarterly-Average Test

Proposed § 1.361–5(d)(2)(i) would provide that, under the eight-quarterly-average test, the aggregate amount of distributing corporation debt generally would equal the average of the amount of distributing corporation debt owed to persons other than distributing corporation related persons as of the close of each of the eight fiscal quarters that end immediately before the earliest applicable date. Proposed § 1.361–5(d)(2)(ii) and (iii) would provide additional rules to address (i) the calculation of distributing corporation debt at the close of each quarter, and (ii) distributing corporation debt held by distributing corporation related persons.

d. Qualifying Debt Elimination Transactions

i. Overview

The Treasury Department and the IRS are proposing bright-line rules for qualifying debt elimination transactions to achieve the transaction facilitation and increased certainty objectives for these proposed regulations. The determination of whether a debt elimination transaction qualifies under section 361(b)(3) and (c)(3), and the extent of that qualification, has created more uncertainty for taxpayers and the IRS than perhaps any other issue arising

from divisive reorganizations. With these proposed rules, the Treasury Department and the IRS are seeking to strike a balance that would facilitate intermediated exchanges and direct issuance transactions in a manner that (i) is consistent with the Code (particularly sections 355, 361, and 368) and underlying legislative history, and (ii) facilitates IRS administration and enforcement.

ii. Section 361 Transactions in Which No Intermediary is Used

Proposed § 1.361–5(e)(2) would set forth rules for qualifying original creditor exchanges. Specifically, proposed § 1.361–5(e)(2) would provide that the satisfaction of distributing corporation debt with section 361 consideration in an exchange not described in proposed § 1.361–5(e)(3) or (4) is treated as a qualifying debt elimination transaction (that is, the exchange will be treated as a nonrecognition transaction for Federal income tax purposes) if all applicable requirements set forth in proposed § 1.361–5(b) through (d) are satisfied. In particular, proposed § 1.361–5(c)(2)(ii)(C) would provide that the refinancing exception set forth in proposed § 1.361–5(c)(2)(ii) would not apply to distributing corporation debt that is refinanced and then eliminated in a qualifying original creditor exchange. In other words, for a distributing corporation to apply that refinancing exception, the distributing corporation would be required to engage in a qualifying intermediated exchange or a qualifying direct issuance transaction (as discussed in parts IV.C.3.d.iii and iv of this Explanation of Provisions).

iii. Qualifying Intermediated Exchanges

Under proposed § 1.361–5(e)(3), an intermediated exchange would not qualify as a qualifying debt elimination transaction unless certain requirements are satisfied. First, proposed § 1.361–5(e)(3)(i)(A) generally would prohibit the holder of historical distributing corporation debt that will be satisfied with section 361 consideration from holding that debt for the benefit of the distributing corporation, the controlled corporation, a distributing corporation related person, or a controlled corporation related person. However, under proposed § 1.361–5(e)(3)(i)(B) this prohibition would not apply to a collateral benefit (such as the efficient purchase by an intermediary of historical distributing debt on the open market) received by a distributing corporation or a distributing corporation related person, from the intermediary's

facilitation of the transfer of section 361 consideration in satisfaction of historical distributing corporation debt.

Second, proposed § 1.361–5(e)(3)(ii) would prohibit the intermediary from acquiring historical distributing corporation debt that is satisfied with section 361 consideration from the distributing corporation, the controlled corporation, or any distributing corporation related person or controlled corporation related person. However, under proposed § 1.361–5(c)(2)(ii)(A) the refinancing exception set forth in proposed § 1.361–5(c)(2)(ii) would be available for distributing corporations that engage in qualifying intermediated exchanges. The Treasury Department and the IRS are of the view that this exception would help achieve the transaction facilitation objective by providing distributing corporations with significant flexibility to engage in debt elimination transactions under section 361 with debt refinanced after the earliest applicable date.

Third, the proposed regulations would impose long-standing requirements consistent with the analysis in the aforementioned technical advice memoranda addressing intermediated exchanges under former section 108. Specifically, proposed § 1.361–5(e)(3)(iii) would require the intermediary and the distributing corporation to effectuate the exchange of section 361 consideration for historical distributing corporation debt based on terms and conditions arrived at by the parties bargaining at arm's length.

Fourth, proposed § 1.361–5(e)(3)(iv) would prohibit the distributing corporation, the controlled corporation, and any distributing corporation related person or controlled corporation related person from (i) participating in any profit gained by the intermediary upon the exchange of section 361 consideration, or (ii) limiting the intermediary's profit by agreement or other arrangement.

Fifth, proposed § 1.361–5(e)(3)(v)(A) and (B) would require the intermediary (i) to act for its own account with regard to all components of the intermediated exchange, and (ii) bear the risk of loss with regard to the historical distributing corporation debt and any subsequent disposition of any section 361 consideration received in the exchange. Accordingly, proposed § 1.361–5(e)(3)(v)(C) would prohibit the intermediary from entering into a variable pricing agreement or similar arrangement with the distributing corporation, the controlled corporation, or any distributing corporation related person or controlled corporation related person (for example, agreements

between the intermediary and the distributing corporation requiring “true-up” payments would be prohibited).

Finally, proposed § 1.361–5(e)(3)(vi) would require the intermediary to hold the historical distributing corporation debt for a period of not less than 30 days ending on the control distribution date. Based on feedback from stakeholders, the Treasury Department and the IRS are of the view that providing a bright-line rule would help achieve the transaction facilitation and increased certainty objectives of these proposed regulations. The proposed rule would depart from the facts-and-circumstances approach set forth in Rev. Proc. 2018–53.

iv. Qualifying Direct Issuance Transaction

Under proposed § 1.361–5(e)(4), a direct issuance transaction would not qualify as a qualifying debt elimination transaction unless certain requirements are satisfied. For this purpose, proposed § 1.361–1(b)(17) would define the term “direct issuance transaction” to mean a transaction, or a series of transactions (or similar transaction or series of transactions), in which (i) the distributing corporation incurs distributing corporation debt with a creditor after the earliest applicable date, (ii) the distributing corporation uses the proceeds of the newly incurred distributing corporation debt (directly or indirectly) to repay historical distributing corporation debt, and (iii) the new creditor exchanges that newly incurred distributing corporation debt for controlled corporation stock or securities held by the distributing corporation.

First, proposed § 1.361–5(e)(4)(i)(A) would require that a direct issuance transaction be determined to comprise a transfer by the distributing corporation of section 361 consideration to the creditor in exchange for the satisfaction of distributing corporation debt held by that creditor (direct issuance debt), and not a sale by the distributing corporation of section 361 consideration to the creditor for the proceeds of that direct issuance debt, for Federal income tax purposes. Proposed § 1.361–5(e)(4)(i)(B) would provide that that determination is made based on all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine. Proposed § 1.361–5(e)(4)(i)(B) also would provide that the substance of the direct issuance transaction must be determined, pursuant to all relevant provisions of the Code and general principles of Federal income tax law,

before the requirements of section 361 can be applied.

Second, proposed § 1.361–5(e)(4)(ii)(A) would provide that, unless the transaction satisfies the safe harbor under proposed § 1.361–5(e)(4)(iii), the determination of whether a direct issuance transaction is an exchange under section 361, and not a sale, is made using a facts-and-circumstances test. For this purpose, proposed § 1.361–5(e)(4)(ii)(B) would provide a set of factors to be used in determining whether the direct issuance transaction exchange qualifies as an exchange under section 361. Proposed § 1.361–5(e)(4)(ii)(B) would provide that each of the specified factors represents either evidence of qualification or non-qualification as an exchange. The strength of evidence provided by the factors is determined based on an analysis of all relevant facts and circumstances.

(a) Prescribed Factors for Facts-and-Circumstances Test

First, proposed § 1.361–5(e)(4)(ii)(B)(1) would provide that an exchange of section 361 consideration by the distributing corporation with a creditor occurs pursuant to an arrangement that comprises part of a prearranged, integrated plan is substantial evidence of non-qualification, whereas, an exchange that does not occur pursuant to an arrangement that comprises part of a prearranged, integrated plan is evidence of qualification.

Second, proposed § 1.361–5(e)(4)(ii)(B)(2)(i) would provide that, if any one of the following requirements are not met, the failure of any one requirement is evidence of non-qualification: (1) an exchange of section 361 consideration for refinanced historical distributing corporation debt between the distributing corporation and the creditor must be effectuated based on arm's-length terms and conditions; (2) neither the distributing corporation, controlled corporation, nor any distributing controlled corporation related person or controlled corporation related person participates in any profit gained by the creditor upon the exchange of section 361 consideration, or limits by agreement or other arrangement any profit of the creditor gained upon the exchange of section 361 consideration; (3) the creditor acts for its own account with regard to all components of the direct issuance transaction; and (4) the creditor bears the risk of loss with respect to the refinanced historical distributing corporation debt and any subsequent sale or other disposition of section 361

consideration transferred to the creditor in satisfaction of the refinanced historical distributing corporation debt. However, pursuant to proposed § 1.361–5(e)(4)(ii)(B)(2)(iii), the satisfaction of all these aforementioned requirements is substantial evidence of qualification.

Third, proposed § 1.361–5(e)(4)(ii)(B)(3) would provide that, if the creditor holds the refinanced historical distribution corporation debt for a period of less than 30 days ending on the control distributing date, then that fact is evidence of non-qualification. Conversely, if the creditor holds that debt for a period of at least 30 days ending on control distribution, then that fact is evidence of qualification.

Fourth, proposed § 1.361–5(e)(4)(ii)(B)(4) would provide that if the distributing corporation has legal or practical dominion or control over any proceeds of the refinanced historical distributing corporation debt (as determined in accordance with § 1.357–(e)(2)), then that fact is substantial evidence of non-qualification. However, the distributing corporation's lack of legal or practical dominion or control over any of those proceeds is substantial evidence of qualification.

Fifth, proposed § 1.361–5(e)(4)(ii)(B)(5) provides that if the distributing corporation issued the refinanced historical distributing corporation debt with a principal purpose of avoiding any of the requirements or limitations of section 361, then that fact is evidence of non-qualification.

(b) Safe Harbor for Direct Issuance Transactions

Proposed § 1.361–5(e)(4)(iii) would provide a safe harbor for direct issuance transactions. A direct issuance transaction would qualify under the safe harbor to be treated as a qualifying debt elimination transaction only if all the following requirements are satisfied: (1) the distributing corporation does not have, at any time, legal or practical dominion or control over any proceeds of the refinanced historical distributing corporation debt, as determined in accordance with § 1.357–(e)(2); (2) the creditor holds the refinanced historical distributing corporation debt for a period of not less than 30 days ending on the control distribution date; (3) each exchange of section 361 consideration for refinanced historical distribution corporation debt between the distributing corporation and the creditor is effectuated on arm's-length terms and conditions; (4) none of the distributing corporation, controlled corporation, or any distributing controlled corporation

related person or controlled corporation related person participates in any profit gained by the creditor upon the exchange of section 361 consideration, or limits by agreement or other arrangement any profit gained by the creditor upon the exchange of section 361 consideration; (5) the creditor acts for its own account with regard to all components of the direct issuance transaction; and (6) the creditor bears the risk of loss with respect to the refinanced historical distributing corporation debt and any subsequent sale or other disposition of section 361 consideration transferred to the creditor in satisfaction of the refinanced historical distributing corporation debt. For purposes of the proceeding requirement, proposed § 1.361–5(e)(4)(iv) would provide that the creditor is not treated as bearing the risk of loss with respect to the refinanced historical distributing corporation debt if the creditor enters into a variable pricing or similar arrangement with the distributing corporation (or a controlled corporation, distributing corporation related person, or controlled corporation related person) with regard to any section 361 consideration.

V. Federal Income Tax Treatment and Consequences of Post-Distribution Payments

A. Notice 2024–38

As stated in section 2.02(6) of Notice 2024–38, the Treasury Department and the IRS are considering the application of the Code to post-distribution payments. Proposed § 1.361–1(b)(42) would define a “post-distribution payment” as a transfer of money or other property by the controlled corporation to the distributing corporation (or vice versa) after the control distribution date pursuant to the plan of reorganization.

In Notice 2024–38, the Treasury Department and the IRS expressed the view that a post-distribution payment is treated as section 361 consideration only if the taxpayer establishes that (i) the character of the payment for Federal income tax purposes is section 361 consideration, (ii) as of the first distribution date, the fair market value of the distributing corporation's right to receive the payment was not (or will not be) reasonably ascertainable (*see Burnet v. Logan*, 283 U.S. 404, 413 (1931)), and (iii) the payment will be properly accounted for when received. For the avoidance of doubt, the Treasury Department and the IRS also expressed the view in Notice 2024–38 that *Arrowsmith v. Commissioner*, 344 U.S. 6 (1952), applies solely to the

requirement described in clause (i) of the preceding sentence (that is, characterization of the post-distribution payment for Federal income tax purposes).

B. Stakeholder Input

As an initial matter, stakeholders have stated in their feedback that post-distribution payments between the distributing corporation and the controlled corporation in connection with both section 355(c) transactions and divisive reorganizations are subject to different doctrines (for example, *Arrowsmith* or the open transaction doctrine) depending on the facts and circumstances. Due to the variable fact patterns, the non-recurring nature of such payments, and the complex interplay of the legal provisions governing such payments, one stakeholder has contended that additional substantive guidance (for example, in the form of Treasury regulations) would not be appropriate, and that the Treasury Department and the IRS should continue to address this topic through the IRS's private letter ruling program.

Stakeholders also have contended that indemnification payments made under the governing transaction documents, which constitute the overwhelming majority of post-distribution payments, clearly are subject to the *Arrowsmith* doctrine and should be characterized as either (i) a contribution by the distributing corporation to the controlled corporation, or (ii) a payment of section 361 consideration by the controlled corporation to the distributing corporation, unless the transaction documents result in the assumption of a liability under section 357(d). Accordingly, other than limited guidance with respect to the treatment of so-called “indemnity purges” (that is, the distributing corporation's satisfaction of a liability with cash on hand and subsequent reimbursement by the controlled corporation), stakeholders have expressed the view that substantive guidance is unnecessary.

With regard to such indemnity purges, stakeholders have recommended different approaches for the proposed regulations. One stakeholder has recommended (i) treating the distributing corporation's receipt of the indemnity payment from the controlled corporation as section 361 consideration, and (ii) treating the distributing corporation's payment of the indemnified liability as a transfer of such section 361 consideration to a creditor in satisfaction of section 361(b)(3) (that is, a post-distribution

payment). Alternatively, other stakeholders have suggested (i) treating the liability giving rise to the indemnity payment as having been assumed by the controlled corporation under the principles of section 357(d), and (ii) treating the distributing corporation as having received payment from, and as making a payment to satisfy the liability as an agent of, the controlled corporation.

C. Proposed Regulations

1. General Treatment of Target Corporations Under Section 361(a)

Consistent with section 361(a), these proposed regulations generally would provide that a target corporation (including a distributing corporation) that is a party to a reorganization does not recognize gain or loss on its transfer of property to an acquiring corporation (including a controlled corporation) if the following three requirements are satisfied. First, proposed § 1.361–2(a)(1) would require that the acquiring corporation (or a corporation controlling the acquiring corporation) must be a party to the reorganization. Second, proposed § 1.361–2(a)(2) would require that the target corporation must receive solely stock or securities of the acquiring corporation (or the corporation controlling the acquiring corporation) in exchange for the transferred property. Third, proposed § 1.361–2(a)(3) would require that the exchange must occur pursuant to the plan of reorganization.

2. Receipt of Money or Other Property

a. In General

If proposed § 1.361–2(a) would apply to an exchange between a target corporation and an acquiring corporation but for the fact that the target corporation receives money or other property in addition to stock and securities of the acquiring corporation (or of a corporation controlling the acquiring corporation), then proposed § 1.361–3 would govern the exchange. See §§ 1.361–2(b) and 1.361–3(a)(1).

In general, proposed § 1.361–3(b)(1) and (2) would provide that, in an acquisitive reorganization, the target corporation does not recognize gain on the receipt of money or other property provided that, pursuant to the plan of reorganization, the target corporation distributes the money or other property to its shareholders or transfers that property to a creditor in satisfaction of target corporation debt.

Additional requirements would apply in the case of a divisive reorganization. In that case, proposed § 1.361–3(c)(1) would provide that the distributing

corporation does not recognize gain on the exchange if, pursuant to the plan of reorganization, (i) the distributing corporation deposits the money received in the exchange in a segregated account, and (ii) the distributing corporation distributes the money or other property received in the exchange to the distributing corporation's shareholders no later than the end of the 12-month period beginning on the date of the exchange. Under proposed § 1.361–3(c)(2)(i), similar rules would apply with respect to transfers of the money or other property received in the exchange to creditors of the distributing corporation in satisfaction of distributing corporation debt.

However, under proposed § 1.361–3(c)(2)(ii), the aggregate amount of money and the fair market value of other property transferred to creditors that is treated as distributed to shareholders would be limited to the amount by which the aggregate adjusted basis of the assets transferred by the distributing corporation to the controlled corporation exceeds the aggregate amount of distributing corporation liabilities assumed by the controlled corporation. Moreover, transfers to creditors of the distributing corporation would be subject to the requirements set forth in proposed § 1.361–5. See the prior discussion in part IV.C.3 of this Explanation of Provisions. Consistent with the Treasury Department's and the IRS's efforts to encourage taxpayers to undertake bona fide corporate reorganizations by providing sufficient transactional flexibility, the proposed regulations governing transfers of section 361 consideration to creditors would be based in part on whether such transfers occur pursuant to a target corporation's (including a distributing corporation's) plan of reorganization. See the prior discussion in part III.C of this Explanation of Provisions.

Under proposed § 1.361–3(d), the failure to distribute the money or other property received in the exchange in the manner set forth in proposed § 1.361–3(b) or (c) would result in the recognition of gain by the target corporation. The amount of gain recognized would not exceed the sum of (i) the amount of money received but not distributed, and (ii) the fair market value of the other property received but not distributed. Consistent with section 361(b)(2), proposed § 1.361–3(e) would provide that the target corporation does not recognize a loss if it receives money or other property in addition to stock or securities of the acquiring corporation.

b. Treatment of Post-Distribution Payments

i. In General

Proposed § 1.361–3(c)(3) would provide that, in a divisive reorganization in which the distributing corporation receives a post-distribution payment, the distributing corporation does not recognize any gain under proposed § 1.361–3(c)(1) or (2) only if three conditions are satisfied. First, the post-distribution payment constitutes section 361 consideration for Federal income tax purposes. Second, the distributing corporation places the post-distribution payment in a segregated account pursuant to the plan of reorganization. Third, pursuant to the plan of reorganization, the distributing corporation distributes the post-distribution payment to its shareholders or to its creditors (in satisfaction of distributing corporation debt in a transfer meeting the requirements set forth in proposed § 1.361–5) by the later of (i) 90 days after the date on which the distributing corporation receives the post-distribution payment, or (ii) the end of the 12-month period beginning on the date of the exchange described in proposed § 1.361–3(a)(1).

For purposes of proposed § 1.361–3(c)(3), a post-distribution payment would constitute section 361 consideration (and not, for example, a separate payment for goods or services) for Federal income tax purposes only if the three requirements in proposed § 1.361–3(c)(3)(i) are satisfied. First, the payment must properly be characterized for Federal income tax purposes as consideration that the distributing corporation receives in the exchange described in proposed § 1.361–3(a)(1). See generally *Arrowsmith*, 344 U.S. 6. Second, the fair market value of the distributing corporation's right to receive the post-distribution payment must not be reasonably ascertainable as of the exchange date. See generally *Burnet*, 283 U.S. 404. Third, the distributing corporation must properly account for the payment upon receipt, in accordance with the plan of reorganization.

Similar rules would apply to the receipt of a post-distribution payment by a controlled corporation. In this respect, proposed § 1.361–3(c)(4) would provide that, if a controlled corporation receives a post-distribution payment, the aggregate adjusted basis of the assets transferred by the distributing corporation to the controlled corporation is increased for purposes of proposed § 1.361–3(c)(2)(ii) only if three requirements similar to those described in the prior paragraph are satisfied.

ii. Treatment of Payments Under Indemnification Agreements

These proposed regulations would not treat payments made in respect of indemnification agreements as post-distribution payments in certain circumstances. Instead, proposed § 1.357-2(e)(2)(iii)(A) would treat (i) the underlying liability as having been assumed by the controlled corporation, and (ii) the receipt of the indemnification payment as not within the legal or practical dominion or control of the distributing corporation for purposes of proposed § 1.357-2(e)(1). *See* the discussion in part VIII.B.3.b of this Explanation of Provisions.

3. Treatment of Distributions

a. Qualified Property

Consistent with section 361(c)(1), proposed § 1.361-4(a)(1) generally would provide that a target corporation (including a distributing corporation) recognizes no gain or loss on a distribution of qualified property to its shareholders pursuant to a plan of reorganization. Proposed § 1.361-4(a)(2)(i) would provide that the target corporation in an acquisitive reorganization is treated as distributing qualified property to its shareholders for purposes of proposed § 1.361-4(a)(1) if the target corporation transfers qualified property to a creditor pursuant to the plan of reorganization and in satisfaction of target corporation debt. To obtain similar treatment in the case of a divisive reorganization, proposed § 1.361-4(a)(2)(ii) would provide that the distributing corporation's transfer of qualified property to a creditor in satisfaction of distributing corporation debt also must meet the requirements in § 1.361-5.

b. Appreciated Nonqualified Property

Under proposed § 1.361-4(b)(1) and (c), if a target corporation distributes appreciated nonqualified property to its shareholders pursuant to a plan of reorganization, the target corporation would recognize gain (but not loss) as if it sold the property to its shareholders at the property's fair market value. Proposed § 1.361-4(b)(2) would provide that, if such property is subject to a liability, or if a shareholder assumes a liability of the target corporation in connection with the distribution, the fair market value of that property for purposes of proposed § 1.361-4(b)(1) is treated as an amount not less than the amount of that liability.

For this purpose, proposed § 1.361-1(b)(4) would define "appreciated nonqualified property" as property

other than qualified property that, at the time of the distribution of that property, has a fair market value that exceeds its adjusted basis in the hands of the target corporation. For example, appreciated nonqualified property would include controlled corporation stock or securities held by the distributing corporation prior to the exchange under section 361. The definition in proposed § 1.361-1(b)(4) also would include all controlled corporation stock or securities that (i) is treated as other property under section 355(a)(3)(B), (ii) is distributed in a disqualified distribution (as defined in section 355(d)(2)), or (iii) is distributed by a distributing corporation pursuant to an acquisition described in section 355(e)(2).

VI. Effect of Transaction Related to Divisive Reorganization on Controlled Securities

A. Notice 2024-38

As stated in section 2.02(7) of Notice 2024-38, the Treasury Department and the IRS are considering the impact of the application of general Federal income tax principles (including the substance-over-form doctrine and other relevant theories) to acquisitions of a controlled corporation following the control distribution date that result in a modification of the controlled corporation's securities. For example, the Treasury Department and the IRS are considering whether general Federal income tax principles could preclude qualification under section 361(c)(3) if (i) the controlled corporation issued securities that were treated by the distributing corporation as section 361 consideration that could be used to satisfy its creditors, and (ii) the controlled corporation subsequently merged into an acquiring corporation in a transaction resulting in the modification of those securities. In response to feedback received following the publication of Rev. Proc. 2018-53, Notice 2024-38 stated the view of the Treasury Department and the IRS that Rev. Rul. 98-27, 1998-1 C.B. 1159, is not relevant for determining whether any such transaction or series of transactions should cause the divisive reorganization to be recast, because that revenue ruling addresses solely whether the controlled corporation was a "controlled corporation" under section 355(a) immediately before the distribution. *See also generally* Rev. Rul. 98-44, 1998-2 C.B. 315.

B. Stakeholder Input

Stakeholders have suggested that the focus on debt instrument modifications

in Notice 2024-38 is directed toward transactions involving a post-distribution merger of a controlled corporation into a third-party corporation and whether the purported controlled corporation debt should be treated as qualified property for purposes of section 361(c)(2)(B). Stakeholders have requested clarification that controlled corporation debt will not be treated as non-qualified property to the extent that (i) modifications of such debt are not "significant modifications" within the meaning of § 1.1001-3 (disregarded modifications), or (ii) the modifications are a "significant modification" under § 1.1001-3 as a result of which the holder of such debt is treated as receiving a new debt instrument in a nonrecognition transaction (nonrecognition modifications).

Stakeholders also have recommended that a deemed or unplanned transaction occurring after the distribution should not cause the controlled corporation's debt to be treated as something other than controlled corporation debt for purposes of section 361(c). Additionally, stakeholders have asserted that (i) step transaction principles should not be applied to the extent the result of the transaction is consistent with the policies of section 361, and (ii) a recast of the transaction would be at odds with the provisions of § 1.1001-3 applicable to nonrecognition modifications.

Stakeholders have recommended that, if guidance is issued on this topic, safe harbors should be provided with respect to both disregarded modifications and nonrecognition modifications to allow controlled corporation debt to be treated as qualified property under section 361(c).

C. Proposed Regulations

The Treasury Department and the IRS anticipate providing proposed guidance on this topic as part of a guidance package that includes the finalization of these proposed regulations. The Treasury Department and the IRS believe that additional study and stakeholder feedback would be appropriate, rather than the publication of proposed rules at this time. It is the position of the Treasury Department and the IRS that the series of transactions described in section 2.02(7) of Notice 2024-38 merit additional scrutiny but, until the completion of this study, should be addressed by the IRS on a case-by-case basis. With regard to additional stakeholder feedback on this topic, the Treasury Department and the IRS particularly would welcome suggestions on appropriate bright-line

rules or safe harbors, as well as supporting analysis that discusses how those suggestions would balance the compliance, increased certainty, and transaction facilitation objectives that guide these proposed regulations.

As set forth in section 2.02(7) of Notice 2024–38, the Treasury Department and the IRS do not view Rev. Rul. 98–27 and Rev. Rul. 98–44 as determinative for questions regarding the impact of the application of general Federal income tax principles to acquisitions of a controlled corporation following the control distribution date that result in a modification of the controlled corporation's securities. For the avoidance of doubt, and consistent with the discussion in part IV.C.1 of this Explanation of Provisions, this view of the Treasury Department and the IRS also directly extends to Rev. Rul. 2003–79, 2003–29 I.R.B. 80. None of Rev. Rul. 98–27, Rev. Rul. 98–44, or Rev. Rul. 2003–79 sets forth broadly applicable principles regarding the application of the step transaction or substance-over-form doctrines beyond the fact patterns directly addressed by those rulings.

VII. Replacement of Distributing Debt

A. Notice 2024–38

As stated in section 2.02(8) of Notice 2024–38, the Treasury Department and the IRS are considering the application of the Code to borrowings by a distributing corporation that replace distributing corporation debt satisfied with section 361 consideration in a divisive reorganization. The Treasury Department and the IRS are concerned that, in certain circumstances, the replacement of distributing corporation debt that was satisfied with section 361 consideration could be used as an artifice for increasing the aggregate debt and other liabilities of the distributing corporation and the controlled corporation.

As one example, the Treasury Department and the IRS have considered situations in which, as of the date on which assets are contributed to a controlled corporation in a divisive reorganization, the distributing corporation anticipates entering into a borrowing that effectively reverses the de-leveraging achieved through the distribution of section 361 consideration pursuant to the plan of reorganization. Such a borrowing would render the de-leveraging merely transitory and without real economic effect. As emphasized in Notice 2024–38, the Treasury Department and the IRS are concerned that this result resembles a partial sale of the controlled corporation that would not qualify for

nonrecognition treatment under section 361.

B. Stakeholder Input

Stakeholders have acknowledged the aforementioned potential for abuse and the potential treatment of such transactions as partial sales. However, stakeholders have contended that distributing corporations generally do not plan to replace historical debt satisfied in the section 355 transaction. Accordingly, stakeholders have suggested that any substantive guidance on this issue (i) should be narrowly tailored to address abusive structures that do not reflect the policies of section 361, and (ii) should take into account distributing corporations' need to borrow in the ordinary course of business and obtain funding for circumstances unrelated to the section 355 transaction. Stakeholders also have suggested that the main difficulty in issuing guidance will be identifying clear anti-abuse principles that sufficiently differentiate between artificial post-distribution re-leveraging transactions (which should be disallowed) and genuine post-distribution re-leveraging transactions with a bona fide commercial purpose unrelated to the divisive transaction (which should be allowed).

One stakeholder has recommended providing a safe harbor for transactions that do not raise debt replacement concerns, in order to increase certainty for taxpayers pursuing bona fide transactions. According to the stakeholder, the common factors in those transactions that should be included in such a safe harbor are: (i) a genuine non-tax business purpose for the re-leveraging transaction; (ii) use of the re-leveraging proceeds in a manner consistent with such business purpose; and (iii) a non-tax economic effect of the re-leveraging transaction.

The stakeholder has further recommended evaluating re-leveraging transactions that fall outside the aforementioned safe harbor based on all facts and circumstances. According to the stakeholder, factors that would support respecting the re-leveraging as a new borrowing for Federal income tax purposes include: (i) the existence of a non-tax business purpose supporting the re-leveraging transaction; (ii) the use of re-leveraging proceeds in a manner consistent with such business purpose; (iii) the absence of a plan to enter into the re-leveraging transaction at the time of the distribution; (iv) the passage of time between the distributing corporation's satisfaction of debt with section 361 consideration and the re-leveraging transaction; (v) the

occurrence of the re-leveraging transaction in the ordinary course of business and/or the consistency of the transaction with historical practices; and (vi) evidence that, as a result of the de-leveraging transaction, the distributing corporation was appropriately leveraged from a capital markets perspective.

In contrast, according to the stakeholder, the following factors would not support respecting the re-leveraging as a new borrowing. First, the lenders with regard to the re-leveraging transaction are the same as those with regard to the distributing corporation debt satisfied in the de-leveraging transaction. Second, the terms of the new distributing corporation debt are the same as (or substantially similar to) the terms of the distributing corporation debt satisfied in the de-leveraging transaction. Third, the proceeds of the re-leveraging transaction are retained (unless such retention is consistent with the business purpose for the re-leveraging). Finally, the de-leveraging transaction, when taken together with the re-leveraging transaction, has little or no economic effect.

C. Proposed Regulations

1. Overview

The Treasury Department and the IRS appreciate the feedback provided by stakeholders regarding transitory borrowings. In developing these proposed regulations, the Treasury Department and the IRS have attempted to balance the compliance and increased certainty objectives with the understanding that distributing corporations should be able to borrow in the ordinary course of business and obtain financing for circumstances demonstrably unrelated to the divisive reorganization (that is, the transaction facilitation objective).

2. General Rule

Proposed § 1.361–5(f)(1) generally would reduce the amount of section 361 consideration that the distributing corporation is treated as transferring to a creditor in a qualifying debt elimination transaction by the amount of eligible distributing corporation debt that is “transitorily eliminated.” Proposed § 1.361–5(f)(2)(i) would treat a distributing corporation as transitorily eliminating an amount of eligible distributing corporation debt equal to the amount of such debt that the distributing corporation or a distributing corporation related person replaces after the earliest applicable date, directly or indirectly, with borrowing that the distributing corporation or any

distributing corporation related person expects or is committed to, directly or indirectly, before that date. For this purpose, relatedness to the distributing corporation would be determined by examining all relevant relationships immediately after the earliest applicable date.

The proposed regulations would set forth the earliest applicable date as the relevant date for examining the issuance of distributing debt that potentially could give rise to a transitory elimination of eligible distributing corporation debt. Principally, the Treasury Department and the IRS have selected the earliest applicable date as the relevant date for purposes of these proposed rules because that date also would serve generally under these proposed regulations as the bright line for determining whether distributing corporation debt qualifies as historical distributing corporation debt. Therefore, a proposed rule that focused on distributing corporation borrowings after that date, and which the distributing corporation expected or was committed to before that date, would connect logically to the proposed earliest applicable date for determining historical distributing corporation debt. Connecting such proposed rules to a single relevant date (that is, the earliest applicable date) is intended to help achieve the increased certainty objective of these proposed regulations, and consequently the compliance and transaction facilitation objectives as well.

3. Exceptions to General Transitory Debt Elimination Rule

Based on feedback from stakeholders, proposed § 1.361–5(f)(2)(ii) and (iii) would provide exceptions to the general transitory debt elimination rule for ordinary course borrowings and borrowings resulting from unexpected events. With regard to each of these exceptions, the intent of the Treasury Department and the IRS is to provide safe harbors for borrowings that could not have had any connection to the distributing corporation's elimination of eligible distributing corporation debt because such borrowings would have occurred regardless of the occurrence of the divisive reorganization. In proposing these exceptions, the Treasury Department and the IRS are guided conceptually by existing regulations under section 355(e) (section 355(e) regulations) addressing non-plan factors for determining the existence of a plan. The intent of extending those principles to these proposed regulations is to increase certainty for taxpayers and the

IRS by providing rules based on long-standing Treasury regulations.

a. Ordinary Course Borrowings

The Treasury Department and the IRS have proposed an ordinary course borrowing exception in proposed § 1.361–5(f)(2)(iii) to help achieve the increased certainty and transaction facilitation goals of these proposed regulations. Specifically, the Treasury Department and the IRS do not intend for the safeguards against transitorily eliminated distributing corporation debt to prevent the distributing corporation from engaging in its ordinary course business activities. Although the Treasury Department and the IRS agree with stakeholders that proposed rules on this issue would be challenging to provide in bright-line form, the purpose of these proposed rules is to reduce uncertainty by removing from consideration of the general rule those borrowings that the distributing corporation readily could identify as part of its ordinary course business operations.

Consequently, the proposed regulations would provide that a replacement borrowing is not treated as transitorily eliminating eligible distributing corporation debt if the replacement borrowing (i) is incurred in the ordinary course of business of the distributing corporation or distributing corporation related person, and (ii) would have been incurred without regard to the divisive reorganization (or any transaction related to the divisive reorganization). See proposed § 1.361–5(f)(2)(iii). The Treasury Department and the IRS based this proposed rule conceptually on § 1.355–7(b)(4)(vi) (“In the case of an acquisition either before or after a distribution, the distribution would have occurred at approximately the same time and in similar form regardless of the acquisition or a similar acquisition.”).

b. Unexpected Borrowings

In addition, proposed § 1.361–5(f)(2)(ii) would provide that certain borrowings are not treated as expected (or otherwise committed) borrowings and, therefore, are not within the scope of the general rule of proposed § 1.361–5(f)(2)(i) if two conditions are met. First, proposed § 1.361–5(f)(2)(ii)(A) would require that a borrowing after the earliest applicable date must result from an event unrelated to the divisive reorganization and not in the ordinary course of business of the distributing corporation. Second, proposed § 1.361–5(f)(2)(ii)(B) would require that the borrowing must result from changed circumstances not expected prior to the

control distribution date. The Treasury Department and the IRS are proposing this exception to provide increased certainty and facilitate bona fide transactions by reinforcing that a borrowing not in the ordinary course of business also should be excepted from application of the general rule, provided that the distributing corporation establishes that such borrowing results from an event that could not have been related to the divisive reorganization.

In formulating the foregoing proposed rules, the Treasury Department and the IRS have relied on the same standard employed by the section 355(e) regulations for determining the existence of a plan. See § 1.355–7(b)(4)(ii) (“In the case of an acquisition after a distribution, there was an identifiable, unexpected change in market or business conditions occurring after the distribution that resulted in the acquisition that was otherwise unexpected at the time of the distribution.”) and (iv) (“In the case of an acquisition before a distribution, there was an identifiable, unexpected change in market or business conditions occurring after the acquisition that resulted in a distribution that was otherwise unexpected.”). It is the intent of the Treasury Department and the IRS that exceptions based on the established section 355(e) regulations would facilitate bona fide transactions in the same manner that the section 355(e) regulations facilitate such transactions while addressing the challenging issue of determining the existence of a plan.

VIII. Application of Section 357 to Assumptions of Liabilities

A. Overview of Proposed Regulations

The Treasury Department and IRS appreciate the feedback received from stakeholders addressing the interaction and separate operation of sections 357 and 361. From the perspective of the Treasury Department and the IRS, such feedback was insightful and has been helpful in the development these proposed regulations, particularly in achieving the three objectives discussed in section 2.01 of Notice 2024–38. Leveraging this feedback, the Treasury Department and IRS have attempted to balance the objectives of (i) facilitating compliance with sections 357 and 361, (ii) providing certainty to taxpayers and the IRS, and (iii) permitting bona-fide corporate readjustments with respect to the assumption of liabilities (including assuming refinanced distributing corporation debt) and the satisfaction of debt with section 361 consideration. In other words, in these proposed regulations, the Treasury Department

and IRS have attempted to provide taxpayers with an appropriate level of transactional flexibility that is consistent, and therefore compliant, with the operation of sections 357 and 361.

B. Liability Assumptions Under Section 357

1. General Rules

Consistent with section 357(a), proposed § 1.357–2(a) generally would provide that, if a transferor receives property that would be permitted to be received under section 351 or 361 without the recognition of gain to the transferor if that property were the sole consideration received by the transferor, and if, as part of the consideration, the transferee corporation assumes a liability of the transferor, then the transferee corporation's assumption of that liability (i) will not be treated as the receipt of money or other property by the transferor, and (ii) will not prevent the exchange from being within the provisions of section 351 or 361. Under proposed § 1.357–2(b), this general rule would not preclude any liability of a transferor that is assumed by a transferee corporation from being taken into account for purposes of computing the amount of gain or loss realized to the transferor under section 1001 resulting from the exchange.

2. Amount of Liability Assumed

Proposed § 1.357–2(c) would provide that, if the transferor issues a debt that converts, pursuant to its terms, into a debt of the transferee corporation (traveling note), the transferee corporation is treated as assuming that traveling note at the time at which the debtor on that debt converts from the transferor to the transferee corporation under the terms of the note. Proposed § 1.357–2(d) also would provide general rules for determining the amount of recourse and nonrecourse liabilities assumed by a transferee corporation for purposes of §§ 1.357–2, 1.357–3, 1.357–4, 1.358–3, 1.358–5, 1.358–7, 1.361–3(c)(2), and 1.368–2(d).

The Treasury Department and the IRS are considering additional rules regarding the amount of a liability a transferee corporation is treated as assuming in connection with a transfer of property and certain tax consequences that result from such an assumption. The Treasury Department and the IRS request comments regarding these issues and rules. See REG–100818–01, *Liabilities Assumed in Certain Transactions*, 68 FR 23931 (May 6, 2003).

a. Recourse Liabilities

Proposed § 1.357–2(d)(1)(i) would provide that a recourse liability (or portion thereof) of a transferor is treated as having been assumed by the transferee corporation if, as determined based on all facts and circumstances, the transferee corporation has agreed to, and is expected to, satisfy the liability (or portion thereof), whether or not the transferor has been relieved of the liability (or portion thereof).

b. Nonrecourse Liabilities

Proposed § 1.357–2(d)(1)(ii)(A) generally would provide that a nonrecourse liability of a transferor is treated as having been assumed by the transferee corporation to which any asset subject to that liability is transferred. However, proposed § 1.357–2(d)(1)(ii)(B) would provide that the amount of any nonrecourse liability of a transferor treated as assumed is reduced by the lesser of (i) the amount of that liability that an owner of other assets not transferred to the transferee corporation and also subject to that liability has agreed with the transferee corporation to, and is expected to, satisfy, or (ii) the fair market value of such other assets (determined without regard to section 7701(g) of the Code).

3. Legal or Practical Dominion or Control Over Payment of Assumed Liability

a. General Rule

Proposed § 1.357–2(e)(1) would apply if a transferee corporation (or, in the case of a divisive reorganization, a member of the CSAG) makes a payment to satisfy an assumed liability, and if the transferor (or, in the case of a divisive reorganization, a member of the DSAG) has legal or practical dominion or control over any part of the payment. If proposed § 1.357–2(e)(1) applies, then (i) that part of the payment is treated as money or other property received by the transferor, (ii) the rules in section 351(b) or 361(b) (as applicable) apply to determine the Federal income tax consequences of the receipt of that money or other property by the transferor, and (iii) the rules in proposed §§ 1.357–2 through 1.357–4 (see the discussion in part VIII.C and D of this Explanation of Provisions) do not apply (that is, the Federal income tax consequences of the payment are not determined under section 357).

Proposed § 1.357–2(e)(2)(i) would provide that the determination of whether a payment is within the transferor's legal or practical dominion or control generally is made based on all facts and circumstances. However,

proposed § 1.357–2(e)(2)(ii) would treat a payment as within a transferor's legal or practical dominion or control if that payment is made to (i) a segregated account of the transferor (or, in the case of a divisive reorganization, a member of the DSAG), or (ii) any person through which the transferor (or, in the case of a divisive reorganization, a member of the DSAG) can direct the treatment or disposition of the payment, regardless of the brevity or transitory nature of the period in which the payment is in such an account.

b. Exceptions for Indemnification Agreements and Other Payments

These proposed regulations also would except from the general facts-and-circumstances determination certain payments that otherwise would result in the transferor having legal or practical dominion or control over the payment. Under proposed § 1.357–2(e)(2)(iii)(A), payments made pursuant to an indemnification agreement would not be treated as within the transferor's legal or practical dominion or control (and, thus, would not be treated as money or other property received by the transferor) if three requirements are satisfied. First, the transferee corporation must be legally prohibited from assuming the liability. Second, the indemnification agreement must require the transferor to first satisfy the obligation that is the subject of the indemnification before seeking payment from the transferee corporation. Third, the transferor must be in the same net economic position as it would have been had the transferee corporation legally assumed the liability.

Under proposed § 1.357–2(e)(2)(iii)(B), a payment not made pursuant to an indemnification agreement would not be treated as within the transferor's legal or practical dominion or control if (i) the payment is dedicated to the satisfaction of a liability of the transferor that is identified in an agreement or the plan of reorganization, (ii) the payment is made to an independent trustee or escrow agent that is not affiliated with the transferor, (iii) the payment is not made to any account of the transferor (or, in the case of a divisive reorganization, a member of the DSAG) or any person through which the transferor (or, in the case of a divisive reorganization, a member of the DSAG) could direct the payment, (iv) the transferor and transferee corporation treat any income, gain, or loss on the payment proceeds as income, gain, or loss of the transferee corporation, and (v) any excess of the payment account (and any income or gain thereon) over

the amount paid in satisfaction of the liability reverts to the transferee corporation.

C. Tax Avoidance Purpose Under Section 357(b)

1. Principal Purpose Standard

These proposed regulations would revise and redesignate current § 1.357–1(c) (concerning tax avoidance purpose) as proposed § 1.357–3(a) through (c). Consistent with section 357(b), proposed § 1.357–3(a)(1) would provide that § 1.357–2(a) does not apply to any exchange involving the assumption of a liability if the principal purpose of the transferor with respect to the assumption is either (i) to avoid Federal income tax on the exchange, or (ii) not a bona fide business purpose. In accordance with caselaw and the long-standing view of the Treasury Department and the IRS, proposed § 1.357–3(a)(2) also would clarify that a principal purpose described in proposed § 1.357–3(a)(1) is presumed to exist if the transferee corporation assumes a liability of the transferor that was not incurred in the ordinary course of a business of the transferor. *See Bryan v. Comm’r*, 281 F.2d 238 (4th Cir. 1960); Rev. Proc. 96–30, 1996–1 C.B. 696, *superseded by* Rev. Proc. 2024–24 (continuing to require a similar representation); Rev. Proc. 83–59, 1983–2 C.B. 575.

Consistent with section 357(b)(1) and current § 1.357–1(c), proposed § 1.357–3(b) would provide that, for purposes of determining the amount of gain recognized upon an exchange described in proposed § 1.357–3(a)(1), the total amount of liabilities assumed or acquired pursuant to the exchange (and not merely a particular liability with respect to which the tax avoidance or non-business purpose existed) is treated as money or other property received by the transferor upon the exchange. Consistent with section 357(b)(2) and current § 1.357–1(c), proposed § 1.357–3(c) would provide that, if the Commissioner determines that the transferor’s principal purpose with respect to the assumption of a liability was to avoid Federal income tax on the exchange or was not a bona fide business purpose, the burden is on the transferor to prove by a clear preponderance of the evidence that the liability assumption should not be treated as the receipt of money or other property.

2. Eligible Distributing Corporation Liabilities

With respect to divisive reorganizations, the Treasury

Department and the IRS view the allocation of distributing corporation liabilities as a fundamental aspect of separating one or more businesses. These proposed regulations are intended to facilitate the assumption of a distributing corporation’s liabilities in bona-fide divisive reorganizations in a manner that balances the objectives of complying with section 357 while providing certainty to taxpayers and the IRS.

Accordingly, as a threshold matter, proposed § 1.357–3(d)(2) generally would permit solely eligible distributing corporation liabilities to be assumed. In other words, these proposed regulations would provide that a distributing corporation is presumed to have had a principal purpose described in proposed § 1.357–3(a)(1) (and, as a result, is presumed to be treated as recognizing an amount of gain determined under proposed § 1.357–3(b)) if the controlled corporation assumes a distributing corporation liability that is not eligible to be assumed under proposed § 1.357–(d)(3). Liabilities of a distributing corporation would be eligible to be assumed under proposed § 1.357–3(d)(3) if (i) the liabilities are described in a plan of reorganization or original plan of reorganization (if amended), (ii) the liabilities were incurred in the ordinary course of business of the distributing corporation, and (iii) the assumption of the liabilities is necessary (A) to ensure the transfer to the controlled corporation of all liabilities properly associated with the business assets transferred to that corporation, and (B) to result in the controlled corporation assuming liabilities in an amount that properly relates to its business operations, the earnings of which will be used to properly satisfy those liabilities.

3. Eligible Distributing Corporation Debt

a. In General

Proposed § 1.357–3(d)(4) would provide additional requirements if the distributing corporation liabilities to be assumed are debt. The general rule in proposed § 1.357–3(d)(4)(i) would provide that distributing corporation debt generally is eligible to be assumed if such debt qualifies as historical distributing corporation debt (as defined in proposed § 1.357–1(b)(13)) (certain exceptions to the general rule are provided in proposed § 1.357–3(d)(4)(ii)).

b. Exceptions to Requirement That Eligible Distributing Corporation Debt be Historical

To facilitate the bona-fide allocation of distributing corporation debt in divisive reorganizations and to provide certainty to taxpayers and the IRS, proposed § 1.357–3(d)(4)(ii) would provide several exceptions to the requirement that the distributing corporation debt must qualify as historical distributing corporation debt. First, proposed § 1.357–3(d)(4)(ii)(A) would provide that any trade payables (as defined in proposed § 1.357–1(b)(19)) of the distributing corporation that meet the requirements set forth in proposed § 1.357–3(d)(3) (that is, the general requirements for distributing corporation liabilities eligible to be assumed) are not required to qualify as historical distributing corporation debt.

Second, proposed § 1.357–3(d)(4)(ii)(B) would provide that, if a controlled corporation assumes refinanced distributing corporation debt (as defined in proposed § 1.357–1(b)(17)), that refinanced distributing corporation debt is treated as historical distributing corporation debt if all the following requirements are met: (i) the distributing corporation has a direct business purpose for the controlled corporation’s assumption of the refinanced distributing corporation debt; (ii) the distributing corporation’s refinancing of its historical distributing corporation debt is completed before the controlled corporation’s assumption of that refinanced distributing corporation debt; (iii) following the controlled corporation’s assumption of the refinanced distributing corporation debt, the distributing corporation and the controlled corporation are in the same net economic position as each corporation would have been had the controlled corporation assumed the historical distributing corporation debt; (iv) the distributing corporation’s refinancing of its historical distributing corporation debt and the subsequent assumption of that refinanced debt are included in the plan of reorganization for the divisive reorganization; (v) there is no untaxed gain or other Federal income tax benefit to the distributing corporation or the controlled corporation resulting from the distributing corporation’s refinancing of a historical distributing corporation debt and the assumption by the controlled corporation of that refinanced distributing corporation debt; (vi) the business assets transferred by the distributing corporation to the controlled corporation in the section 361(a) exchange are associated with the

refinanced distributing corporation debt assumed by the controlled corporation; and (vii) the refinancing of historical distributing corporation debt by the distributing corporation and the subsequent assumption of that refinanced distributing corporation debt by the controlled corporation result in the controlled corporation assuming liabilities in an amount that properly relates to its business operations and will be properly satisfied with earnings generated by those operations. The foregoing requirements are derived directly from Rev. Rul. 79–258, which provides long-standing IRS guidance on the treatment of an assumption of a refinanced historical distributing corporation debt.

Third, proposed § 1.357–3(d)(4)(ii)(C) would provide that a controlled corporation’s assumption of a traveling note issued to refinance a historical distributing corporation debt is treated as an assumption of historical distributing corporation debt if the requirements with respect to refinanced distributing corporation debt described in the foregoing paragraph are met. Because the issuance of a traveling note resembles the issuance and assumption of refinanced debt, the Treasury Department and IRS are of the view that traveling notes should be subject to the same degree of scrutiny as the issuance and assumption of refinanced debt.

Fourth, proposed § 1.357–3(d)(4)(ii)(D) would provide that a revolving credit agreement to which the distributing corporation is a debtor qualifies as historical distributing corporation debt only if the distributing corporation entered into the agreement before the earliest applicable date, the agreement does not expire until after the date of the exchange described in proposed § 1.361–2(a) or 1.361–3(a), and that agreement is identified in the plan of reorganization or original plan of reorganization (if amended).

D. Liabilities in Excess of Basis Under Section 357(c)

Consistent with section 357(c) and current § 1.357–2(a), proposed § 1.357–4(a)(1) generally would provide that, in an exchange described in section 351 or in section 361 (by reason of a divisive reorganization that qualifies under sections 355 and 368(a)(1)(D)), the excess of (i) the sum of the amount of liabilities of the transferor assumed by the transferee corporation, over (ii) the total adjusted basis of the property transferred by the transferor pursuant to the exchange, is treated as gain from the sale or exchange of a capital asset or of property that is not a capital asset, as applicable. The determination of

whether gain resulting from the transfer of capital assets is long-term or short-term capital gain would be made under proposed § 1.357–4(b) by reference to the transferor’s holding period for the transferred assets, based on the proportionate fair market value of the transferor’s long-term assets to its short-term assets.

Under proposed § 1.357–4(a)(2), the general rule in proposed § 1.357–4(a)(1) would not apply to any exchange (i) to which proposed § 1.357–3(a) applies, (ii) that is pursuant to a plan of reorganization for a reorganization described in section 368(a)(1)(G) in which no former shareholder of the transferor corporation receives any consideration for the shareholder’s stock, or (iii) to which section 351 applies if that exchange also (A) qualifies as part of a reorganization described in section 368(a)(1)(A), (C), or (D) or (G) (provided the requirements of section 354(b)(1) of the Code are satisfied), and (B) is described as a reorganization in a filing with the IRS under § 1.368–3.

In addition, the following liabilities generally would be excluded under proposed § 1.357–4(a)(3)(i) for purposes of applying the general rule in proposed § 1.357–4(a)(1): (i) a liability the payment of which would give rise to a deduction; (ii) a liability the payment of which would give rise to the creation of, or increase in, the basis of any property; and (iii) a liability the payment of which would be described in section 736(a) of the Code. However, such liabilities would not be excluded under proposed § 1.357–4(a)(3)(i) to the extent (i) the incurrence of the liability resulted in a deduction, (ii) the incurrence of the liability resulted in the creation of, or an increase in, the basis of any property, or (iii) the liability is not incurred in the ordinary course of business or associated with any assets transferred.

IX. Solvency and Continued Viability of Distributing Corporation and Controlled Corporation

A. Notice 2024–38

Section 2.02(3) of Notice 2024–38 stated the view of the Treasury Department and the IRS that qualification under section 355 is limited to transactions after which the distributing corporation and the controlled corporation are capable of carrying on sustained businesses. In this regard, section 355 and related Code provisions were not enacted to provide nonrecognition treatment for section 355 transactions that burden the distributing corporation or the controlled corporation with excessive

leverage, thereby jeopardizing their ability to continue as a viable going concern. *See, for example*, S. Rep. No. 82–781, at 58 (1951) (providing, in relevant part, that the predecessor statute to section 355 was drafted “so as to limit its benefits to reorganizations in which all of the new corporations as well as the parent are intended to carry on a business after the reorganization”).

B. Stakeholder Input

Stakeholders have contended that substantive guidance under section 355, 357, or 361 is not appropriate to address the foregoing solvency concern and that additional rules to address this concern are unnecessary. First, stakeholders have asserted that section 355 already provides safeguards to prevent an abusive transaction (such as a transaction involving the allocation of excess liabilities to the controlled corporation) from qualifying under sections 355 and 361. Those safeguards include the active trade or business requirement (*see* section 355(b)), the corporate business purpose requirement (*see* § 1.355–2(b)), and the device prohibition (*see* section 355(a)(1)(B) and § 1.355–2(d)). Second, stakeholders have noted that, if a taxpayer’s principal purpose with respect to a liability assumption is to avoid Federal income tax on the exchange or is not a bona fide business purpose, the total amount of liabilities assumed is treated as money received by the taxpayer in the exchange (that is, as taxable boot). *See* section 357(b)(1). Third, stakeholders have contended that, if the controlled corporation is not expected to have the capacity to repay the assumed debt, that debt would not be respected as debt for Federal income tax purposes (and would be recharacterized as non-voting equity). Finally, stakeholders have contended that non-tax safeguards, including commercial constraints on capital allocation and structuring, State law restrictions (such as voidable transfers or fraudulent transfers), bankruptcy law, and third-party evaluations (including credit agency ratings), operate as limitations on the assumption of excessive liabilities by the controlled corporation and, thus, obviate the need for a solvency requirement under section 355.

C. Proposed Regulations

The Treasury Department and the IRS disagree that the foregoing safeguards obviate the need for additional guidance to address the solvency concern. As acknowledged by stakeholders, some distributing corporations facing substantial contingent liabilities have separated those liabilities from the

corporations' primary assets through divisive reorganizations. In numerous instances, the controlled corporation has been unable to support those liabilities through operation of the transferred business and consequently became financially unviable, notwithstanding the safeguards mentioned by stakeholders. Such separations have been successfully challenged as fraudulent transfers. *See, for example, In re Tronox Inc.*, 503 B.R. 239 (Bankr. S.D.N.Y. 2013).

The Treasury Department and the IRS view the aforementioned transactions and resulting outcomes as inconsistent with Congress's intent that section 355 "limit its benefits to reorganizations in which all of the new corporations as well as the parent are intended to carry on a business after the reorganization." S. Rep. No. 82-781, at 58 (1951). For example, the Treasury Department and the IRS are of the view that so-called "spin-to-bankruptcy" transactions, in certain situations, would fail to evidence an intent for the continued conduct of the business following the divisive reorganization.

Accordingly, the Treasury Department and the IRS intend to address these issues in forthcoming guidance concerning the active trade or business requirement under section 355(b). It is the position of the Treasury Department and the IRS that, while such guidance is pending, solvency and financial viability considerations continue to be relevant for purposes of the IRS's private letter ruling program, as reflected in Rev. Proc. 2024-24. The Treasury Department and the IRS request additional comments on this issue, taking into account the views described in this part IX.C.

Proposed Applicability Dates

Each provision of the regulations contained in this notice of proposed rulemaking is proposed to apply to transactions occurring after the date of publication of final regulations in the **Federal Register** (publication date), but only if the earliest of the following dates with respect to the transaction occurs after the publication date (general applicability date): (1) the date of the first public announcement; (2) the date of entry by the taxpayer into a written agreement; (3) the date of approval by the board of directors of the taxpayer; (4) the date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case, only if the taxpayer was a debtor in a case before such court; or (5) the date a ruling request is submitted to the IRS.

Proposed §§ 1.355-2(e), 1.355-4, and 1.355-10 would be applicable to section

355 transactions occurring after the general applicability date. Proposed §§ 1.357-1 through 1.357-4 would be applicable to assumptions of liabilities in transactions intended to qualify under section 351 or section 361 occurring after the general applicability date. Proposed §§ 1.361-1 through 1.361-5 would be applicable to exchanges under section 361 occurring after the general applicability date. Proposed §§ 1.368-1(c), 1.368-2(f), 1.368-3(a)(5), and 1.368-4 would be applicable to transactions occurring after the general applicability date.

Effect on Other Documents

The following revenue rulings are proposed to be obsoleted for transactions occurring after the date of publication of final regulations in the **Federal Register**: Rev. Rul. 2007-8, 2007-1 C.B. 469; Rev. Rul. 95-74, 1995-2 C.B. 36; Rev. Rul. 79-258, 1979-2 C.B. 143; Rev. Rul. 75-469, 1975-2 C.B. 126; Rev. Rul. 75-321, 1975-2 C.B. 123; Rev. Rul. 57-518, 1957-2 C.B. 253.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA) generally requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The general recordkeeping requirements mentioned within these proposed regulations are considered general tax records under § 1.6001-1(e). In connection with a reorganization, these records should include information regarding the amount, basis, and fair market value of all transferred property, and relevant facts regarding any liabilities assumed or extinguished as part of such reorganization. For PRA purposes, these general tax records are already approved under OMB control number 1545-0123.

The reporting requirements set forth in proposed §§ 1.355-5(a)(2) and 1.368-3(a)(5) require parties to a section 355(c) distribution or a corporate reorganization to attach a statement to their return that includes a copy of the plan of distribution or the plan of reorganization satisfying the requirements set forth in proposed §§ 1.355-4 or 1.368-4, respectively. The burden for these requirements will be approved by OMB, in accordance with 5 CFR 1320.10, under OMB control number 1545-0123 for business entities.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these proposed regulations would not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the situations to which these proposed regulations would apply are primarily section 355 transactions and acquisitive reorganizations. Such transactions primarily are engaged in by publicly traded corporations, which tend to be larger businesses. Specifically, the Research, Applied Analytics, and Statistics Division of the IRS estimates that, based on the most recent complete data available, fewer than one percent of small businesses with gross receipts under \$25 million would be subject to the requirements of these regulations annually. To the extent that transactions qualifying under section 351 or 368(a)(1) also are included, the percentage of small businesses impacted remains fewer than one percent of small businesses with gross receipts under \$25 million. In addition, the reporting burden in these proposed regulations is an incremental, additional obligation on small entities to a currently existing collection of information. Moreover, the economic impact of these proposed regulations will not be significant.

Therefore, these proposed regulations would not create significant additional obligations for, or impose any meaningful economic impact on, a substantial number of small entities. Accordingly, the Secretary certifies that the proposed regulations would not have a significant economic impact on a substantial number of small entities and a regulatory flexibility analysis under the Regulatory Flexibility Act is not required.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, the proposed regulations have been submitted to the Chief Counsel for the Office of Advocacy of the Small

Business Administration for comment on its impact on small business.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation.

These proposed regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

VI. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All commenters are strongly encouraged to submit comments electronically. The Treasury Department and the IRS will publish for public availability any comment submitted electronically or on paper to its public docket on <https://www.regulations.gov>.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing also are encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Statement of Availability of IRS Documents

Guidance cited in this preamble is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at <https://www.irs.gov>.

Drafting Information

The principal author of these proposed regulations is Justin R. Du Mouchel of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order for §§ 1.355–2(e), 1.355–4, 1.355–5, 1.355–10, 1.361–1 through 1.361–5, and 1.368–1 through 1.368–4, and removing the entry for § 1.355–2T(g) and (i) to read in part as follows:

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

* * * * *

Section 1.355–2(e) also issued under 26 U.S.C. 337(d).

* * * * *

Section 1.355–4 also issued under 26 U.S.C. 337(d).

Section 1.355–5 also issued under 26 U.S.C. 337(d).

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Section 1.355–10 also issued under 26 U.S.C. 337(d).

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Section 1.361–1 also issued under 26 U.S.C. 337(d).

Section 1.361–2 also issued under 26 U.S.C. 337(d).

Section 1.361–3 also issued under 26 U.S.C. 337(d) and 361(b)(3).

Section 1.361–4 also issued under 26 U.S.C. 337(d) and 361(b)(3).

Section 1.361–5 also issued under 26 U.S.C. 337(d) and 361(b)(3).

* * * * *

Section 1.368–1 also issued under 26 U.S.C. 337(d).

Section 1.368–2 also issued under 26 U.S.C. 337(d).

Section 1.368–3 also issued under 26 U.S.C. 337(d).

Section 1.368–4 also issued under 26 U.S.C. 337(d).

* * * * *

■ **Par. 2.** Section 1.355–1 is revised and republished to read as follows:

§ 1.355–1 Distribution of stock and securities of a controlled corporation.

(a) *Application of section 355—(1) Overview—*(i) *In general.* Section 355 of the Code provides for the separation, without recognition of gain or loss to (or the inclusion in income of) the shareholders and security holders, of one or more existing businesses formerly operated, directly or indirectly, by a single distributing corporation. Section 355 applies only to the separation of existing businesses that have been in active operation for at least five years (or to the division of a business that has been in active operation for at least five years into separate businesses), and that, in general, have been owned, directly or indirectly, for at least five years by the distributing corporation. A separation is achieved through the distribution by the distributing corporation of stock, or of stock and securities, of one or more controlled corporations (which may be pre-existing or newly created subsidiaries) to the distributing corporation's shareholders with respect to its stock or to its security holders in exchange for its securities. Section 355 contemplates the continued operation of the business or businesses existing prior to the separation.

(ii) *Scope.* Paragraph (a)(2) of this section provides general definitions that apply for purposes of the section 355 regulations. Paragraph (b) of this section describes types of distributions that may qualify under section 355, including pro rata distributions and non pro rata distributions. Paragraphs (c) and (d) of this section provide rules regarding stock rights and nonqualified preferred stock, respectively. Paragraph (e) of this section provides applicability dates for certain sections of the section 355 regulations.

(2) *Definitions.* Except as otherwise provided in the section 355 regulations, the following definitions apply for purposes of the section 355 regulations:

(i) *Code.* The term *Code* means the Internal Revenue Code of 1986, as amended.

(ii) *Commissioner.* The term *Commissioner* means the Commissioner of Internal Revenue.

(iii) *Control distribution.* The term *control distribution* means a distribution of controlled corporation stock, or of controlled corporation stock and securities, that results in the distribution by the distributing

corporation of an amount of controlled corporation stock constituting control (within the meaning of section 368(c) of the Code).

(iv) *Control distribution date*. The term *control distribution date* means the date of the control distribution.

(v) *Controlled corporation*. The term *controlled corporation* means the controlled corporation described in section 355(a)(1)(A).

(vi) *Distributing corporation*. The term *distributing corporation* means the distributing corporation described in section 355(a)(1)(A).

(vii) *Distribution*. Unless the context indicates otherwise, the term *distribution* means—

(A) With regard to a section 355(c) distribution, a single distribution or series of distributions of controlled corporation stock and securities (if any) carried out pursuant to a plan of distribution to qualify the distribution or series of distributions under section 355; or

(B) With regard to a divisive reorganization, a single distribution or series of distributions of controlled corporation stock and securities (if any) carried out pursuant to a plan of reorganization to qualify the distribution or series of distributions under section 355.

(viii) *Divisive reorganization*. The term *divisive reorganization* means a series of transactions carried out pursuant to a plan of reorganization that qualify as a reorganization described in sections 355 and 368(a)(1)(D) or (G).

(ix) *Final distribution*. The term *final distribution* means, with respect to a series of distributions, the last distribution that is made by the distributing corporation pursuant to the plan of distribution or plan of reorganization (as appropriate).

(x) *First distribution*. The term *first distribution* means, with respect to a series of distributions, the earliest distribution that is made by the distributing corporation pursuant to the plan of distribution or plan of reorganization (as appropriate).

(xi) *First distribution date*. The term *first distribution date* means the date of the first distribution.

(xii) *IRS*. The term *IRS* means the Internal Revenue Service.

(xiii) *Plan of distribution*. The term *plan of distribution* has the meaning provided in § 1.355-4.

(xiv) *Plan of reorganization*. The term *plan of reorganization* has the meaning provided in § 1.368-4.

(xv) *SEC*. The term *SEC* means the U.S. Securities and Exchange Commission.

(xvi) *Section 355 regulations*. The term *section 355 regulations* means this section and §§ 1.355-2 through 1.355-10.

(xvii) *Section 355 transaction*. The term *section 355 transaction* means either a section 355(c) distribution or a divisive reorganization.

(xviii) *Section 355(c) distribution*. The term *section 355(c) distribution* means a distribution that qualifies under section 355(a) (or so much of section 356 of the Code as relates to section 355) and section 355(c).

(b) *Non pro rata distributions*—(1) *In general*. Section 355 provides for nonrecognition of gain or loss with respect to a distribution whether or not—

(i) The distribution is pro rata with respect to all shareholders of the distributing corporation;

(ii) The distribution is pursuant to a plan of reorganization within the meaning of section 368(a)(1)(D); or

(iii) The shareholders surrender stock in the distributing corporation.

(2) *Controlled corporation stock*. Under section 355, the stock of a controlled corporation may consist of common stock or preferred stock. (See, however, section 306 of the Code and the regulations under section 306.)

(3) *Section 355 not applicable to mere exchanges of stock or securities*. Section 355 does not apply if the substance of a transaction is merely an exchange between shareholders or security holders of stock or securities in one corporation for stock or securities in another corporation. For example, if two individuals, A and B, each own directly 50 percent of the stock of corporation X and 50 percent of the stock of corporation Y, section 355 would not apply to a transaction in which A and B transfer all of their stock of X and Y to a new corporation Z for all of the stock of Z, and Z then distributes the stock of X to A and the stock of Y to B.

(c) *Stock rights*. Except as provided in § 1.356-6, for purposes of section 355, the term *securities* includes rights issued by the distributing corporation or the controlled corporation to acquire the stock of that corporation. For purposes of this section and section 356(d)(2)(B), a right to acquire stock has no principal amount. For this purpose, the term *rights to acquire stock* has the same meaning as it does under sections 305 and 317(a) of the Code. Other Code provisions governing the treatment of rights to acquire stock also may apply to certain distributions occurring in connection with a transaction described in section 355. See, for example, sections 83 and 421 through 424 of the

Code and the regulations under sections 83 and 421 through 424.

(d) *Nonqualified preferred stock*. See § 1.356-7(a) and (b) for the treatment of nonqualified preferred stock (as defined in section 351(g)(2) of the Code) received in certain exchanges for (or in certain distributions with respect to) nonqualified preferred stock or preferred stock. See § 1.356-7(c) for the treatment of the receipt of preferred stock in certain exchanges for (or in certain distributions with respect to) common or preferred stock described in section 351(g)(2)(C)(i)(II).

(e) *Applicability dates*—(1) *Section 1.355-1*—(i) *In general*. This section applies to section 355 transactions for which the earliest of the following dates occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER] (general applicability date):

(A) The date of the first public announcement (as defined in § 1.355-7(h)(10)) of the section 355 transaction.

(B) The date of entry by the distributing corporation into a written agreement to engage in the section 355 transaction.

(C) The date of approval of the section 355 transaction by the board of directors of the distributing corporation.

(D) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A)), but only if the taxpayer was a debtor in a case before such court.

(E) The date a ruling request for the section 355 transaction is submitted to the IRS.

(ii) *Transactions occurring on or before general applicability date*. For section 355 transactions occurring on or before the general applicability date, see 26 CFR 1.355-1 and 1.355-4 (revised as of April 1, 2024).

(2) *Sections 1.355-2 and 1.355-3*—(i) *In general*. Except as otherwise provided in this paragraph (e)(2), §§ 1.355-2 and 1.355-3 apply to section 355 transactions occurring after February 6, 1989. For section 355 transactions occurring on or before that date, see 26 CFR 1.355-2 and 1.355-3 (revised as of April 1, 1988).

(ii) *Section 1.355-2(e)*. Section 1.355-2(e) applies to section 355 transactions for which the earliest of the dates listed in paragraphs (e)(1)(i)(A) through (E) of this section occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER].

(iii) *Section 1.355-2(g)*. Sections 1.355-2(g) applies to section 355 transactions occurring after October 20, 2011. For rules regarding section 355

transactions occurring on or before October 20, 2011, *see* § 1.355–2T(i), as contained in 26 CFR part 1, revised as of April 1, 2011.

(3) *Section 1.355–4*. Section 1.355–4 applies to section 355 transactions for which the earliest of the dates listed in paragraphs (e)(1)(i)(A) through (E) of this section occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**].

(4) [Reserved]

(5) *Section 1.355–10*. Section 1.355–10 applies to section 355 transactions for which the earliest of the dates listed in paragraphs (e)(1)(i)(A) through (E) of this section occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**].

■ **Par. 3.** Section 1.355–2 is amended by:

- 1. Revising paragraph (e); and
- 2. Removing paragraph (i).

The revision reads as follows:

§ 1.355–2 Limitations.

* * * * *

(e) *Stock and securities distributed—*(1) *Overview.* To qualify under section 355, a distributing corporation, as part of the distribution (within the meaning of section 355(a)(1)(D)), must distribute stock, or stock and securities, of the controlled corporation.

(2) *Requirements.* A distribution does not qualify under section 355 unless, pursuant to a plan of distribution (as described in § 1.355–4) or a plan of reorganization (within the meaning of § 1.368–4), the distributing corporation satisfies the requirements set forth in either paragraph (e)(2)(i) or (ii) of this section in addition to satisfying the requirements set forth in paragraph (e)(2)(iii) of this section.

(i) The distributing corporation distributes at least an amount of stock of the controlled corporation that constitutes a control distribution within a single taxable year of the distributing corporation.

(ii) The distributing corporation distributes stock of the controlled corporation as part of a control distribution during two taxable years of the distributing corporation, but only if all distributions up to and including the control distribution are made pursuant to a binding commitment that is described in, as appropriate—

- (A) The plan of distribution; or
- (B) The plan of reorganization.

(iii) Any stock of the controlled corporation not distributed as part of the first distribution satisfies all

requirements for a qualifying retention (as described in § 1.355–10(c)).

* * * * *

■ **Par. 4.** Section 1.355–4 is revised to read as follows:

§ 1.355–4 Plan of distribution.

(a) *Plan of distribution—*(1) *Scope and purpose.* This section sets forth requirements and procedures for the determination of a plan of distribution, including the scope of distributions properly included within that plan. This section applies solely to a section 355(c) distribution. Accordingly, this section does not apply to a reorganization described in section 368(a)(1)(D) or (G) of the Code.

(2) *Definition.* For purposes of section 355 of the Code and the section 355 regulations, the term *plan of distribution* means—

- (i) A plan of distribution of the distributing corporation that—
(A) Satisfies all requirements set forth in paragraph (c) of this section; and
(B) Is filed with the IRS pursuant to § 1.355–5(a)(2);

- (ii) A plan of distribution of the distributing corporation that results from the Commissioner correcting a plan of distribution of a distributing corporation; or

- (iii) A plan of distribution of the distributing corporation that results from the Commissioner identifying a plan of distribution for a distributing corporation (in the event of a failure to file a plan of distribution with the IRS pursuant to § 1.355–5(a)(2)).

(3) *Failure to satisfy requirements.* The failure of a distributing corporation to comply with any particular requirement or procedure set forth in this section (including the failure to file a plan of distribution with the IRS pursuant to § 1.355–5(a)(2)) does not, on its own, prevent a transaction or series of transactions from being considered part of the plan of distribution.

(b) *Determination of plan of distribution—*(1) *Status generally based on plan of distribution filed by distributing corporation.* Except as provided in paragraph (b)(2) of this section, a distributing corporation establishes the plan of distribution for a transaction or series of transactions solely by—

- (i) Satisfying all requirements set forth in paragraph (c) of this section; and
- (ii) Filing the plan of distribution with the IRS pursuant to § 1.355–5(a)(2).

(2) *Correction or identification of plan of distribution due to distributing corporation's failure to file a complete plan of distribution—*(i) *In general.* If a distributing corporation files a plan of distribution with the IRS that fails to

satisfy any requirement set forth in paragraph (c) of this section, or if the distributing corporation fails to file any plan of distribution with the IRS, the Commissioner may correct or identify a plan of distribution in accordance with paragraph (b)(2)(ii) of this section.

(ii) *Status of distributions as part of a plan of distribution.* The Commissioner may determine that a distribution or series of distributions should be included in, or excluded from, a plan of distribution described in paragraph (b)(2)(i) of this section based on—

(A) All facts and circumstances regarding the distribution or series of distributions; and

(B) All relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine.

(c) *Requirements for a plan of distribution.* To qualify as a plan of distribution described in paragraph (a)(2)(i) of this section, the distributing corporation must satisfy all requirements set forth in paragraphs (c)(1) through (3) of this section. For purposes of this paragraph (c) and paragraph (d) of this section, the term *official records* includes a contract or other agreement to which the distributing corporation is a party, a resolution or other document authorized by the distributing corporation's board of directors, or other document filed with the SEC or other Federal regulatory agency.

(1) *Documentation requirement.* The plan of distribution is provided in a single, comprehensive document that—

- (i) Identifies the distributing corporation and each controlled corporation;

- (ii) Identifies all distributions properly included in the plan of distribution (as determined pursuant to paragraph (d) of this section);

- (iii) Describes the intended Federal income tax treatment of the distributions described in paragraph (c)(1)(ii) of this section; and

- (iv) Describes the corporate business purpose for each distribution.

(2) *Adoption of plan of distribution.* Prior to the first distribution, the plan of distribution described in paragraph (a)(2)(i) of this section or an original plan of distribution that becomes the amended plan of distribution (within the meaning of paragraph (e) of this section), as applicable, is finalized and adopted by the distributing corporation, as established by—

- (i) The acts of the distributing corporation's duly authorized officers and directors; and

(ii) The distributing corporation's official records.

(3) *Completion of plan of distribution*—(i) *Expedition of prosecution of plan of distribution*—(A) *General rule.* In accordance with paragraph (c)(3)(ii) of this section, taking into account all facts and circumstances (including the one or more corporate business purposes for each distribution), the distributing corporation completes the plan of distribution as expeditiously as practicable.

(B) *24-month presumption.* The requirement in paragraph (c)(3)(i)(A) of this section is presumed to be satisfied if, in accordance with paragraph (c)(3)(ii) of this section, the distributing corporation completes the plan of distribution within the 24-month period beginning on the first distribution date.

(ii) *Completion of entire plan of distribution*—(A) *General rule.* All distributions included in a plan of distribution must be carried out in the manner described in the plan of distribution.

(B) *Failure to complete entire plan of distribution.* Except as provided in paragraph (e) of this section, if the requirement of paragraph (c)(3)(ii)(A) of this section is not satisfied, section 355 does not apply to any distribution unless the Commissioner determines the existence of a plan of distribution.

(d) *Requirements for distributions to be treated as properly included in plan of distribution.* The requirements set forth in this paragraph (d) must be satisfied for a distribution to be treated as properly included in a plan of distribution. The existence of contingencies or conditions is not conclusive in determining whether a requirement of this paragraph (d) is satisfied.

(1) *Definite intent requirement*—(i) *General rule.* Prior to the first step of the plan of distribution or of an original plan of distribution that becomes the amended plan of distribution (within the meaning of paragraph (e) of this section), the distributing corporation evidences a definite intent to carry out the distribution through a written commitment in one or more official records of the distributing corporation that substantiate the plan of distribution.

(ii) *Section 355 transactions.* With regard to a control distribution that occurs in the next taxable year after the first distribution, the distributing corporation does not establish a definite intent under paragraph (d)(1)(i) of this section unless all distributions up to and including the control distribution are effectuated pursuant to a binding

commitment of the distributing corporation. *See* § 1.355–2(e)(2)(ii).

(iii) *Relevancy of contemplated possibilities*—(A) *Contemplation irrelevant to distributing corporation's determination.* The contemplation by the distributing corporation that it may carry out a distribution is not sufficient for the distributing corporation to establish a definite intent to carry out that distribution, regardless of whether that contemplated distribution is included in an official record.

(B) *Contemplation relevant to Commissioner's determination.* The distributing corporation's contemplation of a distribution may be relevant for purposes of the correction or identification of a plan of distribution by the Commissioner pursuant to paragraph (b)(2) of this section.

(2) *Proximate relationship requirement*—(i) *General rule.* Taking into account paragraphs (d)(2)(ii) and (iii) of this section, a distribution is part of the plan of distribution to which the provisions of section 355 apply only if, on its own or as part of a series of distributions, the distribution is necessary to satisfy one or more requirements of section 355, or is an integral part of a series of distributions carried out to satisfy the requirements of section 355, as evidenced by a written commitment in one or more official records of the distributing corporation.

(ii) *Existence of independent significance not determinative.* The independent significance of a distribution (for example, the fact that a distribution has a separate business motive apart from one or more other distributions) does not preclude the satisfaction of the requirements under paragraph (d)(2)(i) of this section.

(iii) *Temporal proximity.* A distribution that takes place in close temporal proximity to one or more other distributions is not properly included in a plan of distribution under paragraph (d)(2)(i) of this section unless Federal income tax principles (including the step transaction doctrine) would apply to determine that the distribution was in substance part of the plan of distribution.

(3) *Corporate business purpose consistency requirement.* A distribution, on its own or as part of a series of distributions, is consistent with, and directly related to, one or more corporate business purposes for the one or more other distributions (for example, the distribution directly furthers one or more corporate business purposes for the one or more other distributions).

(e) *Amended plan of distribution*—(1) *Conditions.* If the distributing

corporation amends a plan of distribution described in paragraph (a)(2)(i) of this section (original plan of distribution) after the first step of the original plan of distribution (amended plan of distribution), those amendments will not cause the distributing corporation to fail to satisfy the requirements set forth in paragraph (c) of this section only if—

(i) Those amendments are in direct response to an identifiable, unexpected, and material change in market or business conditions that occurs after the date on which the original plan of distribution is adopted by the distributing corporation in the manner described in paragraph (c)(2) of this section;

(ii) Those amendments are necessary to achieve the one or more corporate business purposes for the distribution; and

(iii) The amended plan of distribution satisfies all requirements set forth in paragraph (c) of this section.

(2) *Consequences of plan of distribution amended due to changed circumstances*—(i) *Qualifying amended plan of distribution.* If the requirements set forth in paragraph (e)(1) of this section are satisfied, the provisions set forth in section 355 will apply to distributions identified in, and carried out pursuant to, the amended plan of distribution. That is, the Federal income tax consequences of all distributions included in the amended plan of distribution will be determined based on that plan of distribution (and not on the original plan of distribution).

(ii) *Non-qualifying amended plan of distribution.* If an amended plan of distribution fails to satisfy all requirements set forth in paragraph (e)(1) of this section, the Commissioner may correct the amended plan of distribution or may identify an amended plan of distribution.

(f) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples, unless otherwise provided: a distributing corporation (Distributing) owns all the stock of an existing controlled corporation (Controlled); Distributing properly files a plan of distribution with the IRS pursuant to § 1.355–5 that satisfies all requirements set forth in paragraph (c) of this section, including providing the corporate business purpose for each distribution and the intended Federal income tax treatment of those distributions (that is, a section 355(c) distribution, as defined in § 1.355–1(a)(2)(xviii)) and completing the plan of distribution as expeditiously as practicable; Distributing satisfies all requirements for qualification under

section 355; and with regard to any retained controlled corporation stock (as defined in § 1.355–10(b)(7)), the requirements set forth in § 1.355–10(c) are satisfied.

(1) *Example 1: Status of distributions as part of the plan of distribution—(i) Facts.* Official records of Distributing provide that Distributing will distribute, in a single distribution, an amount of Controlled stock constituting control (control distribution) to Distributing's shareholders during Distributing's 2025 taxable year. Such records also provide that, during Distributing's 2026 taxable year, Distributing will distribute, in a single distribution, the remaining 20 percent of Controlled stock to Distributing's shareholders (the final distribution; together with the control distribution, the separation). Official records of Distributing also provide that, during Distributing's 2026 taxable year, Distributing will distribute an appreciated asset (Asset 1) to its shareholders (Asset 1 distribution). However, the official records express only a contemplated possibility that Distributing will distribute another appreciated asset (Asset 2) to its shareholders during Distributing's 2026 taxable year (Asset 2 distribution). As reflected in official records of Distributing, the control and final distributions, and the Asset 1 and Asset 2 distributions, will enable Distributing to focus on its retained, core businesses (that is, a fit-and-focus corporate business purpose).

(ii) *Analysis—(A) Distribution of Controlled stock.* Each of the control distribution and the final distribution is properly included in the plan of distribution for the separation. First, as reflected in official records, Distributing evidences a definite intent, prior to the first step of the plan of distribution, to carry out, through a written commitment in those official records, the control distribution and the final distribution. See paragraph (d)(1)(i) of this section. Second, each of these distributions is necessary to satisfy the requirements for qualification under section 355, as evidenced by the official records of Distributing, which impose a written commitment on Distributing to make both distributions. See paragraph (d)(2)(i) of this section. Third, the control distribution and the final distribution are consistent with, and directly relate to, the fit-and-focus corporate business purpose for the distributions. See paragraph (d)(3) of this section. Accordingly, based on the correct and properly filed plan of distribution, the Federal income tax consequences of the control and final

distributions are determined under section 355.

(B) *Distribution of Asset 1.* The analysis is the same as in paragraph (f)(1)(ii)(A) of this section. Accordingly, because the Asset 1 distribution is properly included in the plan of distribution for the separation, Distributing recognizes gain on its distribution of Asset 1 under section 355(c)(2) (as opposed to section 311(b) of the Code).

(C) *Distribution of Asset 2.* The Asset 2 distribution is not properly included in the plan of distribution for the separation because not all requirements set forth in paragraph (d) of this section are satisfied. Specifically, as evidenced by official records of Distributing, Distributing treats the Asset 2 distribution as a contemplated possibility, thereby failing to evidence a definite intent to carry out the transaction. See paragraph (d)(1)(iii)(A) of this section. Accordingly, Distributing recognizes gain on its distribution of Asset 2 under section 311(b) (as opposed to section 355(c)(2)).

(2) *Example 2: Identifiable, unexpected change in market or business conditions—(i) Facts.* The facts are the same as in paragraph (f)(1)(i) of this section (*Example 1*), except for the following. Following the date of adoption of Distributing's plan of distribution for the separation, and before the intended date of the final distribution, market conditions unexpectedly deteriorate to such an extent that, in the judgment of Distributing and its advisors, the final distribution should be postponed. In response, Distributing amends its plan of distribution during its 2026 taxable year to reflect Distributing's definite intent to make the final distribution when market conditions sufficiently improve, in the judgment of Distributing and its advisors. During Distributing's 2027 taxable year, market conditions improve sufficiently to permit the final distribution, and Distributing accordingly makes the final distribution during that taxable year.

(ii) *Analysis.* The final distribution is properly included in the plan of distribution for the separation. See the analysis in paragraph (f)(1)(ii)(A) of this section (*Example 1*). Distributing's amendment of its original plan of distribution (amended plan of distribution) does not cause Distributing to fail to satisfy the requirements under paragraph (c) of this section for the following reasons. First, the amendments are in direct response to an identifiable, unexpected, and material change in market or business conditions that occurs after the date of adoption of

the original plan of reorganization. See paragraph (e)(1)(i) of this section. Second, those amendments are necessary to achieve the fit-and-focus corporate business purpose for the separation. See paragraph (e)(1)(ii) of this section. Third, Distributing's amended plan of distribution satisfies all other requirements set forth in paragraph (c) of this section. See paragraph (e)(1)(iii) of this section. Consequently, all the requirements set forth in paragraph (e)(1) of this section are satisfied and therefore the final distribution will be treated as carried out pursuant to the amended plan of distribution. That is, the Federal income tax consequences of the control distribution and final distribution, which are included in the amended plan of distribution, will be determined based on that amended plan of distribution (and not on the original plan of distribution). See paragraph (e)(2)(i) of this section.

■ **Par. 5.** Section 1.355–5 is revised to read as follows:

§ 1.355–5 Information reporting and record retention requirements.

(a) *Reporting of transaction information—(1) [Reserved]*

(2) *Plan of distribution.* With regard to a section 355(c) distribution, the distributing corporation must include, with its return for the taxable year of the first distribution, a copy of its plan of distribution for the section 355(c) distribution satisfying the requirements of § 1.355–4.

(3) *Plan of reorganization.* With regard to a divisive reorganization, see § 1.368–3(a).

(b) [Reserved]

(c) [Reserved]

(d) *Applicability date—(1) [Reserved]*

(2) *Paragraphs (a)(2) and (3).*

Paragraphs (a)(2) and (3) of this section apply to section 355 transactions for which the earliest of the following dates occurs after [date of publication of final regulations in the **Federal Register**]:

(i) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the section 355 transaction.

(ii) The date of entry by the distributing corporation into a written agreement to engage in the section 355 transaction.

(iii) The date of approval of the section 355 transaction by the board of directors of the distributing corporation.

(iv) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(v) The date a ruling request for the section 355 transaction is submitted to the IRS.

■ **Par. 6.** Section 1.355–10 is added to read as follows:

§ 1.355–10 Qualifying retentions of controlled corporation stock or securities.

(a) *Overview.* For a distribution to qualify as a section 355 transaction, there must be a genuine separation of the DSAG and the CSAG. In the case of a retention, the distributing corporation must establish to the satisfaction of the Commissioner that the retention was not pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax.

(b) *Definitions.* The following definitions apply for purposes of this section:

(1) *CSAG*—(i) *In general.* Except as provided in paragraph (b)(1)(ii) of this section, the term *CSAG* means the separate affiliated group (as defined in section 355(b)(3)(B) of the Code) of which the controlled corporation is the common parent.

(ii) *Controlled corporation not common parent.* If the controlled corporation is not the common parent of a separate affiliated group, the term *CSAG* refers to the controlled corporation.

(2) *Distributing corporation related person.* The term *distributing corporation related person* means a person that is related to a distributing corporation within the meaning of section 267(b) or 707(b)(1) of the Code, determined immediately before the control distribution date.

(3) *DSAG*—(i) *In general.* The term *DSAG* means the separate affiliated group (as defined in section 355(b)(3)(B)) of which the distributing corporation is the common parent.

(ii) *Distributing corporation not common parent.* If the distributing corporation is not the common parent of a separate affiliated group, the term *DSAG* means the distributing corporation.

(4) *Key employee.* The term *key employee* means, with regard to a business of the DSAG or CSAG, an employee—

(i) Who possesses specialized and unique expertise with regard to that business and applies that expertise in a manner that significantly preserves or improves the strength of that business (for example, through innovation or other advancement of the business);

(ii) Whose departure would be significantly detrimental to that business; and

(iii) Who would be difficult to replace due to the attributes described in paragraph (b)(4)(i) of this section.

(5) *Option.* The term *option* means a call option, a warrant, a convertible obligation, a conversion feature of convertible stock, a put option, a redemption agreement (including the right to cause the redemption of stock), any other instrument that provides for the right or possibility to issue, redeem, or transfer stock (including an option on an option), or any other similar interest.

(6) *Qualifying retention.* The term *qualifying retention* means a retention described in paragraph (c)(2) of this section.

(7) *Retained controlled corporation stock (or securities).* The term *retained controlled corporation stock (or securities)* means the following instruments that the distributing corporation continues to hold after the first distribution date:

(i) Stock or securities in a controlled corporation or another member of the CSAG.

(ii) Options to acquire stock or securities in a controlled corporation or another member of the CSAG.

(iii) Stock or securities in a controlled corporation or another member of the CSAG acquired upon the exercise of an option.

(8) *Retention.* The term *retention* means the continued ownership of retained controlled corporation stock (or securities) by a distributing corporation after the first distribution date.

(c) *General rule*—(1) *Presumption of tax avoidance.* A retention is treated as pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax unless the retention is a qualifying retention.

(2) *Qualifying retention*—(i) *In general.* A *qualifying retention* is a retention that—

(A) Satisfies all requirements set forth in paragraphs (c)(2)(ii) and (iii) of this section; or

(B) Satisfies the requirements set forth in paragraph (c)(2)(iii) of this section and meets the safe harbor set forth in paragraph (c)(3) of this section.

(ii) *Facts-and-circumstances test.* A distributing corporation establishes to the satisfaction of the Commissioner, based on all facts and circumstances (including the extent to which the safe harbor requirements described in paragraph (c)(3) of this section are satisfied), that the requirements set forth in each of paragraphs (c)(2)(ii)(A) through (E) of this section are satisfied.

(A) The distribution resulted in a genuine separation of the DSAG and the CSAG.

(B) The retention does not allow the DSAG to retain any practical control over the CSAG.

(C) There is a sufficient corporate business purpose for the retention as of the date on which the plan of distribution or the plan of reorganization (as applicable) is adopted in accordance with § 1.355–4(c)(2) or 1.368–4(d)(2), respectively.

(D) There is a sufficient corporate business purpose for the retention at all times during the period of retention.

(E) The disposition of retained controlled corporation stock (or securities) would not result in less Federal income tax to the distributing corporation (determined based on the fair market value and adjusted basis of such stock or securities on the first distribution date) than if that retained controlled corporation stock (or securities) had been distributed in the first distribution.

(iii) *Proportionate voting requirement.* The DSAG votes any retained controlled corporation stock in proportion to the votes cast by the controlled corporation's other shareholders (other than distributing corporation related persons).

(3) *Safe harbor for rebutting tax avoidance presumption*—(i) *General rule.* A distributing corporation is considered to have met the requirements of the facts-and-circumstances test set forth in paragraph (c)(2)(ii) of this section if the distributing corporation satisfies all requirements described in paragraphs (c)(3)(ii) through (vii) of this section and either—

(A) With regard to a section 355(c) distribution, includes in its plan of distribution a description of each agreement and transaction that establishes the satisfaction of the requirements described in paragraphs (c)(3)(ii) through (vii) of this section; or

(B) With regard to a divisive reorganization, includes in its plan of reorganization a description of each agreement and transaction that establishes the satisfaction of the requirements described in paragraphs (c)(3)(ii) through (vii) of this section.

(ii) *Corporate business purpose.* The distributing corporation has a specific corporate business purpose for the retention—

(A) As of the date on which the plan of distribution or the plan of reorganization (as applicable) is adopted in accordance with § 1.355–4(c)(2) or 1.368–4(d)(2), respectively; and

(B) At all times during the period of retention.

(iii) *Controlled corporation stock is widely held.* Stock of the controlled corporation (including a successor to the controlled corporation (within the meaning of § 1.355–8(c)(2))) is widely

held during the period of retention after the first distribution date. For example, stock of the controlled corporation is considered to be widely held if it is traded on an established securities market (within the meaning of § 1.7704–1(b)).

(iv) *Overlapping officers, directors, or key employees.* No officers, directors, or key employees of a member of the DSAG serve as an officer, a director, or a key employee of a member of the CSAG during the period of retention, unless—

(A) The officer, director, or key employee of a member of the DSAG serves as an officer, a director, or a key employee of a member of the CSAG solely to accommodate the CSAG's business needs;

(B) The overlapping directors do not constitute a majority of the CSAG member's board; and

(C) The duration of the overlap for officers, directors, and key employees is for an identified, limited period of time, not in excess of two years after the first distribution date.

(v) *Continuing arrangements.* Any continuing arrangement between the distributing corporation and the controlled corporation during the period of retention—

(A) Is negotiated on, and reflects, arm's-length terms; or

(B) If the arrangement is not described in paragraph (c)(3)(v)(A) of this section, is—

(1) Terminated within two years after the first distribution date; or

(2) Renegotiated within two years after the first distribution date to reflect arm's-length terms.

(vi) *Disposition of retained controlled corporation stock (or securities).* The plan of distribution or plan of reorganization, as appropriate, reflects a definite intent in the official records of the distributing corporation that the distributing corporation will dispose of all retained controlled corporation stock (or securities) by not later than the end of the five-year period beginning on the first distribution date. For purposes of this paragraph (c)(3)(vi) and paragraph (d) of this section, the term *official records* includes a contract or other agreement to which the distributing corporation is a party, a resolution or other document authorized by the distributing corporation's board of directors, or other document filed with the SEC or other Federal regulatory agency.

(vii) *Disposition of retained controlled corporation stock does not result in less Federal income tax.* The disposition of retained controlled corporation stock (or securities) would not result in less

Federal income tax to the distributing corporation (determined based on the fair market value and adjusted basis of such stock or securities on the first distribution date) than if that controlled corporation stock (or securities) had been distributed in the first distribution.

(d) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples: a distributing corporation (Distributing) is the common parent of a separate affiliated group of corporations (DSAG); the DSAG includes an existing, wholly owned controlled corporation (Controlled) with a single class of outstanding stock that is directly owned by Distributing; and the DSAG operates a banking business and a title insurance business, with Controlled operating the banking business, and the remaining DSAG members (including Distributing) operating the title insurance business.

(1) *Example 1: Not a qualifying retention—(i) Facts.* Distributing distributes 80 percent of Controlled's stock to Distributing's shareholders in a single distribution on a pro rata basis during Distributing's 2025 taxable year (first distribution). Distributing retains the remaining 20 percent of the Controlled stock (retention).

Distributing does not evidence any definite intent in its official records to dispose of the retained Controlled stock within the five-year period beginning on the first distribution date. The directors of Distributing will serve as half of the directors of Controlled for a four-year period after the first distribution date, after which time they can seek reelection. One of Distributing's purposes for the retention is to reduce the likelihood that new minority investors could acquire a substantial ownership interest in Controlled, thereby reducing Distributing's continued effective control over Controlled. Apart from whether the retention is a qualifying retention, the distribution satisfies all requirements to qualify under section 355.

(ii) *Analysis.* The retention is treated as pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax unless the retention is a qualifying retention. See paragraph (c)(1) of this section. To be a qualifying retention, the retention must satisfy the requirements under either the facts-and-circumstances test set forth in paragraph (c)(2)(ii) of this section or the safe harbor set forth in paragraph (c)(3) of this section, among other requirements. See paragraph (c)(2)(i) of this section. Distributing does not satisfy the requirements for the safe harbor set forth in paragraph (c)(3) of this section

because directors of Distributing will serve as directors of Controlled for a period that is not limited to two years after the first distribution date, and Distributing does not evidence any definite intent in its official records to dispose of the retained Controlled stock within the five-year period beginning on the first distribution date. See paragraphs (c)(3)(iv) and (vi) of this section. Distributing also fails the facts-and-circumstances test set forth in paragraph (c)(2)(ii) of this section because the control distribution does not result in a genuine separation, Distributing retains practical control over Controlled, and there is not a sufficient corporate business purpose for the retention. See paragraphs (c)(2)(ii)(A) through (D) of this section. Accordingly, Distributing's retention is not a qualifying retention. Consequently, the first distribution (and any subsequent distribution of Controlled stock) does not qualify under section 355. See paragraphs (a) and (c)(1) of this section and § 1.355–2(e)(2)(iii).

(2) *Example 2: Safe harbor—(i) Facts.* Distributing distributes 95 percent of Controlled's stock to Distributing's shareholders in a single distribution on a pro rata basis during Distributing's 2025 taxable year (first distribution) and retains 5 percent of Controlled stock (retention). The corporate business purpose for the retention, as of the date on which the plan of distribution is adopted in accordance with § 1.355–4(c)(2) and throughout the period of retention, is to enable Distributing to have assets of sufficient value (which otherwise would not be available absent the retention) to serve as collateral for needed short-term financing for Distributing's remaining business enterprise. The stock of Controlled is traded on an established securities market (within the meaning of § 1.7704–1(b)) throughout the period of retention. The plan of distribution reflects a definite intent in the official records of Distributing that Distributing will dispose of the retained Controlled stock within five years after the first distribution date. No officers, directors, or key employees of a member of the DSAG will serve as an officer, a director, or a key employee of a member of the CSAG during the period of retention. Any continuing arrangements between Distributing and Controlled during the period of retention either are negotiated on arm's-length terms or will terminate within two years after the first distribution date. The disposition of retained Controlled stock will not result in less Federal income tax to

Distributing (determined based on the fair market value and adjusted basis of such stock on the first distribution date) than if that Controlled stock had been distributed in the first distribution. The plan of distribution describes each of the foregoing agreements and transactions. Apart from whether the retention is a qualifying retention, the distribution satisfies all requirements to qualify under section 355.

(ii) *Analysis*. Distributing satisfies all requirements for the safe harbor set forth in paragraph (c)(3) of this section. However, to have a qualifying retention, Distributing also must meet the requirement set forth in paragraph (c)(2)(iii) of this section. *See* paragraph (c)(2)(i)(B) of this section.

(3) *Example 3: Overlapping directors*—(i) *Facts*. The facts are the same as in paragraph (d)(2)(i) of this section (*Example 2*), except that directors of Distributing that are recognized as experts in the banking industry will serve as two of the six directors of Controlled after the first distribution date. Their presence on the Controlled board is intended to reassure the financial markets by providing a sense of continuity. Their terms will expire after two years, at which point they cannot seek reelection during the period of retention.

(ii) *Analysis*. The two directors of Distributing that will serve as directors of Controlled do so solely to accommodate Controlled's business needs, do not constitute a majority of Controlled's board, and will not serve as directors of Controlled's board for more than two years after the first distribution date. *See* paragraph (c)(3)(iv) of this section. Accordingly, Distributing satisfies all requirements for the safe harbor set forth in paragraph (c)(3) of this section. However, to have a qualifying retention, Distributing also must meet the requirement set forth in paragraph (c)(2)(iii) of this section. *See* paragraph (c)(2)(i)(B) of this section.

(iii) *Ability to seek reelection during retention period*. The facts are the same as in paragraph (d)(3)(i) of this section (*Example 3*), except that the two directors of Distributing that will serve as directors of Controlled after the first distribution date may seek reelection after their two-year term expires. Distributing does not satisfy all requirements for the safe harbor set forth in paragraph (c)(3) of this section. *See* paragraph (c)(3)(iv)(C) of this section.

(4) *Example 4: Safe harbor is not met but facts-and-circumstances test is met*—(i) *Facts*. The facts are the same as in paragraph (d)(2)(i) of this section (*Example 2*), except that Distributing

must retain the Controlled stock (to meet collateral requirements) for at least six years after the first distribution date, as reflected in the plan of distribution and the official records of Distributing.

(ii) *Analysis*—(A) *Safe harbor requirements not satisfied*. Distributing's retention of Controlled stock does not qualify for the safe harbor set forth in paragraph (c)(3) of this section because the plan of distribution does not reflect a definite intent in the official records of Distributing that Distributing will dispose of all retained Controlled stock within five years of the first distribution date. *See* paragraph (c)(3)(vi) of this section.

(B) *Facts-and-circumstances test satisfied*. The facts-and-circumstances test set forth in paragraph (c)(2)(ii) of this section is satisfied because the control distribution results in a genuine separation of Distributing and Controlled, the retention does not allow Distributing to retain any practical control over Controlled, there is a sufficient corporate business purpose for the retention as of the date on which the plan of distribution is adopted in accordance with § 1.355-4(c)(2), there is a sufficient corporate business purpose for the retention at all times during the period of retention, and the disposition of the retained Controlled stock will not result in less Federal income tax to Distributing than if Distributing had distributed the Controlled stock in the first distribution. Accordingly, provided Distributing also meets the requirement set forth in paragraph (c)(2)(iii) of this section, the retention is a qualifying retention under paragraph (c)(2)(i)(A) of this section.

(5) *Example 5: Not a qualifying retention*—(i) *Facts*. The facts are the same as in paragraph (d)(2)(i) of this section (*Example 2*), except that Distributing owns multiple blocks of Controlled stock and the shares of retained Controlled stock are specifically designated for retention because the adjusted basis of that stock exceeds its fair market value as of the first distribution date. Distributing subsequently sells the retained Controlled stock in a transaction in which Distributing recognizes a loss for Federal income tax purposes.

(ii) *Analysis*. The retention is treated as pursuant to a plan having as one of its principal purposes the avoidance of Federal income tax unless the retention is a qualifying retention. *See* paragraph (c)(1) of this section. Distributing does not satisfy the requirements for the safe harbor set forth in paragraph (c)(3) of this section, because the disposition of the retained Controlled stock results in less Federal income tax to Distributing

than if that Controlled stock had been distributed in the first distribution. *See* paragraph (c)(3)(vii) of this section. For the same reason, the retention does not satisfy the facts-and-circumstances test set forth in paragraph (c)(2)(ii) of this section. *See* paragraph (c)(2)(ii)(E) of this section. Accordingly, the retention is not a qualifying retention. *See* paragraph (c)(2)(i) of this section. Consequently, the distribution does not qualify under section 355. *See* paragraphs (a) and (c)(1) of this section and § 1.355-2(e)(2)(iii).

■ **Par. 7.** Section 1.357-0 is added to read as follows:

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This section lists the major captions that appear in §§ 1.357-1 through 1.357-5.

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 - (4) Distributing corporation debt.
 - (i) In general.
 - (ii) Exceptions.
 - (e) Examples.
 - (1) Example 1: Application of general rule.
 - (2) Example 2: Refinanced distributing corporation debt.
 - (3) Example 3: Traveling note.
 - (4) Example 4: Trade payables.
 - (5) Example 5: Assumption to avoid Federal income tax in a divisive reorganization.
 - (6) Example 6: Assumption to avoid Federal income tax in a section 351 exchange.

(3) Example 3: Traveling note.

(4) Example 4: Trade payables.

(5) Example 5: Assumption to avoid Federal income tax in a divisive reorganization.

(6) Example 6: Assumption to avoid Federal income tax in a section 351 exchange.

§ 1.357–4 Application of section 357(c).

- (a) Liabilities in excess of adjusted basis.
 - (1) General rule.
 - (2) Exceptions.
 - (3) Certain liabilities excluded.
 - (i) General rule.
 - (ii) Exceptions.
 - (b) Determination of character of gain of multiple capital assets.
 - (c) Examples.
 - (1) Example 1: Determination of character of gain.
 - (2) Example 2: Capital and non-capital assets.
 - (3) Example 3: Liabilities in excess of adjusted basis.

§ 1.357–5 Applicability date.

- (a) Applicability date.
- **Par. 8.** Section 1.357–1 is revised to read as follows:

§ 1.357–1 Assumption of liability.

(a) *Overview.* The section 357 regulations apply to the assumption by a transferee corporation of a liability of a transferor pursuant to an exchange between the transferor and the transferee corporation in a transaction qualifying under section 351 of the Code (relating to a transfer of property to a corporation controlled by the transferor) or section 361 of the Code (relating to the nonrecognition of gain or loss to a corporation upon the exchange of

property pursuant to a plan of reorganization).

(b) *Definitions.* The following definitions apply for purposes of the section 357 regulations:

(1) *Code.* The term *Code* means the Internal Revenue Code of 1986, as amended.

(2) *Commissioner.* The term *Commissioner* means the Commissioner of Internal Revenue.

(3) *Contingent liability.* The term *contingent liability* means a liability (other than a debt) that includes one or more contingent payments.

(4) *Controlled corporation.* The term *controlled corporation* means the controlled corporation described in section 355(a)(1)(A) of the Code.

(5) *CSAG*—(i) *In general.* Except as provided in paragraph (b)(5)(ii) of this section, the term *CSAG* means the separate affiliated group (as defined in section 355(b)(3)(B)) of which a controlled corporation is the common parent.

(ii) *Controlled corporation not a common parent.* If the controlled corporation is not the common parent of a separate affiliated group, the term *CSAG* refers to the controlled corporation.

(6) *Debt.* The term *debt* means a liability pursuant to an instrument or a contractual arrangement that constitutes debt under general principles of Federal income tax law. *See* § 1.1275–1(d).

(7) *Distributing corporation.* The term *distributing corporation* means the distributing corporation described in section 355(a)(1)(A).

(8) *Distributing corporation debt*—(i) *In general.* The term *distributing corporation debt* means debt for which the distributing corporation is the obligor.

(ii) *Section 381(a) transactions.* The term *distributing corporation debt* includes a debt that satisfies both of the following requirements:

(A) The distributing corporation assumed the debt in a transaction to which section 381(a) of the Code applies; and

(B) The debt assumed in the transaction was incurred prior to the earliest applicable date.

(9) *Distributing corporation liability.* The term *distributing corporation liability* means a liability for which the distributing corporation is the obligor.

(10) *Divisive reorganization.* The term *divisive reorganization* means a series of transactions carried out pursuant to a plan of reorganization that qualify as a reorganization described in sections 355 and 368(a)(1)(D) or (G) of the Code.

(11) *DSAG*—(i) *In general.* Except as provided in paragraph (b)(11)(ii) of this

section, the term *DSAG* means the separate affiliated group (as defined in section 355(b)(3)(B)) of which the distributing corporation is the common parent.

(ii) *Distributing corporation not a common parent.* If the distributing corporation is not the common parent of a separate affiliated group, the term *DSAG* means the distributing corporation.

(12) *Earliest applicable date*—(i) *In general.* The term *earliest applicable date* means the date that is the earliest of—

(A) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the divisive reorganization or a similar transaction;

(B) The date of entry by the distributing corporation into a written agreement to engage in the divisive reorganization or a similar transaction; and

(C) The date of approval of the divisive reorganization or a similar transaction by the board of directors of the distributing corporation.

(ii) *Similar transaction.* For purposes of paragraph (b)(12)(i) of this section, the term *similar transaction* means a similar acquisition within the meaning of § 1.355–7(h)(12) and (13).

(13) *Historical distributing corporation debt.* The term *historical distributing corporation debt* means a debt of the distributing corporation that was in existence as of the earliest applicable date, has an original term that ends after the date of the exchange described in § 1.361–2(a) or 1.361–3(a), and is identified in the plan of reorganization or original plan of reorganization (if amended).

(14) *IRS.* The term *IRS* means the Internal Revenue Service.

(15) *Liability*—(i) *In general.* The term *liability* means a debt, a contingent liability, or any other fixed or contingent obligation, without regard to whether the obligation otherwise has been taken into account for Federal income tax purposes.

(ii) *Certain obligations incurred in the ordinary course of business*—(A) *In general.* Except as provided in paragraph (b)(15)(ii)(B) of this section, an obligation incurred in the ordinary course of business pursuant to a bilateral contract is not a liability.

(B) *Exception regarding financial statements.* An obligation described in paragraph (b)(15)(ii)(A) of this section is a liability, in whole or in part, to the extent the obligation is reflected in one or more financial statements of the obligor as a liability, reserve, or similar item.

(16) *Plan of reorganization*. The term *plan of reorganization* has the meaning provided in § 1.368–4.

(17) *Refinanced distributing corporation debt*. The term *refinanced distributing corporation debt* means debt of a distributing corporation—

(i) That is incurred on or after the earliest applicable date; and

(ii) The proceeds of which are used to satisfy a historical distributing corporation debt.

(18) *Section 357 regulations*. The term *section 357 regulations* means this section and §§ 1.357–2 through 1.357–5.

(19) *Trade payable*. The term *trade payable* means debt arising in the ordinary course of a business from sales, leases, licenses, or the rendition of services provided to or for the distributing corporation.

(20) *Transferee corporation*. The term *transferee corporation* means a corporation to which property is transferred pursuant to an exchange described in section 351 or 361.

(21) *Transferor*. The term *transferor* means the person that transfers property to a transferee corporation pursuant to an exchange described in section 351 or 361.

(22) *Traveling note*. The term *traveling note* means, with regard to an exchange described in section 351 or 361, a debt of the transferor that converts, pursuant to its terms, into a debt of the transferee corporation.

■ **Par. 9.** Section 1.357–2 is revised to read as follows:

§ 1.357–2 Application of section 357(a).

(a) *In general*. Except as provided in §§ 1.357–3 and 1.357–4, and subject to the requirements set forth in paragraph (e) of this section, the assumption by a transferee corporation of a liability of a transferor will not be treated as money or other property received by the transferor, and will not prevent an exchange between the transferee corporation and the transferor from being within the provisions of section 351 or 361 of the Code, if—

(1) The transferor receives property that would be permitted to be received under section 351 or 361 without the recognition of gain to the transferor if that property were the sole consideration received by the transferor; and

(2) As part of the consideration, the transferee corporation assumes a liability of the transferor.

(b) *Amount realized*. Neither section 357(a) of the Code nor this section precludes any liability of a transferor that is assumed by a transferee corporation from being taken into account for purposes of computing the

amount of gain or loss realized to the transferor under section 1001 of the Code resulting from the exchange between the transferor and the transferee corporation.

(c) *Treatment of traveling notes*. A transferee corporation is treated as assuming a traveling note with respect to which the transferor is the debtor at the time at which the debtor on the traveling note converts from the transferor to the transferee corporation under the terms of the note.

(d) *Determination of amount of liability assumed*—(1) *In general*. For purposes of this section and §§ 1.357–3, 1.357–4, 1.358–3, 1.358–5, 1.358–7, 1.361–3(c)(2), and 1.368–2(d), the rules of this paragraph (d) apply in determining the amount of liabilities assumed by a transferee corporation.

(i) *Recourse liability*. A recourse liability (or portion thereof) of a transferor is treated as having been assumed by the transferee corporation if, as determined based on all facts and circumstances, the transferee corporation has agreed to, and is expected to, satisfy or indemnify the transferor for the liability (or portion thereof), whether or not the transferor has been relieved of the liability (or portion thereof).

(ii) *Nonrecourse liability*—(A) *In general*. A nonrecourse liability of a transferor is treated as having been assumed by the transferee corporation to which any asset subject to that liability is transferred.

(B) *Limitation on amount of nonrecourse liability treated as assumed*. The amount of any nonrecourse liability of a transferor treated as assumed under paragraph (d)(1)(ii)(A) of this section is reduced by the lesser of—

(1) The amount of that liability that an owner of other assets not transferred to the transferee corporation and also subject to that liability has agreed with the transferee corporation to, and is expected to, satisfy; or

(2) The fair market value of the assets described in paragraph (d)(1)(ii)(B)(1) of this section (determined without regard to section 7701(g) of the Code).

(2) [Reserved]

(e) *Dominion or control over payment of assumed liability*—(1) *General rule*. If the transferee corporation (or, in the case of a divisive reorganization, a member of the CSAG) makes a payment to satisfy an assumed liability that results in the transferor (or, in the case of a divisive reorganization, a member of the DSAG) having legal or practical dominion or control over any part of the payment—

(i) That part of the payment is treated as money or other property received by the transferor;

(ii) The rules in section 351(b) or 361(b) (as applicable) apply to determine the Federal income tax consequences of the receipt by the transferor of the money or other property; and

(iii) The rules in this section and §§ 1.357–3 and 1.357–4 do not apply (that is, the Federal income tax consequences of the payment are not determined under section 357).

(2) *Dominion or control*—(i) *In general*. Except as provided in paragraph (e)(2)(ii) or (iii) of this section, the determination of whether a payment is within a transferor's legal or practical dominion or control is made based on all facts and circumstances.

(ii) *Segregated account; related person*. For purposes of this paragraph (e), a payment is treated as within a transferor's legal or practical dominion or control if made to a segregated account of the transferor (or, in the case of a divisive reorganization, a member of the DSAG) or any person through which the transferor (or, in the case of a divisive reorganization, a member of the DSAG) can direct the treatment or disposition of the payment, regardless of the brevity or transitory nature of the period in which the payment is in such an account.

(iii) *No legal or practical dominion or control*. For purposes of this paragraph (e), a payment is treated as not within the legal or practical dominion or control of a transferor if all conditions set forth in paragraph (e)(2)(iii)(A) or (B) of this section (as appropriate) are satisfied.

(A) *Indemnification agreements*. For payments made pursuant to an indemnification agreement:

(1) The transferee corporation is legally prohibited from assuming the liability (for example, because the transferor is prohibited from causing any other person to assume the liability).

(2) The indemnification agreement requires the transferor to first satisfy the obligation that is the subject of the indemnification agreement before the transferor is permitted to receive payment from the transferee corporation.

(3) The transferor is in the same net economic position it would have been in if the transferee corporation legally were allowed to assume the liability.

(B) *Other payments*. For any payment not made pursuant to an indemnification agreement:

(1) The payment is dedicated to the satisfaction of a liability of the transferor

identified in an agreement or the plan of reorganization.

(2) The payment is made to an independent trustee or escrow agent that is not affiliated with the transferor.

(3) The payment is not made to any account of the transferor (or, in the case of a divisive reorganization, a member of the DSAG) or any person through which the transferor (or, in the case of a divisive reorganization, a member of the DSAG) could direct the payment.

(4) The transferor and the transferee corporation treat any income, gain, or loss on the payment proceeds as income, gain, or loss to the transferee corporation.

(5) Any excess of the payment amount (and any income or gain thereon) over the amount paid to satisfy the liability reverts to the transferee corporation.

(f) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples: the principal purpose of the transferor with respect to the assumption of liabilities is not to avoid Federal income tax on the exchange; there is a bona fide business purpose for the assumption of liabilities; the amount of liabilities assumed by the transferee corporation does not exceed the adjusted basis of the assets transferred to the transferee corporation in the exchange; and any liability assumption is provided for in an agreement or a plan of reorganization entered into between the transferor and the transferee corporation before the date of the exchange.

(1) *Example 1: Application of general rule—(i) Facts.* In an exchange that qualifies under section 351, Individual A transfers to a transferee corporation property with an adjusted basis of \$10,000x in exchange for stock of the corporation with a fair market value of \$8,000x, money amounting to \$3,000x, and the assumption by the corporation of a liability of Individual A amounting to \$4,000x.

(ii) *Analysis.* Individual A's realized gain is \$5,000x, computed as follows:

TABLE 1 TO PARAGRAPH (f)(1)(ii)

Stock received, fair market value	\$8,000x
Money received	3,000x
Liability assumed by transferee corporation	4,000x
Total consideration received	15,000x
Less: Adjusted basis of property transferred	10,000x
Gain realized	5,000x

The gain recognized to Individual A is limited to the \$3,000x of money received, because the assumption of the \$4,000x liability does not constitute

money or other property. *See* paragraph (a) of this section and section 351(b).

(2) *Example 2: Dominion or control—(i) Facts.* A distributing corporation (Distributing) transfers one of its businesses to a newly formed controlled corporation (Controlled) in exchange for Controlled stock (contribution). Distributing distributes all the Controlled stock to its shareholders (distribution; together with the contribution, the separation). As part of the contribution, Controlled agrees to assume a contingent liability of Distributing. The separation satisfies all requirements to qualify as a divisive reorganization. In a taxable year following the year of the distribution, the contingent liability becomes fixed and determinable. To satisfy the liability, Controlled makes a \$200x payment to a segregated account maintained by Distributing, and Distributing uses the \$200x in the segregated account to make payment to the obligee.

(ii) *Analysis.* Distributing is treated as having dominion or control over the \$200x payment despite its receipt of the payment in a segregated account. *See* paragraphs (e)(2)(i) and (ii) of this section. Accordingly, the \$200x payment is treated as money received by Distributing in the contribution, and the rules in section 361(b) apply. *See* paragraph (e)(1) of this section.

(3) *Example 3: Exception to dominion or control—(i) Facts.* The facts are the same as in paragraph (f)(2)(i) of this section (*Example 2*), except that, as part of the contribution, Distributing and Controlled enter into an indemnity agreement with respect to a contingent liability of Distributing that Controlled cannot assume in form under State law. Pursuant to the indemnity agreement, Distributing remains the primary obligor for State law purposes, but Controlled must reimburse Distributing for any payment that Distributing is required to make to satisfy the contingent liability. The indemnity agreement is treated as an assumption by Controlled of the contingent liability under paragraph (d) of this section. In a taxable year following the year of the distribution, the contingent liability becomes fixed and determinable, and Distributing makes a \$200x payment to the obligee to satisfy the liability. Pursuant to the terms of the indemnity agreement, Controlled transfers to Distributing \$200x, which Distributing retains. The \$200x payment from Controlled to Distributing places Distributing in the same net economic position it would have been in if Controlled were allowed to assume the contingent liability under State law.

(ii) *Analysis.* For purposes of paragraph (e)(1) of this section, Distributing is treated as not having dominion or control over the \$200x payment despite its receipt of the payment. *See* paragraph (e)(2)(iii)(A) of this section. Accordingly, the \$200x payment is not treated as money received by Distributing in the contribution. *See* paragraph (a) of this section.

■ **Par. 10.** Sections 1.357–3 through 1.357–5 are added to read as follows:

§ 1.357–3 Application of section 357(b).

(a) *Principal purpose standard—(1) General rule.* Section 1.357–2(a) does not apply to any exchange involving the assumption by a transferee corporation of a liability of a transferor if the principal purpose of the transferor with respect to that assumption is either—

(i) To avoid Federal income tax on the exchange; or

(ii) Not a bona fide business purpose.

(2) *Ordinary course of business requirement.* With regard to an assumption by a transferee corporation of a liability described in paragraph (a)(1) of this section, a principal purpose is presumed to exist if the liability was not incurred in the ordinary course of a business of the transferor.

(b) *Amount of gain recognized.* For purposes of determining the amount of gain recognized upon an exchange described in paragraph (a) of this section, the total amount of liabilities assumed or acquired pursuant to that exchange (and not merely a particular liability with respect to which the tax avoidance or non-business purpose existed) is treated as money or other property received by the transferor under section 351(b) or 361(b) (as applicable) of the Code upon the exchange.

(c) *Burden of proof.* If the Commissioner determines that the transferor's principal purpose with respect to the assumption of a liability by a transferee corporation was to avoid Federal income tax on the exchange or was not a bona fide business purpose, and if the transferor contests that determination, the burden is on the transferor to prove by a clear preponderance of the evidence that the liability assumption should not be treated as the receipt of money or other property. Therefore, the transferor must prove by such a clear preponderance of all the evidence that the absence of a purpose to avoid Federal income tax on the exchange, or the presence of a bona fide business purpose, is unmistakable.

(d) *Eligible distributing corporation liabilities—(1) Scope.* The rules of this

paragraph (d) apply solely to divisive reorganizations.

(2) *In general.* A distributing corporation is presumed to have the principal purpose described in paragraph (a) of this section (and, as a result, is presumed to be treated as recognizing an amount of gain determined under paragraph (b) of this section) if the controlled corporation assumes a distributing corporation liability that is not eligible to be assumed under paragraph (d)(3) of this section.

(3) *Eligible assumptions of Distributing corporation liabilities.* Distributing corporation liabilities are eligible to be assumed under § 1.357–2(a) in a divisive reorganization if—

- (i) The distributing corporation liabilities to be assumed are described in a plan of reorganization or original plan of reorganization (if amended);
- (ii) The distributing corporation liabilities were incurred in the ordinary course of business of the distributing corporation; and
- (iii) The assumption of such distributing corporation liabilities is necessary—

(A) To ensure the transfer to the controlled corporation of all liabilities properly associated with the business assets transferred to that corporation; and

(B) To result in the controlled corporation assuming liabilities in an amount that properly relates to its business operations, the earnings of which will be used to properly satisfy those liabilities.

(4) *Distributing corporation debt—(i) In general.* Except as provided in paragraph (d)(4)(ii) of this section, distributing corporation debt eligible to be assumed under paragraph (d)(3) of this section must qualify as historical distributing corporation debt.

(ii) *Exceptions.* The following exceptions apply to the general rule in paragraph (d)(4)(i) of this section:

(A) *Qualifying trade payables.* For purposes of paragraph (d)(4)(i) of this section, solely trade payables of the distributing corporation that meet the requirements set forth in paragraph (d)(3) of this section are not required to qualify as historical distributing corporation debt.

(B) *Assumptions of refinanced distributing corporation debt.* For purposes of paragraph (d)(4)(i) of this section, refinanced distributing corporation debt is treated as historical distributing corporation debt if all the following requirements are met:

(1) The distributing corporation has a direct business purpose for the controlled corporation’s assumption of

the refinanced distributing corporation debt. For purposes of this paragraph (d)(4)(ii)(B)(1), the modification of the capital structure of the distributing corporation or the controlled corporation is not a direct business purpose unless that modification directly accomplishes a corporate business purpose of the distributing corporation.

(2) The distributing corporation’s refinancing of its historical distributing corporation debt is completed before the controlled corporation’s assumption of that refinanced distributing corporation debt.

(3) Following the controlled corporation’s assumption of the refinanced distributing corporation debt, the distributing corporation and the controlled corporation are in the same net economic position as each corporation would have been had the controlled corporation assumed the historical distributing corporation debt.

(4) The distributing corporation’s refinancing of its historical distributing corporation debt and the subsequent assumption of that refinanced distributing corporation debt are included in the plan of reorganization for the divisive reorganization.

(5) There is no untaxed gain or other Federal income tax benefit resulting to the distributing corporation or the controlled corporation from the distributing corporation’s refinancing of a historical distributing corporation debt and the assumption by the controlled corporation of that refinanced distributing corporation debt.

(6) The business assets transferred by the distributing corporation to the controlled corporation in the exchange described in section 361(a) are associated with the refinanced distributing corporation debt assumed by the controlled corporation.

(7) The refinancing of a historical distributing corporation debt by the distributing corporation and the subsequent assumption of that refinanced distributing corporation debt by the controlled corporation result in the controlled corporation assuming liabilities in an amount that properly relates to its business operations and will be properly satisfied with earnings generated by those operations.

(C) *Qualifying assumption of a traveling note.* For purposes of paragraph (d)(4)(i) of this section, a controlled corporation’s assumption of a traveling note (within the meaning of § 1.357–2(c)) issued to refinance a historical distributing corporation debt will be treated as historical distributing corporation debt only if all requirements

set forth in paragraph (d)(4)(ii)(B) of this section are satisfied.

(D) *Revolving credit agreements.* For purposes of paragraph (d)(4)(i) of this section, a revolving credit agreement to which the distributing corporation is a debtor qualifies as historical distributing corporation debt only if—

(1) The distributing corporation entered into the agreement before the earliest applicable date;

(2) That agreement does not expire until after the date of the exchange described in § 1.361–2(a) or 1.361–3(a); and

(3) That agreement is identified in the plan of reorganization or original plan of reorganization (if amended).

(e) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples: any liability assumption is provided for in an agreement or a plan of reorganization entered into between the transferor and transferee corporation before the date of the exchange; and the amount of liabilities assumed by the transferee corporation does not exceed the adjusted basis of the assets transferred to the transferee corporation in the exchange.

(1) *Example 1: Application of general rule—(i) Facts.* In an exchange that qualifies under section 351, Individual A transfers to a transferee corporation property with an adjusted basis of \$10,000x in exchange for stock of the corporation with a fair market value of \$8,000x, money amounting to \$3,000x, and the assumption by the corporation of debt of Individual A amounting to \$4,000x. Individual A’s principal purpose for causing the transferee corporation to assume the \$4,000x liability is to avoid Federal income tax on the exchange.

(ii) *Analysis.* Individual A’s realized gain is \$5,000x, computed as follows:

TABLE 1 TO PARAGRAPH (e)(1)(ii)	
Stock received, fair market value	\$8,000x
Money received	3,000x
Liability assumed by transferee corporation	4,000x
Total consideration received	15,000x
Less: Adjusted basis of property transferred	10,000x
Gain realized	5,000x

Because Individual A’s principal purpose for the assumption of the \$4,000x liability is to avoid Federal income tax on the exchange, the amount of gain recognized is \$5,000x. See paragraphs (a) and (b) of this section and section 351(b).

(2) *Example 2: Refinanced distributing corporation debt—(i)*

Facts—(A) In general. A distributing corporation (Distributing) transfers one of its businesses to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and Controlled's assumption of liabilities of Distributing (contribution). Distributing distributes all the Controlled stock to its shareholders (distribution; together with the contribution, the separation). The separation satisfies all requirements to qualify as a divisive reorganization.

(B) *Refinanced debt.* One liability that Distributing intended Controlled to assume in the contribution is a \$4,000x portion of a \$25,000x historical Distributing debt to a creditor that Distributing incurred in connection with the transferred business. However, Distributing is unable to apportion this historical debt with Controlled because the creditor refuses to relieve Distributing of its primary liability for repayment of the debt. Therefore, unless Distributing refinances that portion of its historical debt, Distributing will be unable to have Controlled assume an amount of existing historical debt that properly relates to, and to have that debt properly be satisfied with earnings from, the transferred business. Accordingly, pursuant to the plan of reorganization for the separation, Distributing obtains from a bank a new long-term \$4,000x loan on which Distributing is primarily liable (New Loan). Distributing uses the proceeds from the New Loan to repay \$4,000x of the \$25,000x historical debt. Controlled then assumes the New Loan in the contribution (Controlled refinanced debt assumption), and the bank relieves Distributing of its primary liability for repayment of the New Loan.

(ii) *Analysis.* The Controlled refinanced debt assumption satisfies all requirements set forth in paragraph (d)(4)(ii)(B) of this section and, therefore, is treated under paragraph (d)(3) of this section as an eligible assumption by Controlled to which § 1.357-2(a) applies. Distributing has a direct business purpose for Controlled's assumption of the New Loan. See paragraph (d)(4)(ii)(B)(1) of this section. Distributing's refinancing of its historical debt is completed before Controlled's assumption of the New Loan. See paragraph (d)(4)(ii)(B)(2) of this section. Following the Controlled refinanced debt assumption, Distributing and Controlled are in the same net economic position as they would have been had Controlled assumed an equivalent portion of Distributing's historical debt. See paragraph (d)(4)(ii)(B)(3) of this section. Distributing's refinancing of historical debt and the Controlled refinanced debt assumption occur pursuant to the plan

of reorganization for the separation. See paragraph (d)(4)(ii)(B)(4) of this section. No untaxed gain or other Federal income tax benefit results to Distributing or Controlled from Distributing's refinancing of historical Distributing debt and the Controlled refinanced debt assumption. See paragraph (d)(4)(ii)(B)(5) of this section. The business assets transferred by Distributing to Controlled in the section 361 exchange are associated with the New Loan. See paragraph (d)(4)(ii)(B)(6) of this section. Lastly, the Distributing refinancing of historical debt and the Controlled refinanced debt assumption result in Controlled assuming liabilities in an amount that properly relates to, and that properly will be satisfied with earnings generated by, its business operations. See paragraph (d)(4)(ii)(B)(7) of this section.

(3) *Example 3: Traveling note—(i) Facts.* The facts are the same as in paragraph (e)(2)(i) of this section (*Example 2*), except that, pursuant to the terms of the New Loan, Controlled replaces Distributing as the debtor on the New Loan upon the contribution. (ii) *Analysis.* The New Loan is treated as a traveling note. See § 1.357-1(b)(22). Therefore, Controlled is treated as assuming the New Loan at the time Controlled becomes the debtor on the New Loan (that is, upon the contribution). See § 1.357-2(c). The analysis is the same as in paragraph (e)(2)(ii) of this section (*Example 2*).

(4) *Example 4: Trade payables—(i) Facts—(A) In general.* Pursuant to a plan of reorganization, a distributing corporation (Distributing) transfers one of its two operating divisions (Business B) to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and the assumption of \$20,000x of Distributing liabilities (contribution), and Distributing distributes all the Controlled stock to its shareholders on a pro rata basis (distribution; together with the contribution, the separation). The separation satisfies all requirements to qualify as a divisive reorganization.

(B) *Liabilities assumed.* The \$20,000x of liabilities assumed by Controlled arose in the ordinary course of Business B's operations from the rendition of services to or for Distributing. The liabilities were incurred after the earliest applicable date, but before the contribution date identified in the plan of reorganization for the separation. The assumption of those liabilities is necessary to ensure the transfer to Controlled of all liabilities properly associated with Business B and to result in Controlled assuming an amount of Distributing liabilities that properly

relates to, and that will be properly satisfied with earnings from, Business B.

(ii) *Analysis.* The \$20,000x of liabilities assumed by Controlled are trade payables because they constitute debt that arose in the ordinary course of Business B's operations from the rendition of services to or for Distributing. See § 1.357-1(b)(19). Accordingly, these liabilities are not required to qualify as historical distributing corporation debt to be eligible for assumption by Controlled. See paragraph (d)(4)(ii)(A) of this section. Consequently, all \$20,000x of trade payables are eligible to be assumed by Controlled under paragraph (d)(3) of this section. See paragraph (d)(4)(i) of this section. Therefore, Distributing is not treated as having the principal purpose described in paragraph (a)(1) of this section for Controlled's assumption of the \$20,000x of liabilities, and, consequently, those liabilities are not treated as money received by Distributing in the contribution. See paragraphs (a) and (d)(2) of this section.

(5) *Example 5: Assumption to avoid Federal income tax in a divisive reorganization—(i) Facts.* A distributing corporation (Distributing) transfers one of its businesses (Business A) to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and Controlled's assumption of historical Distributing debt (contribution). The historical Distributing debt consists of two loans (Loan 1 and Loan 2) that were incurred by Distributing prior to the earliest applicable date and have an original term that ends after the date of the contribution. Loan 1 was incurred in the ordinary course of business and is associated with Business A. Loan 2 was not incurred in the ordinary course of business and is not associated with Business A. Distributing distributes all the Controlled stock to its shareholders (distribution; together with the contribution, the separation). The separation satisfies all requirements to qualify as a divisive reorganization.

(ii) *Analysis.* Because Loan 2 was not incurred in the ordinary course of business and the assumption of that debt is not necessary to ensure the transfer to Controlled of all liabilities properly associated with Business A, Loan 2 is presumed to have been assumed for a principal purpose described in paragraph (a) of this section. See paragraphs (d)(2) and (3) of this section. Accordingly, Controlled's assumption of the historical Distributing debt (that is, both Loan 1 and Loan 2) is presumed to be treated as money received by Distributing in the

exchange. See paragraphs (a) and (b) of this section and § 1.357–2(a). However, Distributing would recognize no gain on the exchange if, pursuant to the plan of reorganization, Distributing distributes to its shareholders an amount of money equivalent to the amount it is treated as having received in the contribution or transfers an equivalent amount of money to its creditors in satisfaction of Distributing debt in a distribution or transfer meeting the requirements set forth in § 1.361–3(b)(2).

(6) *Example 6: Assumption to avoid Federal income tax in a section 351 exchange*—(i) *Facts*. In a transaction that qualifies as a section 351 exchange, Corporation A contributes one of its two businesses to newly formed Corporation B in exchange for all of B's stock and B's assumption of liabilities of A. One of the liabilities assumed by B was not incurred in the ordinary course of A's business.

(ii) *Analysis*. Because the liability assumed by B was not incurred in the ordinary course of business, the liability is presumed to have been assumed for a principal purpose described in paragraph (a)(1) of this section. See paragraph (a)(2) of this section. Accordingly, B's assumption of liabilities is presumed to be treated as money received by A on the exchange. For purposes of determining the amount of gain A recognizes on the exchange under section 351(b), the total amount of liabilities assumed by B would be treated as money received by A. See paragraph (b) of this section.

§ 1.357–4 Application of section 357(c).

(a) *Liabilities in excess of adjusted basis*—(1) *General rule*. Except as provided in paragraph (a)(2) of this section, in an exchange to which section 351 of the Code is applicable, or to which section 361 of the Code is applicable by reason of a divisive reorganization that qualifies under sections 355 and 368(a)(1)(D) of the Code, a transferor is treated as recognizing gain from the sale or exchange of a capital asset or of property that is not a capital asset, as applicable, in an amount equal to the excess of—

(i) The sum of the amount of liabilities of the transferor assumed by the transferee corporation; over

(ii) The total adjusted basis of the property transferred by the transferor pursuant to the exchange.

(2) *Exceptions*. Paragraph (a)(1) of this section does not apply to any exchange—

(i) To which § 1.357–3(a) applies;

(ii) That is pursuant to a plan of reorganization for a transaction that

qualifies as a reorganization under section 368(a)(1)(G) in which no former shareholder of the transferor corporation receives any consideration for the shareholder's stock; or

(iii) To which section 351 applies if the exchange—

(A) Also qualifies as part of a reorganization described in section 368(a)(1)(A), (C), (D) (provided the requirements of section 354(b)(1) of the Code are satisfied), or (G) (provided the requirements of section 354(b)(1) are satisfied); and

(B) Is described as a reorganization pursuant to a filing with the IRS under § 1.368–3.

(3) *Certain liabilities excluded*—(i) *General rule*. Except as provided in paragraph (a)(3)(ii) of this section, the following liabilities are excluded for purposes of applying paragraph (a)(1) of this section:

(A) A liability the payment of which would give rise to a deduction.

(B) A liability the payment of which would give rise to the creation of, or increase in, the basis of any property.

(C) A liability the payment of which would be described in section 736(a) of the Code.

(ii) *Exceptions*. Paragraph (a)(3)(i) of this section does not apply to any liability to the extent that—

(A) The incurrence of the liability resulted in a deduction;

(B) The incurrence of the liability resulted in the creation of, or an increase in, the basis of any property; or

(C) The liability is not—

(1) Incurred in the ordinary course of business; or

(2) Associated with any assets transferred.

(b) *Determination of character of gain of multiple capital assets*. The determination of whether gain resulting from the transfer of capital assets is long-term or short-term capital gain is made by reference to the transferor's holding period for the transferred assets, based on the proportionate fair market value of the transferor's long-term assets to its short-term assets.

(c) *Examples*. The following examples illustrate the application of the rules of this section. For purposes of these examples: no exchange is described in paragraph (a)(2) of this section; any liability assumption is provided for in an agreement or a plan of reorganization entered into between the transferor and the transferee corporation before the date of the exchange; no liability is described in paragraph (a)(3)(i) of this section; all liabilities were incurred in the ordinary course of business and are associated with the assets transferred; the transferor's principal purpose with

respect to the assumption of liabilities is not to avoid Federal income tax on the exchange; and there is a bona fide business purpose for the assumption of liabilities.

(1) *Example 1: Determination of character of gain*—(i) *Facts*. In an exchange that qualifies under section 351, Individual A transfers to a transferee corporation property with an adjusted basis of \$1,000x in exchange for stock of the transferee corporation with a fair market value of \$8,000x and the assumption by the transferee corporation of Individual A debt amounting to \$4,000x. All assets transferred by Individual A to the transferee corporation are capital assets. By reference to Individual A's holding period at the time of the exchange, one half of the assets transferred (with a fair market value of \$4,000x and an adjusted basis of \$500x) have a long-term holding period, and the other half of the assets transferred (with a fair market value of \$4,000x and an adjusted basis of \$500x) have a short-term holding period.

(ii) *Analysis*. The excess of the amount of liabilities assumed over the adjusted basis of the assets transferred (\$4,000x – \$1,000x = \$3,000x) is treated as gain from the sale or exchange of a capital asset. See paragraph (a)(1) of this section. Half of Individual A's capital gain resulting from the deemed sale or exchange of a capital asset (that is, \$1,500x) is long-term capital gain, and the other half is short-term capital gain. See paragraph (b) of this section.

(2) *Example 2: Capital and non-capital assets*—(i) *Facts*. The facts are the same as in paragraph (c)(1)(i) of this section (*Example 1*), except that the long-term assets transferred are capital assets, and the short-term assets are other than capital assets.

(ii) *Analysis*. Half of the gain recognized by Individual A is treated as capital gain, and the other half of the gain recognized by Individual A is treated as gain from the sale or exchange of assets other than capital assets. See paragraph (a)(1) of this section.

(3) *Example 3: Liabilities in excess of adjusted basis*—(i) *Facts*. Pursuant to a plan of reorganization, a distributing corporation (Distributing) transfers one of its businesses (Business A) to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and Controlled's assumption of a historical Distributing debt (contribution), and Distributing distributes all the Controlled stock to its shareholders (distribution; together with the contribution, the separation). The separation satisfies all requirements to qualify as a divisive reorganization. At the time of the contribution,

Distributing has an aggregate adjusted basis of \$5,000x in the Business A assets, which are the only assets subject to a nonrecourse loan of \$10,000x.

(ii) *Analysis.* Under paragraph (a) of this section, Controlled's assumption of Distributing's Business A loan causes Distributing to recognize gain on the transfer of Business A to Controlled as though Distributing had sold or exchanged the Business A assets to Controlled. Specifically, because the amount of the loan (\$10,000x) exceeds the total adjusted basis of the Business A assets (\$5,000x), Distributing recognizes gain of \$5,000x (\$10,000x – \$5,000x) on the exchange. See paragraph (a)(1) of this section. The character of that gain depends on the character of the assets transferred in the exchange. See paragraph (b) of this section.

§ 1.357–5 Applicability date.

(a) *Applicability date.* The rules of §§ 1.357–1 through 1.357–4 apply to transactions intended to qualify under section 351 or 361 of the Code for which the earliest of the following dates occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER]:

(1) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(2) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(3) The date of approval of the transaction by the board of directors of the taxpayer.

(4) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(5) The date a ruling request for the transaction is submitted to the IRS.

■ **Par. 11.** Section 1.361–0 is added to read as follows:

§ 1.361–0 Table of contents.

This section lists the major captions that appear in §§ 1.361–1 through 1.361–6.

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§ 1.361–2 Exchanges solely for stock or securities under section 361(a).

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§ 1.361–6 Applicability date.

(a) Applicability date.

■ **Par. 12.** Section 1.361–1 is revised to read as follows:

§ 1.361–1 Nonrecognition of gain or loss to corporations under section 361.

(a) *Overview*—(1) *In general.* The section 361 regulations apply—

(i) To exchanges of property by a target corporation pursuant to a plan of reorganization for property from an acquiring corporation that is a party to the reorganization; and

(ii) To distributions by the target corporation to its shareholders of property pursuant to a plan of reorganization (including transfers by the target corporation treated as such distributions).

(2) *Scope.* Paragraph (b) of this section provides definitions for purposes of the regulations under section 361 of the Code. Section 1.361–2 provides rules regarding exchanges in which a target corporation receives solely stock or securities in an acquiring corporation. Section 1.361–3 provides rules regarding exchanges in which a target corporation receives money or other property in addition to stock or securities in an acquiring corporation. Section 1.361–4 provides rules regarding distributions of property received by a target corporation in the exchange. Section 1.361–5 provides rules regarding transfers of section 361 consideration to creditors of a distributing corporation in a divisive reorganization. Section 1.361–6 provides the applicability date.

(b) *Definitions.* The following definitions apply for purposes of the section 361 regulations:

(1) *Acquiring corporation.* The term *acquiring corporation* means a corporation (including a controlled corporation) that receives property transferred by a target corporation in an exchange to which section 361(a) applies.

(2) *Acquisitive reorganization.* The term *acquisitive reorganization* means a transaction that qualifies as a reorganization under—

(i) Section 368(a)(1)(A) of the Code (including by reason of section 368(a)(2)(D) or section 368(a)(2)(E));

(ii) Section 368(a)(1)(C);

(iii) Section 368(a)(1)(D) (provided the requirements of section 354(b)(1) of the Code are satisfied);

(iv) Section 368(a)(1)(F); or

(v) Section 368(a)(1)(G) (provided the requirements of section 354(b)(1) are satisfied).

(3) *Amount.* The term *amount* means:

(i) With respect to liabilities, except as provided under paragraph (b)(3)(ii) or (iii) of this section, the amount of cash that a willing assignor would pay to a willing assignee to assume the liability in an arm's-length transaction.

(ii) With respect to debt, except as provided in paragraph (b)(3)(iii) of this section, the adjusted issue price (as defined in § 1.1275–1(b)) of the debt.

(iii) With respect to covered convertible debt, the fair market value of the covered convertible debt as of the earliest applicable date.

(4) *Appreciated nonqualified property*—(i) *In general.* The term *appreciated nonqualified property* means property distributed by a target corporation under § 1.361–4(b) that—

(A) Is property other than qualified property; and

(B) At the time of the distribution of that property under section 361(c), has a fair market value that exceeds the adjusted basis of that property in the hands of the target corporation.

(ii) *Inclusions.* The term *appreciated nonqualified property* includes all controlled corporation stock or securities—

(A) Treated as other property under section 355(a)(3)(B) of the Code;

(B) Distributed in a disqualified distribution, as defined in section 355(d)(2); or

(C) Distributed by a distributing corporation pursuant to an acquisition described in section 355(e)(2).

(5) *Assume; assumption.* With respect to a liability, the terms *assume*, *assumption*, and similar terms have the meaning of “assumed” as set forth in § 1.357–2(d).

(6) *Code.* The term *Code* means the Internal Revenue Code of 1986, as amended.

(7) *Contingent liability.* The term *contingent liability* means a liability (other than a debt) that includes one or more contingent payments.

(8) *Control distribution.* The term *control distribution* means a distribution of controlled corporation stock, or of controlled corporation stock and securities, that results in the distribution by the distributing corporation of an amount of controlled corporation stock constituting control (within the meaning of section 368(c) of the Code).

(9) *Control distribution date.* The term *control distribution date* means the date of the control distribution.

(10) *Controlled corporation.* The term *controlled corporation* means the

controlled corporation described in section 355(a)(1)(A).

(11) *Controlled corporation contingent liability*. The term *controlled corporation contingent liability* means a contingent liability for which a controlled corporation is the obligor.

(12) *Controlled corporation debt*. The term *controlled corporation debt* means debt for which a controlled corporation is the obligor.

(13) *Controlled corporation related person*. The term *controlled corporation related person* means a related person with respect to a controlled corporation.

(14) *Covered convertible debt*. The term *covered convertible debt* means debt with a conversion option described in § 1.1275-4(a)(4) that is reasonably certain to be exercised as of the earliest applicable date based on all facts and circumstances—

(i) Taking into account § 1.1504-4(g) (to the extent relevant); but

(ii) Not taking into account the safe harbors described in § 1.1504-4(g)(3).

(15) *Debt*. The term *debt* means a liability pursuant to an instrument or a contractual arrangement that constitutes debt under general principles of Federal income tax law. See § 1.1275-1(d).

(16) *Direct issuance debt*. The term *direct issuance debt* means the newly incurred debt a distributing corporation incurs with a creditor as part of a direct issuance transaction and the proceeds of which are used to repay historical distributing corporation debt.

(17) *Direct issuance transaction*. The term *direct issuance transaction* means a transaction, or a series of transactions (or similar transaction or series of transactions), in which—

(i) The distributing corporation incurs distributing corporation debt with a creditor after the earliest applicable date;

(ii) The distributing corporation uses the proceeds of the newly incurred distributing corporation debt (directly or indirectly) to repay historical distributing corporation debt; and

(iii) The new creditor exchanges that newly incurred distributing corporation debt for controlled corporation stock or securities held by the distributing corporation.

(18) *Distributing corporation*. The term *distributing corporation* means the distributing corporation described in section 355(a)(1)(A).

(19) *Distributing corporation contingent liability*. The term *distributing corporation contingent liability* means a contingent liability for which the distributing corporation is the obligor.

(20) *Distributing corporation debt*—(i) *In general*. The term *distributing*

corporation debt means debt for which the distributing corporation is the obligor.

(ii) *Section 381(a) transactions*. The term *distributing corporation debt* includes a debt that satisfies the following requirements:

(A) The distributing corporation assumed the debt in a transaction to which section 381(a) of the Code applies; and

(B) The debt assumed in the transaction was incurred prior to the earliest applicable date.

(21) *Distributing corporation liability*. The term *distributing corporation liability* means a liability for which the distributing corporation is the obligor.

(22) *Distributing corporation related person*. The term *distributing corporation related person* means a related person with respect to the distributing corporation.

(23) *Distribution*. The term *distribution* means a single distribution, or one of a series of distributions, of controlled corporation stock, or of controlled corporation stock and securities—

(i) Intended to qualify as a divisive reorganization; and

(ii) Made by the distributing corporation pursuant to the plan of reorganization.

(24) *Distribution date*. If all distributions comprising an intended divisive reorganization take place on one date—

(i) The term *distribution date* means that date; and

(ii) Each of the terms *first distribution date*, *control distribution date*, and *final distribution date* refers to the distribution date.

(25) *Distribution period*. The term *distribution period* means the period of time that—

(i) Begins at the time of the first distribution; and

(ii) Ends at the time of the final distribution.

(26) *Divisive reorganization*. The term *divisive reorganization* means a series of transactions carried out pursuant to a plan of reorganization that qualify as a reorganization under sections 355 and 368(a)(1)(D) or (G).

(27) *Earliest applicable date*—(i) *In general*. The term *earliest applicable date* means the date that is the earliest of—

(A) The date of the first public announcement (as defined in § 1.355-7(h)(10)) of the divisive reorganization or a similar transaction;

(B) The date of entry by the distributing corporation into a written agreement to engage in the divisive reorganization or a similar transaction; and

(C) The date of approval of the divisive reorganization or a similar transaction by the board of directors of the distributing corporation.

(ii) *Similar transaction*. For purposes of paragraph (b)(27)(i) of this section, the term *similar transaction* means a similar acquisition within the meaning of § 1.355-7(h)(12) and (13).

(28) *Eligible distributing corporation debt*. The term *eligible distributing corporation debt* means distributing corporation debt described in § 1.361-5(c).

(29) *Final distribution*. The term *final distribution* means, with respect to a series of distributions, the last distribution that is made by the distributing corporation pursuant to the plan of reorganization.

(30) *Final distribution date*. The term *final distribution date* means the date of the final distribution.

(31) *First distribution*. The term *first distribution* means, with respect to a series of distributions, the earliest distribution that is made by the distributing corporation pursuant to the plan of reorganization.

(32) *First distribution date*. The term *first distribution date* means the date of the first distribution.

(33) *Historical distributing corporation debt*. The term *historical distributing corporation debt* means distributing corporation debt described in § 1.361-5(c)(2).

(34) *Intermediary*—(i) *In general*. The term *intermediary* means an investment bank or other person that—

(A) Is not a distributing corporation related person or a controlled corporation related person, at any time during the period beginning on the earliest applicable date and ending on the date of completion of the plan of reorganization; and

(B) Provides capital or financial services to the distributing corporation or the controlled corporation, directly or indirectly, to facilitate the divisive reorganization.

(ii) *Inclusion*. The term *intermediary* includes a related person of the intermediary.

(35) *Intermediated exchange*. The term *intermediated exchange* means a transaction, or a series of transactions (or similar transaction or series of transactions), in which an intermediary—

(i) Acquires historical distributing corporation debt on a secondary market from the holders of that debt; and

(ii) Exchanges that historical distributing corporation debt for controlled corporation stock or securities held by the distributing corporation.

(36) *Liability*—(i) *In general*. The term *liability* means a debt, a contingent liability, or any other fixed or contingent obligation, without regard to whether the obligation otherwise has been taken into account for Federal income tax purposes.

(ii) *Certain obligations incurred in the ordinary course of business*—(A) *In general*. Except as provided in paragraph (b)(36)(ii)(B) of this section, an obligation incurred in the ordinary course of business pursuant to a bilateral contract is not a liability.

(B) *Exception regarding financial statements*. An obligation described in paragraph (b)(36)(ii)(A) of this section is a liability, in whole or in part, to the extent the obligation is reflected in one or more financial statements of the obligor as a liability, reserve, or similar item.

(37) *Non-qualifying creditor*. The term *non-qualifying creditor* has the meaning provided in § 1.361–5(b)(2)(i).

(38) *Obligor*. With regard to a liability, the term *obligor* means the person that has agreed and is expected (as determined based on all facts and circumstances) to satisfy the liability, taking into account—

(i) All relevant provisions of the Code (including the principles of section 357(d) (liability treated as assumed));

(ii) Treasury regulations (26 CFR chapter I); and

(iii) General principles of Federal income tax law, including the substance-over-form doctrine.

(39) *Other property*. The term *other property* means section 361 consideration other than money, acquiring corporation stock or securities, and stock of a corporation controlling the acquiring corporation (within the meaning of section 368(c)).

(40) *Party to a reorganization*. The term *party to a reorganization* has the meaning provided in § 1.368–2(f).

(41) *Plan of reorganization*. The term *plan of reorganization* has the meaning provided in § 1.368–4.

(42) *Post-distribution payment*. The term *post-distribution payment* means a transfer of money or other property by the controlled corporation to the distributing corporation or by the distributing corporation to the controlled corporation—

(i) Pursuant to the plan of reorganization; and

(ii) Subsequent to the control distribution date.

(43) *Qualified property*. The term *qualified property* means any stock in (or right to acquire stock in), or obligation of—

(i) The target corporation;

(ii) The acquiring corporation, if that stock (or right) or obligation is received

by the target corporation in an exchange described in § 1.361–2 or § 1.361–3; or

(iii) A corporation controlling the acquiring corporation (within the meaning of section 368(c)), if—

(A) The controlling corporation is a party to the reorganization; and

(B) That stock (or right) or obligation is received by the target corporation in an exchange described in § 1.361–2 or § 1.361–3.

(44) *Qualifying creditor*. The term *qualifying creditor* means a creditor described in § 1.361–5(b).

(45) *Qualifying debt elimination transaction*. The term *qualifying debt elimination transaction* means a transaction described in § 1.361–5(e).

(46) *Refinanced historical distributing corporation debt*. The term *refinanced historical distributing corporation debt* has the meaning provided in § 1.361–5(c)(2)(ii).

(47) *Related person*. The term *related person* means a person related within the meaning of section 267(b) or section 707(b)(1) of the Code.

(48) *Revolving credit agreement*. The term *revolving credit agreement* means a loan structure that—

(i) Permits the borrower to make multiple borrowings and re-borrowings during the term of the revolving credit facility;

(ii) Limits the aggregate borrowings to a pre-determined maximum amount that the one or more lenders agree to fund; and

(iii) May, or may not, require the borrower to pledge any of its assets as security for the loan (that is, it may be a secured or unsecured loan structure).

(49) *Section 361 consideration*—(i) *In general*. The term *section 361 consideration* means, with regard to an exchange to which § 1.361–2 or § 1.361–3 applies, the consideration received by a target corporation from an acquiring corporation in exchange for property transferred by the target corporation to the acquiring corporation pursuant to the plan of reorganization.

(ii) *Inclusions*. The term *section 361 consideration* includes—

(A) Acquiring corporation stock or stock of a corporation controlling the acquiring corporation (within the meaning of section 368(c));

(B) Acquiring corporation securities;

(C) Acquiring corporation non-security debt;

(D) Money transferred by the acquiring corporation; and

(E) Other property (other than acquiring corporation non-security debt) transferred by the acquiring corporation.

(iii) *Exclusion*. The term *section 361 consideration* does not include an assumption of a liability described in § 1.357–2(a).

(50) *Section 361 regulations*. The term *section 361 regulations* means this section and §§ 1.361–2 through 1.361–6.

(51) *Target corporation*—(i) *In general*. The term *target corporation* means the corporation that is treated under section 361(a) or (b) as exchanging its property pursuant to a plan of reorganization for section 361 consideration.

(ii) *Inclusions*. The term *target corporation* includes solely—

(A) A corporation that is acquired in an acquisitive reorganization; and

(B) A distributing corporation in a divisive reorganization.

(52) *Trade payable*. The term *trade payable* means debt arising in the ordinary course of a business from sales, leases, licenses, or the rendition of services provided to or for the distributing corporation.

(53) *True-up payment*. The term *true-up payment* means, with respect to an exchange of controlled corporation stock or securities, or controlled corporation non-security debt, for distributing corporation debt pursuant to a plan of reorganization of a divisive reorganization, a payment—

(i) Under an agreement entered into between the distributing corporation (including any distributing corporation related person) and an intermediary (including any related person with regard to the intermediary); and

(ii) Made pursuant to that agreement by—

(A) The distributing corporation to the intermediary as the result of a decrease in value of any controlled corporation stock or securities or controlled corporation non-security debt (as applicable) between an initial valuation date and a subsequent valuation date; or

(B) The intermediary to the distributing corporation as the result of an increase in value of any controlled corporation stock or securities or controlled corporation non-security debt (as applicable) between an initial valuation date and a subsequent valuation date.

(54) *Unrelated ultimate creditor*. The term *unrelated ultimate creditor* means a creditor that is not—

(i) A distributing corporation related person; or

(ii) A related person with regard to a distributing corporation related person.

■ **Par. 13.** Sections 1.361–2 through 1.361–6 are added to read as follows:

§ 1.361–2 Exchanges solely for stock or securities under section 361(a).

(a) *General rule*. A target corporation that is a party to a reorganization does not recognize any gain or loss on a transfer of property by that corporation to an acquiring corporation if—

(1) The acquiring corporation or a corporation controlling the acquiring corporation is a party to the reorganization;

(2) The target corporation receives solely stock or securities of—

(i) The acquiring corporation in exchange for the transferred property; or

(ii) The corporation controlling the acquiring corporation in exchange for the transferred property; and

(3) The exchange occurs pursuant to the plan of reorganization.

(b) *Exchanges not solely for stock or securities.* With regard to an exchange to which paragraph (a) of this section would apply but for the fact that the target corporation receives money or other property in addition to stock and securities of an acquiring corporation or a corporation controlling the acquiring corporation, *see* § 1.361–3.

(c) *Example—(1) Facts.* Pursuant to a plan of reorganization for a transaction that qualifies as a reorganization described in section 368(a)(1)(C), a target corporation (Target) transfers all its property to an acquiring corporation (Acquiring) solely in exchange for Acquiring stock, which Target distributes to its shareholders in complete liquidation of Target. Target properly files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) that satisfies all requirements set forth in § 1.368–4, including properly including and identifying Target and Acquiring as parties to the reorganization.

(2) *Analysis.* Target recognizes no gain or loss on the transfer of its property to Acquiring solely in exchange for Acquiring stock because Target and Acquiring are parties to the reorganization, Target receives solely Acquiring stock in exchange for Target's property, and the exchange occurs pursuant to the plan of reorganization. *See* paragraph (a) of this section.

§ 1.361–3 Exchanges not solely for stock or securities under section 361(b).

(a) *Scope—(1) In general.* If § 1.361–2(a) would apply to an exchange between a target corporation and an acquiring corporation but for the fact that the target corporation receives money or other property, in addition to stock and securities of the acquiring corporation or stock of the corporation controlling the acquiring corporation, the exchange is governed by paragraphs (b) through (e) of this section.

(2) *Exception.* If the exchange is pursuant to a reorganization that qualifies under section 368(a)(1)(F) of the Code, the exchange is not governed by paragraphs (b) through (e) of this section. *See* § 1.368–2(m)(3)(iii).

(b) *Money or other property distributed in acquisitive reorganizations—(1) Distributions to shareholders.* In an acquisitive reorganization, the target corporation recognizes no gain from an exchange described in paragraph (a)(1) of this section if the target corporation distributes the money or other property received in the exchange to its shareholders pursuant to the plan of reorganization.

(2) *Transfers to creditors.* In an acquisitive reorganization, if a target corporation receives money or other property in an exchange described in paragraph (a)(1) of this section, the target corporation is treated as distributing the money or other property to its shareholders for purposes of paragraph (b)(1) of this section if the target corporation transfers that money or other property to a creditor—

(i) Pursuant to the plan of reorganization; and

(ii) In satisfaction of debt of the target corporation.

(c) *Money or other property distributed in divisive reorganizations—(1) Distributions to shareholders.* In a divisive reorganization, the distributing corporation recognizes no gain from an exchange described in paragraph (a)(1) of this section if, pursuant to the plan of reorganization, the distributing corporation—

(i) Deposits the money received in the exchange in a segregated account; and

(ii) Distributes the money or other property received in the exchange to its shareholders no later than the end of the 12-month period beginning on the date of the exchange.

(2) *Transfers to creditors—(i) In general.* Subject to the adjusted basis limitation set forth in paragraph (c)(2)(ii) of this section, in a divisive reorganization, if a distributing corporation receives money or other property in an exchange described in paragraph (a)(1) of this section, the distributing corporation is treated as distributing the money or other property to its shareholders for purposes of paragraph (c)(1) of this section if, pursuant to the plan of reorganization, the distributing corporation—

(A) Deposits the money received in the exchange in a segregated account; and

(B) Transfers that money or other property to a creditor—

(1) In satisfaction of distributing corporation debt in a transfer meeting the requirements set forth in § 1.361–5; and

(2) Within the period described in paragraph (c)(1)(ii) of this section.

(ii) *Application of adjusted basis limitation to divisive reorganizations described in sections 355 and 368(a)(1)(D).* The aggregate amount of money and the fair market value of any other property transferred to a creditor that is treated as a distribution under paragraph (c)(1) of this section is limited to the amount by which the aggregate adjusted basis of the assets transferred by a distributing corporation to a controlled corporation in a divisive reorganization described in sections 355 and 368(a)(1)(D) exceeds the aggregate amount of distributing corporation liabilities assumed by the controlled corporation.

(3) *Post-distribution payments received by a distributing corporation.* Paragraphs (c)(1) and (2) of this section (without regard to paragraph (c)(1)(ii) of this section) apply to any post-distribution payment received by a distributing corporation only if all the following requirements are satisfied:

(i) *Treatment as section 361 consideration.* The post-distribution payment constitutes section 361 consideration for Federal income tax purposes. For purposes of this paragraph (c)(3), a post-distribution payment constitutes section 361 consideration for Federal income tax purposes (and not, for example, a payment for goods or services separate from and, therefore, not pursuant to the plan of reorganization for the divisive reorganization) only if all the following requirements are satisfied:

(A) *Characterization as section 361 consideration.* The post-distribution payment properly is characterized for Federal income tax purposes as consideration that the distributing corporation receives in the exchange described in § 1.361–3(a).

(B) *Value not reasonably ascertainable.* As of the date of the exchange described in § 1.361–3(a), the fair market value of the distributing corporation's right to receive the post-distribution payment is not reasonably ascertainable.

(C) *Proper accounting.* In accordance with the plan of reorganization, the distributing corporation properly accounts for the post-distribution payment as part of the contribution when the distributing corporation receives that payment.

(ii) *Segregated account requirement.* The distributing corporation deposits the post-distribution payment in a segregated account pursuant to the plan of reorganization.

(iii) *Disposition requirement.* By the later of 90 days after the date on which the distributing corporation receives the post-distribution payment or the date

specified in paragraph (c)(1)(ii) of this section, the distributing corporation, pursuant to the plan of reorganization—

(A) Distributes that post-distribution payment to the distributing corporation's shareholders; or

(B) Transfers that post-distribution payment to the distributing corporation's creditors in satisfaction of distributing corporation debt in a transfer meeting the requirements set forth in § 1.361-5.

(4) *Post-distribution payments received by a controlled corporation.* For purposes of the adjusted basis limitation set forth in paragraph (c)(2)(ii) of this section, any post-distribution payment received by the controlled corporation from the distributing corporation will increase the aggregate adjusted basis of the assets transferred by the distributing corporation to the controlled corporation only if all the following requirements are satisfied:

(i) *Characterization as contribution in the reorganization exchange.* The post-distribution payment properly is characterized for Federal income tax purposes as consideration that the controlled corporation receives in the exchange described in § 1.361-3(a).

(ii) *Value not reasonably ascertainable.* As of the date of the exchange described in § 1.361-3(a), the fair market value of the controlled corporation's right to receive the post-distribution payment is not reasonably ascertainable.

(iii) *Proper accounting.* In accordance with the plan of reorganization, the controlled corporation properly accounts for the post-distribution payment as part of the contribution when the controlled corporation receives that payment.

(d) *Money or other property not distributed.* If a target corporation does not satisfy the requirements set forth in paragraph (b) or (c) of this section with respect to an exchange described in paragraph (a)(1) of this section, the target corporation recognizes gain (if any) from the exchange in an amount that does not exceed the sum of—

(1) The amount of money received but not distributed; and

(2) The fair market value of other property received but not distributed.

(e) *No recognition of loss.* A target corporation does not recognize any loss on an exchange described in paragraph (a)(1) of this section.

(f) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples: Distributing is a distributing corporation, and Controlled is a controlled corporation, in a divisive

reorganization; Target is a target corporation, and Acquiring is an acquiring corporation, in an acquisitive reorganization; all taxpayers are calendar-year taxpayers; and for each transaction, a plan of reorganization has been properly filed with the IRS pursuant to § 1.368-3(a)(5) that satisfies all requirements set forth in § 1.368-4, including identifying all parties to the reorganization, identifying all transactions included in the plan of reorganization, and describing the intended Federal income tax treatment of the transaction.

(1) *Example 1: Acquisitive reorganization—(i) Facts.* Pursuant to a plan of reorganization for a transaction that qualifies as a reorganization described in section 368(a)(1)(C), Target transfers all its property to Acquiring in exchange for Acquiring stock and money (exchange), and Target distributes the Acquiring stock and money to Target's shareholders in complete liquidation of Target.

(ii) *Analysis.* Target recognizes no gain on the exchange because Target distributes the money received in the exchange to its shareholders pursuant to the plan of reorganization. See paragraph (b)(1) of this section.

(2) *Example 2: Divisive reorganization with money or other property distributed pursuant to plan of reorganization—(i) Facts—(A) In general.* On June 1, 2025, pursuant to a plan of reorganization for a transaction that qualifies as a divisive reorganization, Distributing transfers one of its businesses (Business B) to newly formed Controlled in exchange for \$10,000x of Controlled stock and \$10,000x of cash (contribution) and distributes all the Controlled stock to Distributing's shareholders (distribution). The Business B assets have an aggregate adjusted basis of \$10,000x. Pursuant to its plan of reorganization, Distributing will deposit the \$10,000x of cash received in the contribution in a segregated account.

(B) *Special distribution.* On December 1, 2025, Distributing distributes the \$10,000x of cash received to Distributing's shareholders in a special distribution (special dividend) pursuant to the plan of reorganization. A separation and distribution agreement filed by Distributing with the U.S. Securities and Exchange Commission (SEC), a resolution by Distributing's board of directors, and other official records of Distributing collectively evidence a definite intent, prior to the first step of the transaction, to have Distributing distribute the \$10,000x of cash pursuant to the special dividend. Specifically, those documents provide

that the special dividend is in addition to any regularly occurring dividends distributed to Distributing's shareholders pursuant to Distributing's dividend payment policy (as reflected in documents filed by Distributing with the SEC).

(ii) *Analysis.* The special dividend satisfies all requirements set forth in § 1.368-4(e). Accordingly, the special dividend is properly included in the plan of reorganization for the divisive reorganization. Distributing recognizes no gain on the contribution because, pursuant to the plan of reorganization, Distributing deposits the money received in the contribution in a segregated account, and it distributes the money received in the contribution to its shareholders no later than the end of the 12-month period beginning on the date of the contribution. See paragraph (c)(1) of this section.

(3) *Example 3: Ordinary course distribution—(i) Facts.* The facts are the same as in paragraph (f)(2)(i) of this section (*Example 2*), except that Distributing provides in the separation and distribution agreement, or in Distributing's other official records, that Distributing will distribute the \$10,000x of cash received from Controlled to Distributing's shareholders through an ordinary course dividend pursuant to Distributing's dividend payment policy (as reflected in documents filed by Distributing with the SEC). Distributing distributes the cash in an ordinary course dividend on November 1, 2025.

(ii) *Analysis.* The ordinary course dividend is not properly included in the plan of reorganization for the divisive reorganization because the dividend does not satisfy the requirements set forth in § 1.368-4(e)(2)(i)(B) (that is, the dividend would have occurred regardless of the divisive reorganization). Because the \$10,000x of cash received from Controlled is not distributed to Distributing's shareholders pursuant to the plan of reorganization, Distributing recognizes gain (but not loss) on the exchange in an amount that does not exceed the amount of money received (that is, \$10,000x). See paragraphs (c)(1), (d), and (e) of this section. The Federal income tax consequences of the ordinary course dividend are determined under section 301 of the Code.

(4) *Example 4: Special stock repurchase program—(i) Facts.* The facts are the same as in paragraph (f)(2)(i) of this section (*Example 2*), except that, pursuant to the plan of reorganization, and as reflected in the official records of Distributing and Controlled, Distributing uses the \$10,000x of cash received from

Controlled to fund a special repurchase of Distributing stock (and, accordingly, is not part of an existing stock repurchase program approved by Distributing's board of directors). The redemptions occur on February 1, 2026, and March 1, 2026.

(ii) *Analysis.* The analysis is the same as in paragraph (f)(2)(ii) of this section (*Example 2*).

(5) *Example 5: Existing stock repurchase program*—(i) *Facts.* The facts are the same as in paragraph (f)(4)(i) of this section (*Example 4*), except that Distributing uses the \$10,000x of cash received from Controlled to fund a repurchase of Distributing stock pursuant to an existing stock repurchase program approved by Distributing's board of directors.

(ii) *Analysis.* The analysis is the same as in paragraph (f)(3)(ii) of this section (*Example 3*). Accordingly, the Federal income tax consequences of the ordinary course stock repurchase are determined under section 301 or 302 of the Code.

(6) *Example 6: Divisive reorganization with money or other property not distributed within the 12-month period*—(i) *Facts.* The facts are the same as in paragraph (f)(2)(i)(A) of this section (*Example 2*), except that Distributing distributes the \$10,000x of cash received from Controlled to Distributing's shareholders on July 1, 2026, and, therefore, after the end of the 12-month period beginning on June 1, 2025.

(ii) *Analysis.* Distributing recognizes gain (but not loss) on the exchange in an amount that does not exceed the amount of money received (that is, \$10,000x). See paragraphs (c)(1), (d), and (e) of this section.

(7) *Example 7: Post-distribution payments from a distributing corporation to a controlled corporation*—(i) *Facts.* The facts are the same as in paragraph (f)(2)(i)(A) of this section (*Example 2*), except that Distributing and Controlled enter into a capital contribution agreement, which is identified and properly included in the plan of reorganization, under which Distributing will make one or more transfers of working capital to Controlled after the contribution to fund Business B's post-distribution operations. Distributing's obligation to make any such transfer, and the amount of any such transfer (if required to be made), is subject to certain conditions such that, as of the date of the contribution, the fair market value of Controlled's right to receive any one or more post-distribution payments is not reasonably ascertainable. On September

30, 2025, it is determined that Distributing must transfer \$200x to Controlled under this agreement. Distributing and Controlled both treat the \$200x payment as part of the contribution.

(ii) *Analysis.* The \$200x payment is treated as increasing the aggregate adjusted basis of the assets transferred by Distributing to Controlled in the contribution. See paragraph (c)(4) of this section. First, the \$200x is a post-distribution payment because the transfer of \$200x from Distributing to Controlled occurs pursuant to the plan of reorganization and after the control distribution date. See § 1.361–1(b)(42). Based on all facts and circumstances, including because the capital contribution agreement is identified and properly included in the plan of reorganization, the \$200x properly is characterized for Federal income tax purposes as consideration that Controlled receives in an exchange described in paragraph (a)(1) of this section (that is, the contribution). See paragraph (c)(4)(i) of this section. In addition, Controlled's right to receive the post-distribution payment is not reasonably ascertainable as of the contribution date, and, in accordance with the plan of reorganization, Controlled properly accounts for the post-distribution payment as part of the contribution when Controlled receives that payment. See paragraphs (c)(4)(ii) and (iii) of this section.

(8) *Example 8: Post-distribution payment from a controlled corporation to a distributing corporation*—(i) *Facts*—(A) *In general.* The facts are the same as in paragraph (f)(7)(i) of this section (*Example 7*), except for the following. Distributing transferred \$10,000x received from Controlled in the contribution to a qualifying creditor in a transfer meeting the requirements set forth in paragraph (c)(3) of this section and § 1.361–5. Distributing and Controlled also enter into an indemnification agreement whereby Controlled agrees to satisfy a contingent liability (Liability) that is associated with Business B but that Controlled cannot assume under State law. Under the indemnification agreement, Distributing may demand payment from Controlled once the amount of the Liability becomes fixed and determinable, without regard to whether Distributing has satisfied the Liability. The fair market value of Distributing's right to receive any such payment, and the amount of any such payment (if required to be made), is not reasonably ascertainable at the time of the contribution. On November 1, 2026, the

Liability becomes fixed and determinable in the amount of \$300x.

(B) *Payment under indemnification agreement.* After November 1, 2026, Distributing seeks payment from Controlled under the indemnification agreement without first satisfying the Liability with Distributing's own funds. Upon receiving the \$300x payment from Controlled, Distributing properly accounts for the payment as section 361 consideration and deposits the \$300x in a segregated account pursuant to the plan of reorganization. Not later than 90 days after the date on which Distributing receives the \$300x from Controlled, pursuant to the plan of reorganization, Distributing transfers the \$300x to a qualifying creditor in satisfaction of Distributing debt in a manner that satisfies all requirements set forth in § 1.361–5.

(ii) *Analysis*—(A) *Post-distribution payment; section 361 consideration; treatment as distribution to shareholders.* The \$300x that Distributing receives from Controlled is a post-distribution payment because that transfer occurs pursuant to the plan of reorganization and after the control distribution date. See § 1.361–1(b)(42). Based on all facts and circumstances, including because the indemnification agreement is identified and properly included in the plan of reorganization, the \$300x payment properly is characterized for Federal income tax purposes as consideration that Distributing receives in an exchange described in paragraph (a)(1) of this section (that is, the contribution). See paragraph (c)(3)(i)(A) of this section. In addition, the fair market value of Distributing's right to receive the post-distribution payment is not reasonably ascertainable as of the contribution date, and, in accordance with the plan of reorganization, Distributing properly accounts for the post-distribution payment as part of the contribution when Distributing receives that payment. See paragraphs (c)(3)(i)(B) and (C) of this section. Paragraph (c)(2) of this section applies to Distributing's receipt and transfer of the \$300x payment because the payment constitutes section 361 consideration and, pursuant to the plan of reorganization, Distributing deposits the payment in a segregated account and transfers the \$300x to a qualifying creditor in satisfaction of Distributing debt in a transfer meeting the requirements set forth in § 1.361–5 not later than 90 days after the date on which Distributing receives the payment. See paragraph (c)(2) of this section. Accordingly, and subject to the adjusted basis limitation set forth in

paragraph (c)(2)(ii) of this section, Distributing would be treated as distributing to its shareholders for purposes of paragraph (c)(1) of this section the \$300x post-distribution payment. See paragraph (c)(2)(i) of this section.

(B) *Adjusted basis limitation.* The aggregate amount of money and the fair market value of any other property that Distributing may transfer to a creditor under paragraph (c)(2)(i) of this section that is treated as a distribution under paragraph (c)(1) of this section is limited to the amount by which the aggregate adjusted basis of the Business B assets transferred by Distributing to Controlled in the contribution (\$10,200x) exceeds the sum of the aggregate amount of Distributing liabilities assumed by Controlled (\$0), as further reduced by the \$10,000x that Distributing had transferred to a qualifying creditor. See paragraph (c)(2)(ii) of this section. Therefore, Distributing has \$200x remaining in its adjusted basis limitation (\$10,200x – \$10,000x) under paragraph (c)(2)(ii) of this section. As a result, \$100x of the post-distribution payment (\$300x – \$200x) is treated as money not distributed to Distributing's shareholders for purposes of paragraph (c)(1) of this section. See paragraph (c)(2)(i) of this section. Therefore, Distributing recognizes \$100x of gain (that is, an amount that does not exceed the sum of the money received but not distributed and the fair market value of other property received but not distributed). See paragraph (d) of this section.

§ 1.361–4 Distributions of property under section 361(c).

(a) *Distributions of qualified property*—(1) *Distributions to shareholders.* A target corporation recognizes no gain or loss on a distribution of qualified property received in an exchange described in § 1.361–2(a) or § 1.361–3(a) to the target corporation's shareholders pursuant to a plan of reorganization.

(2) *Treatment of certain transfers to creditors*—(i) *Acquisitive reorganizations.* In an acquisitive reorganization, if a target corporation receives qualified property in an exchange described in § 1.361–2(a) or § 1.361–3(a), the target corporation is treated as distributing the qualified property to its shareholders for purposes of paragraph (a)(1) of this section if the target corporation transfers that qualified property to a creditor—

(A) Pursuant to the plan of reorganization; and

(B) In satisfaction of target corporation debt.

(ii) *Divisive reorganizations.* In a divisive reorganization, if a distributing corporation receives qualified property in an exchange described in § 1.361–2(a) or § 1.361–3(a), the distributing corporation is treated as distributing the qualified property to its shareholders for purposes of paragraph (a)(1) of this section if the distributing corporation transfers that qualified property to a creditor—

(A) Pursuant to a plan of reorganization; and

(B) In satisfaction of distributing corporation debt in a transfer meeting the requirements set forth in § 1.361–5.

(b) *Distributions of appreciated nonqualified property*—(1) *Deemed sale treatment.* If a target corporation distributes appreciated nonqualified property received in an exchange described in § 1.361–3(a) to its shareholders pursuant to a plan of reorganization, the target corporation recognizes gain as if the target corporation had sold that property to its shareholders at the property's fair market value.

(2) *Treatment of liabilities.* If a target corporation distributes appreciated nonqualified property subject to a liability to its shareholders pursuant to a plan of reorganization, or if a shareholder assumes a liability of the target corporation pursuant to the plan of reorganization, the fair market value of that appreciated nonqualified property for purposes of paragraph (b)(1) of this section is treated as not less than the amount of that liability.

(c) *No recognition of loss.* If a target corporation distributes property received in an exchange described in § 1.361–2(a) or § 1.361–3(a) to its shareholders pursuant to a plan of reorganization, the target corporation does not recognize loss.

(d) *Coordination with other provisions; cross-references.* Sections 311 and 336 through 338 of the Code do not apply to a target corporation's distribution of property described in paragraph (a) or (b) of this section. See sections 355(a)(3)(B), (d), and (e) of the Code for purposes of determining whether a distributing corporation recognizes gain on a distribution of controlled corporation stock or securities.

(e) *Examples.* The following examples illustrate the application of the rules of this section.

(1) *Example 1: Distribution of qualified property*—(i) *Facts.* On June 1, 2025, a calendar-year distributing corporation (Distributing) transfers one of its businesses to a newly formed controlled corporation (Controlled) in exchange for Controlled stock

(contribution). On June 2, 2025, Distributing distributes 80 percent of the Controlled stock to Distributing's shareholders on a pro rata basis (control distribution). As reflected in the separation and distribution agreement filed by Distributing with the U.S. Securities and Exchange Commission, Distributing evidences a definite intent to distribute the Controlled stock not distributed in the control distribution (retained Controlled stock) in 2026 pursuant to, and in completion of, the plan of reorganization (final distribution; together with the contribution and the control distribution, the separation). The retention of the retained Controlled stock is a qualifying retention within the meaning of § 1.355–10(c). Distributing properly files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) satisfying all requirements set forth in § 1.368–4, including identifying Distributing and Controlled as parties to the reorganization, determining that the contribution and each distribution are properly included in the plan of reorganization, and describing the intended Federal income tax treatment of the contribution and each distribution. The separation qualifies as a divisive reorganization.

(ii) *Analysis.* The Controlled stock Distributing receives in the contribution is qualified property. See § 1.361–1(b)(43). The contribution is an exchange described in § 1.361–2(a), because Controlled is a party to the reorganization, Distributing receives solely Controlled stock in the contribution, and the contribution and each distribution of Controlled stock occurs pursuant to the plan of reorganization. Consequently, Distributing recognizes no gain or loss on the control distribution or the final distribution. See paragraph (a)(1) of this section.

(2) *Example 2: Distribution timing requirement*—(i) *Facts.* The facts are the same as in paragraph (e)(1)(i) of this section (*Example 1*), except that the plan of reorganization evidences a definite intent to distribute the retained Controlled stock three years after the date of the first step of the plan of reorganization.

(ii) *Analysis.* The 24-month presumption for the expeditious prosecution of the plan of reorganization requirement is not satisfied. See § 1.368–4(d)(3)(i)(B). However, if Distributing demonstrates, based on all facts and circumstances, that Distributing has transferred the retained Controlled stock to its shareholders as expeditiously as

practicable in completion of the plan of reorganization, Distributing recognizes no gain or loss on the control distribution or final distribution. *See* § 1.368–4(d)(3)(i)(A) and paragraph (a)(1) of this section.

(3) *Example 3: Distribution of nonqualified property*—(i) *Facts*. Pursuant to a plan of reorganization for a transaction that qualifies as a reorganization under section 368(a)(1)(C), a target corporation (Target) transfers all its property other than an appreciated asset (Asset) to an acquiring corporation (Acquiring) solely in exchange for Acquiring voting stock, which Target distributes, along with Asset, to its shareholders in complete liquidation of Target. Asset has a fair market value of \$100x and an adjusted basis of \$50x and is subject to a \$130x nonrecourse liability. Target properly files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) satisfying all requirements set forth in § 1.368–4, including identifying Target and Acquiring as parties to the reorganization, determining that the distribution of Asset is properly included in the plan of reorganization, and describing the intended Federal income tax treatment of the reorganization.

(ii) *Analysis*—(A) *In general*. The Acquiring stock Target receives in the exchange is qualified property. *See* § 1.361–1(b)(43). The exchange of Target assets for Acquiring stock is described in § 1.361–2(a), because the exchange occurs pursuant to a plan of reorganization, Target and Acquiring are parties to the reorganization, and Target receives solely Acquiring stock in the exchange. Accordingly, Target recognizes no gain on the distribution of Acquiring stock to Target shareholders. *See* paragraph (a)(1) of this section.

(B) *Asset distribution*. Asset is appreciated nonqualified property. *See* § 1.361–1(b)(4). Accordingly, Target recognizes gain on the distribution of Asset to its shareholders pursuant to the plan of reorganization as if Target had sold Asset to its shareholders at Asset's fair market value. *See* paragraph (b)(1) of this section. Because Target distributed Asset to its shareholders subject to the \$130 nonrecourse liability, the fair market value of Asset is treated as not less than the amount of that liability. *See* paragraph (b)(2) of this section. Accordingly, the amount of gain Target recognizes on the distribution is \$80x (\$130x fair market value – \$50x adjusted basis).

§ 1.361–5 Transfers to creditors of distributing corporation in divisive reorganizations under section 361(b)(3) and (c)(3).

(a) *General rule*. The transfer of section 361 consideration by a distributing corporation to a creditor of the distributing corporation under § 1.361–3(c)(2) or 1.361–4(a)(2)(ii) (as appropriate) in a divisive reorganization is not treated as a distribution by the distributing corporation to its shareholders pursuant to the plan of reorganization unless the transfer is—

(1) To a qualifying creditor of the distributing corporation, as determined under paragraph (b) of this section;

(2) In satisfaction of eligible distributing corporation debt, as determined under paragraph (c) of this section;

(3) In an amount not greater than the maximum amount of distributing corporation debt, as determined under paragraph (d) of this section; and

(4) Part of a qualifying debt elimination transaction, as determined under paragraph (e) of this section.

(b) *Qualifying creditor*—(1) *General status as a creditor with regard to distributing corporation debt*. Each creditor to which the distributing corporation transfers section 361 consideration must be a creditor (qualifying creditor) that—

(i) Holds historical distributing corporation debt, qualifying trade payables, or direct issuance debt; and

(ii) Satisfies the requirements set forth in paragraph (b)(2) of this section.

(2) *Related-creditor prohibition*—(i) *General rule*. Except as provided in paragraph (b)(2)(ii) of this section, the following persons are not qualifying creditors of the distributing corporation (non-qualifying creditors):

(A) A distributing corporation related person.

(B) A controlled corporation related person.

(C) A related person with respect to a distributing corporation related person.

(D) A related person with respect to a controlled corporation related person.

(ii) *Exception for certain distributing corporation related persons*. A distributing corporation related person or a related person with respect to a distributing corporation related person (each as determined in accordance with paragraph (b)(2)(iii) of this section) is a qualifying creditor of the distributing corporation only if the following requirements are satisfied:

(A) *Transfer to unrelated ultimate creditor*—(1) *Money or other property*. No later than the end of the 12-month period beginning on the date the distributing corporation receives the

money or other property, the section 361 consideration composed of money or other property is transferred to an unrelated ultimate creditor pursuant to the plan of reorganization to satisfy debt owed by the distributing corporation related person or the related person with regard to a distributing corporation related person, respectively, to the unrelated ultimate creditor.

(2) *Qualified property*. The section 361 consideration composed of qualified property is transferred pursuant to the plan of reorganization to an unrelated ultimate creditor to satisfy debt owed by the distributing corporation related person or the related person with regard to a distributing corporation related person, respectively, to the unrelated ultimate creditor. For rules regarding the expeditious completion of the plan of reorganization, *see* § 1.368–4(d)(3).

(3) *Intermediate transfers*. For purposes of paragraph (b)(2)(ii)(A)(1) and (2) of this section, one or more intermediate transfers of section 361 consideration between or among distributing corporation related persons or related persons with regard to distributing corporation related persons to satisfy debts (including the initial distributing corporation debt) are permissible if those intermediate transfers culminate in a transfer of section 361 consideration to an unrelated ultimate creditor.

(B) *Debt in existence as of earliest applicable date*—(1) *In general*. Except as provided in paragraph (b)(2)(ii)(B)(2) of this section, all debt for which section 361 consideration is exchanged pursuant to the transfers described in paragraph (b)(2)(ii)(A) of this section is in existence as of the earliest applicable date.

(2) *Distributing corporation debt directly held by internal creditor*. Distributing corporation debt held directly by a distributing corporation related person or a related person with regard to a distributing corporation related person qualifies as historical distributing corporation debt described in paragraph (c)(2)(i) of this section.

(C) *Transactions, debts, and creditors identified in plan of reorganization*. Each transaction (including each intermediate and unrelated ultimate creditor transfer), creditor (including the unrelated ultimate creditor), and debt referenced in paragraph (b)(2)(ii)(A) of this section is identified and described in the plan of reorganization with regard to the divisive reorganization.

(iii) *Determination of related-person status*. For purposes of paragraph (b)(2) of this section, the status of a person as a distributing corporation related person

or a controlled related person, or as a related person with regard to any distributing corporation related person or as a related person with respect to any controlled corporation related person, is determined as of the date on which that person receives section 361 consideration in a transfer or series or transfers described in paragraph (b)(2)(ii)(A) of this section.

(c) *Eligible distributing corporation debt*—(1) *Overview*. Distributing corporation debt is not eligible to be satisfied with section 361 consideration under paragraph (a) of this section unless that debt qualifies under paragraph (c)(2) of this section.

(2) *Qualification as eligible distributing corporation debt*—(i) *Historical distributing corporation debt*. Historical distributing corporation debt is eligible to be satisfied with section 361 consideration under paragraph (c)(1) of this section. Except as provided in paragraph (c)(2)(ii) or (iii) of this section, for a distributing corporation debt to qualify as historical distributing corporation debt—

(A) The distributing corporation must have incurred the distributing corporation debt before the earliest applicable date;

(B) That debt must have an original term that ends after the date of the exchange described in § 1.361–2(a) or 1.361–3(a); and

(C) That debt must be identified in the plan of reorganization or original plan of reorganization (if amended).

(ii) *Refinancing exception for historical distributing corporation debt*. Distributing corporation debt incurred by the distributing corporation after the earliest applicable date is treated as historical distributing corporation debt only if—

(A) The distributing corporation debt is—

(1) A refinancing of historical distributing corporation debt (refinanced historical distributing corporation debt); or

(2) A refinancing of refinanced historical distributing corporation debt (that is, the debt is traced directly through one or more refinancings to debt that qualifies as historical distributing corporation debt pursuant to this paragraph (c)(2)(ii);

(B) The incurrence of the refinanced historical distributing corporation debt described in paragraph (c)(2)(ii)(A) of this section is not part of a plan to incur debt in addition to historical distributing corporation debt determined under paragraph (c)(2)(i) of this section (or an amount of debt in addition to the amount of historical distributing corporation debt

determined under paragraph (d) of this section, without regard to paragraph (d)(2)(iv) of this section) in anticipation of the divisive reorganization (for example, the incurrence of the refinanced historical distributing corporation debt would have occurred without regard to the divisive reorganization);

(C) The distributing corporation engages in a qualifying debt elimination transaction solely under paragraph (e)(3) or (4) of this section to eliminate that refinanced historical distributing corporation debt; and

(D) The qualifying debt elimination transaction described in paragraph (c)(2)(ii)(C) of this section is described and identified in the plan of reorganization or original plan of reorganization (if amended) for the divisive reorganization.

(iii) *Revolving credit agreements*. A revolving credit agreement to which the distributing corporation is a debtor qualifies as historical distributing corporation debt only if—

(A) The distributing corporation entered into the agreement before the earliest applicable date;

(B) That agreement does not expire until after the date of the exchange described in § 1.361–2(a) or 1.361–3(a); and

(C) That agreement is identified in the plan of reorganization or original plan of reorganization (if amended).

(iv) *Qualifying trade payables*. Trade payables of the distributing corporation that meet the following requirements are eligible to be satisfied with section 361 consideration under paragraph (c)(1) of this section:

(A) The trade payables are described in a plan of reorganization or original plan of reorganization (if amended).

(B) The trade payables were incurred in the ordinary course of business of the distributing corporation.

(C) The satisfaction such trade payables is necessary—

(1) To ensure the allocation to the controlled corporation of all liabilities properly associated with the business assets transferred to that corporation; and

(2) To result in the controlled corporation being allocated liabilities in an amount that properly relates to its business operations, the earnings of which will be used to properly satisfy those liabilities.

(v) *Direct issuance debt*. Direct issuance debt incurred as part of a direct issuance transaction satisfying the requirements of paragraph (e)(4) of this section is eligible to be satisfied with section 361 consideration under paragraph (c)(1) of this section.

(3) *Determination of amount of distributing corporation debt*—(i) *Purpose*. The rules in this paragraph (c)(3) apply to determine the aggregate amount of distributing corporation debt. For rules to determine the maximum amount of distributing corporation debt that can be satisfied with section 361 consideration under paragraph (a) of this section, see paragraph (d) of this section.

(ii) *Aggregate amount of distributing corporation debt*. The aggregate amount of distributing corporation debt includes solely the amounts described in paragraphs (c)(3)(ii)(A) through (E) of this section, as applicable, taking into account any reduction required by paragraph (c)(3)(iii) of this section.

(A) *Historical distributing corporation debt*. The aggregate amount of historical distributing corporation debt equals the aggregate remaining principal amount, as of the earliest applicable date, of all historical distributing corporation debt other than historical distributing corporation debt that is eliminated as part of a qualifying direct issuance transaction under paragraph (e)(4) of this section.

(B) *Refinanced distributing corporation debt*. If the distributing corporation relies on the exception set forth in paragraph (c)(2)(ii) of this section (that is, the refinancing exception for historical distributing corporation debt) with regard to any distributing corporation debt, the amount of that distributing corporation debt equals the lesser of—

(1) The original principal amount of the refinanced distributing corporation debt; and

(2) The principal amount of the original historical distributing corporation debt (that is, the distributing corporation debt to which the refinanced distributing corporation debt is traced) as of the earliest applicable date.

(C) *Revolving credit agreements*. With regard to a revolving credit agreement that satisfies the requirements set forth in paragraph (c)(2)(iii) of this section, the amount of that revolving credit agreement equals the lesser of—

(1) The balance under that agreement as of the earliest applicable date (and not the maximum amount that could be incurred by the distributing corporation under that agreement); and

(2) The lowest balance under that agreement beginning on the earliest applicable date and ending on the control distribution date.

(D) *Qualifying trade payables*. With regard to trade payables of the distributing corporation that satisfy the requirements set forth in paragraph

(c)(2)(iv) of this section, the amount of those payables equals the aggregate amount of those payables on the date of the exchange described in § 1.361–2(a) or 1.361–3(a).

(E) *Direct issuance debt.* With regard to direct issuance debt that satisfies the requirements set forth in paragraph (c)(2)(v) of this section, the amount of that debt equals the aggregate principal amount of that debt on the date of the exchange described in § 1.361–2(a) or 1.361–3(a).

(iii) *Offsetting debts taken into account.* The aggregate amount of distributing corporation debt determined under paragraph (c)(3)(ii) of this section must be reduced by the aggregate principal amount (or the balance, in the case of a revolving credit agreement) of any debt for which—

(A) The distributing corporation is a creditor; and

(B) The debtor of that debt is a creditor with respect to distributing corporation debt described in paragraph (c)(3)(ii) of this section.

(d) *Maximum amount of distributing corporation debt—(1) General calculation.* The maximum amount of distributing corporation debt that can be satisfied with section 361 consideration under paragraph (a) of this section equals the amount obtained by subtracting the aggregate amount of distributing corporation debt that the controlled corporation assumes pursuant to the plan of reorganization from the lesser of—

(i) The aggregate amount of distributing corporation debt (as determined under paragraph (c)(3) of this section); and

(ii) The aggregate amount of distributing corporation debt determined under the eight-quarterly-average test (as set forth in paragraph (d)(2) of this section).

(2) *Eight-quarterly-average test—(i) Determination.* In accordance with paragraphs (d)(2)(ii) and (iii) of this section, the aggregate amount of distributing corporation debt under the eight-quarterly-average test, measured as of the close of each of the eight fiscal quarters that end immediately before the earliest applicable date, equals the average of the amount of distributing corporation debt owed to persons other than distributing corporation related persons.

(ii) *Calculation of distributing corporation debt at the close of each quarter.* The methodology for determining the maximum amount of distributing corporation debt under paragraph (c)(3) of this section must be used to determine the amount of distributing corporation debt at the

close of each quarter for purposes of paragraph (d)(2)(i) of this section.

(iii) *Distributing corporation debt held by distributing corporation related person.* If the distributing corporation relies on the exception set forth in paragraph (b)(2)(ii) of this section (that is, the related-creditor exception), the amount determined under paragraph (d)(2)(i) of this section includes an amount equal to the least of—

(A) The amount of distributing corporation debt directly held by distributing corporation related persons or related persons with respect to distributing corporation related persons (each, a related person);

(B) The amount of debt of a related person (related person debt) held by any other related person; and

(C) The amount of related person debt held by the unrelated ultimate creditor.

(e) *Qualifying debt elimination transactions—(1) Overview.* A transaction that satisfies the requirements set forth in this paragraph (e) qualifies as a qualifying debt elimination transaction for purposes of paragraph (a) of this section.

(2) *Qualifying original creditor exchanges.* The satisfaction of distributing corporation debt with section 361 consideration in an exchange not described in paragraph (e)(3) or (4) of this section (original creditor exchange) qualifies as a qualifying debt elimination transaction if all applicable requirements set forth in paragraphs (b) through (d) of this section (without regard to paragraph (c)(2)(ii)(A) of this section) are satisfied.

(3) *Qualifying intermediated exchanges.* An intermediated exchange qualifies as a qualifying debt elimination transaction if all applicable requirements set forth in paragraphs (b) through (d) and (e)(3)(i) through (vi) of this section are satisfied.

(i) *Prohibition on intermediary benefits—(A) In general.* Except as provided in paragraph (e)(3)(i)(B) of this section, no holder of a distributing corporation debt satisfied with section 361 consideration holds the distributing corporation debt for the benefit of—

(1) The distributing corporation;

(2) The controlled corporation;

(3) A distributing corporation related person; or

(4) A controlled corporation related person.

(B) *Exception.* The prohibition described in paragraph (e)(3)(i)(A) of this section does not apply to the collateral benefit received by a distributing corporation, or a distributing corporation related person, from the intermediary's facilitation of the transfer of section 361 consideration

in satisfaction of historical distributing corporation debt.

(ii) *Prohibition on acquiring debt from distributing corporation.* The intermediary does not acquire historical distributing corporation debt satisfied with section 361 consideration from the distributing corporation, the controlled corporation, or any distributing corporation related person or controlled corporation related person.

(iii) *Arm's-length bargaining required.* Each exchange of section 361 consideration for historical distributing corporation debt between the distributing corporation and the intermediary is effectuated based on terms and conditions arrived at by the parties bargaining at arm's length.

(iv) *Prohibition on profit-sharing or limitation.* None of the distributing corporation, the controlled corporation, or any distributing corporation related person or controlled corporation related person—

(A) Participates in any profit gained by the intermediary upon an exchange of section 361 consideration; or

(B) Limits by agreement or other arrangement any profit described in paragraph (e)(3)(iv)(A) of this section.

(v) *Independence requirement—(A) General rule.* The intermediary acts for its own account with regard to all components of the intermediated exchange.

(B) *Risk of loss.* The intermediary bears the risk of loss with respect to—

(1) The historical distributing corporation debt; and

(2) Any subsequent sale or other disposition of section 361 consideration transferred to the intermediary to satisfy the historical distributing corporation debt.

(C) *Prohibition regarding variable pricing and similar agreements.* The requirement set forth in paragraph (e)(3)(v)(B) of this section is not satisfied if the intermediary enters into a variable pricing agreement or similar arrangement with the distributing corporation (or a controlled corporation, distributing corporation related person, or controlled corporation related person) with regard to any section 361 consideration, including—

(1) True-up payments;

(2) Forward exchange agreements; and

(3) Any similar agreement or arrangement.

(vi) *Minimum temporal requirement.* The intermediary holds the historical distributing corporation debt for a period of not less than 30 days ending on the control distribution date.

(4) *Qualifying direct issuance transactions—(i) Overview—(A) In general.* To qualify as a qualifying debt

elimination transaction, a direct issuance transaction must be determined to comprise a transfer by the distributing corporation of section 361 consideration to the creditor in exchange for the satisfaction of the distributing corporation debt held by the creditor (direct issuance debt), and not a sale by the distributing corporation of section 361 consideration to the creditor for the proceeds of that direct issuance debt, for Federal income tax purposes.

(B) *Application of Code and general principles of Federal income tax law.* The determination under paragraph (e)(4)(i)(A) of this section is made based on all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine. Specifically, the substance of the direct issuance transaction must be determined under all relevant provisions of the Code and general principles of Federal income tax law before the requirements under section 361 can be applied to determine whether the transaction qualifies for nonrecognition treatment under that section.

(ii) *Facts-and-circumstances test—(A) In general.* The determination of whether a direct issuance transaction qualifies as an exchange under section 361 (and not as a sale under section 1001) is made based on the factors specified in paragraph (e)(4)(ii)(B) of this section, each of which provides evidence of qualification or non-qualification as an exchange under section 361 as set forth in paragraph (e)(4)(ii)(B) of this section, unless the transaction satisfies the safe harbor under paragraph (e)(4)(iii) of this section. The strength of the evidence provided by those factors is determined based on an analysis of all relevant facts and circumstances.

(B) *Factors—(1) Exchange part of prearranged, integrated plan—(i) Substantial evidence of non-qualification.* An exchange of section 361 consideration by the distributing corporation with the creditor pursuant to an arrangement that comprises part of a prearranged, integrated plan is substantial evidence of non-qualification.

(ii) *Evidence of qualification.* An exchange of section 361 consideration by the distributing corporation with the creditor that is not pursuant to an arrangement that comprises part of a prearranged, integrated plan is evidence of qualification.

(2) *Specified agency and substance-over-form requirements—(i) Evidence of non-qualification.* The failure to satisfy one or more requirements set forth in

paragraphs (e)(4)(iii)(C) through (F) of this section is evidence of non-qualification.

(ii) *Substantial evidence of non-qualification.* Substantial failure to satisfy any of the requirements set forth in paragraphs (e)(4)(iii)(C) through (F) of this section, as determined based on all relevant facts and circumstances, or any failure to satisfy a substantial number of those requirements, is substantial evidence of non-qualification.

(iii) *Substantial evidence of qualification.* The satisfaction of all requirements set forth in paragraphs (e)(4)(iii)(C) through (F) of this section is substantial evidence of qualification.

(3) *Temporal proximity—(i) Evidence of non-qualification.* The fact that the creditor holds the refinanced historical distributing corporation debt for a period of less than 30 days ending on the control distribution date is evidence of non-qualification.

(ii) *Evidence of qualification.* The fact that the creditor holds the refinanced historical distributing corporation debt for a period of at least 30 days ending on the control distribution date is evidence of qualification.

(4) *Dominion or control of cash proceeds of refinanced distributing corporation debt—(i) Substantial evidence of non-qualification.* The distributing corporation's legal or practical dominion or control over any proceeds of the refinanced historical distributing corporation debt (as determined in accordance with § 1.357-2(e)(2)) is substantial evidence of non-qualification.

(ii) *Substantial evidence of qualification.* The distributing corporation's lack of legal or practical dominion or control over any proceeds of the refinanced historical distributing corporation debt (as determined in accordance with § 1.357-2(e)(2)) is substantial evidence of qualification.

(5) *Purpose of avoiding requirements or limitations of section 361.* The distributing corporation's issuance of the refinanced historical distributing corporation debt with a principal purpose of avoiding any of the requirements or limitations of section 361 is evidence of non-qualification.

(iii) *Safe harbor for direct issuance transactions.* A direct issuance transaction is treated as a qualifying debt elimination transaction under this paragraph (e)(4)(iii) only if all the following requirements are satisfied:

(A) The distributing corporation does not have, at any time, legal or practical dominion or control over any proceeds of the refinanced historical distributing corporation debt, as determined in accordance with § 1.357-2(e)(2).

(B) The creditor holds the refinanced historical distributing corporation debt for a period of not less than 30 days ending on the control distribution date.

(C) Each exchange of section 361 consideration for refinanced historical distributing corporation debt between the distributing corporation and the creditor is effectuated based on terms and conditions arrived at by the parties bargaining at arm's length.

(D) None of the distributing corporation, the controlled corporation, or any distributing corporation related person or controlled corporation related person—

(1) Participates in any profit gained by the creditor upon an exchange of section 361 consideration; or

(2) Limits by agreement or other arrangement any profit of the creditor described in paragraph (e)(4)(iii)(D)(1) of this section.

(E) The creditor acts for its own account with regard to all components of the direct issuance transaction.

(F) The creditor bears the risk of loss with respect to—

(1) The refinanced historical distributing corporation debt; and

(2) Any subsequent sale or other disposition of section 361 consideration transferred to the creditor to satisfy the refinanced historical distributing corporation debt.

(iv) *Prohibition regarding variable pricing and similar agreements.* The requirement set forth in paragraph (e)(4)(iii)(F) of this section is not satisfied if the creditor enters into a variable pricing agreement or similar arrangement with the distributing corporation (or a controlled corporation, distributing corporation related person, or controlled corporation related person) with regard to any section 361 consideration, including—

(A) True-up payments;

(B) Forward exchange agreements; and

(C) Any similar agreement or arrangement.

(f) *Transitorily eliminated eligible distributing corporation debt—(1) Overview.* The amount of section 361 consideration treated as transferred by a distributing corporation to a creditor of the distributing corporation in a qualifying debt elimination transaction (and, therefore, treated as distributed to shareholders pursuant to the plan of reorganization under section 361(b)(3) or (c)(3), as appropriate) is reduced by the amount of eligible distributing corporation debt that is transitorily eliminated pursuant to paragraph (f)(2)(i) of this section.

(2) *Transitory elimination—(i) General rule.* Unless the exception

described in paragraph (f)(2)(iii) of this section applies, a distributing corporation is treated as transitively eliminating an amount of eligible distributing corporation debt equal to the amount of such debt that the distributing corporation or a distributing corporation related person (determined immediately after the earliest applicable date) replaces after the earliest applicable date, directly or indirectly, with borrowing that the distributing corporation or any distributing corporation related person (determined immediately after the earliest applicable date) expects or is committed to, directly or indirectly, before that date.

(ii) *Borrowings not in the ordinary course.* For purposes of paragraph (f)(2)(i) of this section, a borrowing is not treated as expected if the borrowing results from—

(A) An event unrelated to the divisive reorganization and not in the ordinary course of business of the distributing corporation; and

(B) Changed circumstances that were not expected prior to the control distribution date (therefore, the borrowing is unrelated to, and demonstrably independent of, the divisive reorganization or any transaction related to the divisive reorganization).

(iii) *Borrowings in the ordinary course.* A borrowing described in paragraph (f)(2)(i) of this section is not treated as transitively eliminating eligible distributing corporation debt if the borrowing—

(A) Is incurred in the ordinary course of business of the distributing corporation or distributing corporation related person (as appropriate); and

(B) Would have been incurred by the distributing corporation or distributing corporation related person (as appropriate) without regard to the divisive reorganization or any transaction related to the divisive reorganization (that is, the borrowing is unrelated to, and demonstrably independent of, any such transaction).

(g) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples, the following facts apply: A distributing corporation (Distributing) transfers one of its businesses to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and other section 361 consideration (contribution); Distributing distributes all the Controlled stock to its shareholders on a pro rata basis (distribution); Distributing transfers the other section 361 consideration to holders of Distributing debt (together with the

contribution and the distribution, the separation); Distributing properly files a plan of reorganization for the separation with the IRS pursuant to § 1.368–3(a)(5) that satisfies all requirements set forth in § 1.368–4; the separation qualifies as a divisive reorganization under sections 355 and 368(a)(1)(D); and the aggregate amount of adjusted basis of the assets transferred in the contribution exceeds the sum of the aggregate amount of liabilities assumed by Controlled plus the amount of money and the fair market value of any other property received by Distributing. Unless otherwise provided, no Distributing debt was transitively eliminated within the meaning of paragraph (f) of this section.

(1) *Example 1: Transfer of money or other property to related creditor—(i) Facts.* The section 361 consideration received by Distributing in the contribution consists of Controlled stock and \$100x of cash. Distributing has an outstanding debt of \$100x owed to a wholly owned subsidiary that is a Distributing related person (Subsidiary, and such debt, Internal Debt). Subsidiary has an outstanding debt of \$100x owed to an unrelated ultimate creditor (External Debt). The External Debt was incurred prior to the earliest applicable date. The Internal Debt qualifies as historical Distributing debt described in paragraph (c)(2)(i) of this section. The maximum amount of Distributing debt that can be satisfied with section 361 consideration, as determined under paragraph (d) of this section, is \$100x. Pursuant to the plan of reorganization, Distributing deposits the \$100x of cash received in the contribution in a segregated account. Subsequently, Distributing, pursuant to the plan of reorganization, transfers the \$100x of cash to Subsidiary in satisfaction of the Internal Debt (which Subsidiary deposits into a segregated account), and Subsidiary transfers the \$100x of cash to the unrelated ultimate creditor in satisfaction of the External Debt. The transfers from Distributing to Subsidiary, and from Subsidiary to the unrelated ultimate creditor, occur no later than the end of the 12-month period beginning on the date that Distributing receives the \$100x of cash from Controlled. Each transaction, creditor (Subsidiary and unrelated ultimate creditor), and debt (Internal Debt and External Debt) is identified and described in the plan of reorganization with regard to the separation.

(ii) *Analysis.* Distributing's transfer of the \$100x of cash to Subsidiary satisfies all requirements under this section and § 1.361–3(c)(2)(i) to be treated as a

distribution to Distributing's shareholders pursuant to the plan of reorganization for purposes of § 1.361–3(c)(1). *See* paragraph (a) of this section. First, each of Distributing and Subsidiary deposits the \$100x of cash they received into a segregated account. *See* § 1.361–3(c)(2)(i)(A). Second, Distributing's transfer of the \$100x of cash to Subsidiary is a transfer to a qualifying creditor because, pursuant to the plan of reorganization, Subsidiary transfers the \$100x of cash to an unrelated ultimate creditor by no later than the end of the 12-month period beginning on the date Distributing receives the \$100x of cash from Controlled (*see* paragraph (b)(2)(ii)(A)(1) of this section), the Internal Debt qualifies as historical distributing corporation debt and therefore is eligible distributing corporation debt, the External Debt is in existence as of the earliest applicable date (*see* paragraphs (a)(2) and (b)(2)(ii)(B) of this section), and each transfer of the \$100x provided by Controlled, each of the Internal Debt and External Debt, and each of Subsidiary and the unrelated ultimate creditor, is identified and described in the plan of reorganization (*see* paragraph (b)(2)(ii)(C) of this section). Second, the amount of historical distributing corporation debt satisfied by Distributing (that is, \$100x) does not exceed the maximum amount of distributing corporation debt determined under paragraph (d) of this section (that is, \$100x). *See* paragraph (a)(3) of this section. Lastly, the transfer of the \$100x of cash by Distributing to Subsidiary in satisfaction of the Internal Debt is a qualifying original creditor exchange under paragraph (e)(2) of this section. *See* paragraph (a)(4) of this section.

(2) *Example 2: Refinancing of historical distributing corporation debt—(i) Facts.* The section 361 consideration received by Distributing in the contribution consists of Controlled stock and \$100x of cash. Distributing has an outstanding \$100x debt owed to an unrelated creditor that is a qualifying creditor (Distributing debt). The Distributing debt was incurred before the earliest applicable date and has an original term that ends after the date of the contribution. This debt was identified in the plan of reorganization. Before the date of the contribution, but after the earliest applicable date, Distributing refinances the Distributing debt with a bank that is a qualifying creditor (refinanced Distributing debt). The incurrence of the refinanced Distributing debt is not part of a plan to incur additional debt

prohibited by paragraph (c)(2)(ii)(B) of this section, because Distributing needed to refinance the Distributing debt in response to an identifiable, material, and unexpected delay in the date of the contribution. Thereafter, Distributing satisfies the refinanced Distributing debt through an intermediated exchange that is a qualifying debt elimination transaction under paragraph (e)(3) of this section (Distributing intermediated exchange). The Distributing debt refinancing and the Distributing intermediated exchange are described and identified in the amended plan of reorganization for the separation.

(ii) *Analysis.* The refinanced Distributing debt is treated as historical distributing corporation debt because it satisfies the requirements for the refinancing exception set forth in paragraph (c)(2)(ii) of this section. First, the refinanced Distributing debt is a refinancing of historical distributing corporation debt (that is, the original Distributing debt). See paragraph (c)(2)(ii)(A)(1) of this section. Second, Distributing did not refinance the Distributing debt as part of a plan to incur additional debt prohibited by paragraph (c)(2)(ii)(B) of this section. Third, the refinanced Distributing debt was eliminated by Distributing through a qualifying debt elimination transaction under paragraph (e)(3) of this section. See paragraph (c)(2)(ii)(C) of this section. Lastly, the qualifying debt elimination transaction and the refinancing of the Distributing debt are described and identified in the amended plan of reorganization for the separation. See paragraph (c)(2)(ii)(D) of this section and proposed § 1.368–4(d)(1)(iv). Accordingly, the refinanced Distributing debt is eligible to be satisfied with section 361 consideration under paragraph (a) of this section. See paragraph (c)(1) of this section.

(3) *Example 3: Eight-quarterly-average test—(i) Facts.* The section 361 consideration received by Distributing in the contribution consists of Controlled stock and \$100x of cash. As of the earliest applicable date (July 10, 2025), Distributing has outstanding debt of \$180x owed to an unrelated creditor that is a qualifying creditor (Distributing debt). The \$180x of Distributing debt consists of three loans: a \$100x loan incurred in the eighth fiscal quarter that ended immediately before the earliest applicable date (September 30, 2023); a \$60x loan incurred in the first fiscal quarter that ended immediately before the earliest applicable date (June 30, 2025); and a \$20x loan incurred in the first fiscal quarter that ended immediately before the earliest

applicable date (June 30, 2025). The three loans that comprise the \$180x of Distributing debt have an original term that ends after the date of the contribution, as identified in the plan of reorganization. Controlled assumes the \$20x loan in the contribution.

(ii) *Analysis.* All \$180x of the Distributing debt qualifies as historical Distributing debt, and therefore eligible Distributing debt, because Distributing incurred each of the debts before the earliest applicable date and each of the debts has an original term that ends after the date of the contribution and is identified in the plan of reorganization. See paragraph (c)(2)(i) of this section. However, the maximum amount of eligible Distributing debt that Distributing can satisfy with section 361 consideration is limited under paragraphs (c)(3) and (d) of this section. The aggregate amount of Distributing debt is equal to \$180x (that is, the remaining principal amount of all historical Distributing debt as of the earliest applicable date). See paragraph (c)(3)(ii)(A) of this section. The aggregate amount of Distributing debt determined under the eight-quarterly-average test is equal to \$110x (that is, the eight quarterly average of \$880x—the \$180x of Distributing debt outstanding at the close of the first fiscal quarter ending immediately before the earliest applicable date and the \$100x of Distributing debt outstanding at the close of each of the preceding seven fiscal quarters $((\$180x \times 1) + (\$100x \times 7))/8 = \$110x$). See paragraph (d)(2) of this section. Accordingly, the maximum amount of eligible Distributing debt that Distributing can satisfy with the section 361 consideration received from Controlled is \$90x (that is, the lesser of the \$180x of eligible Distributing debt and the \$110x of Distributing debt determined under the eight-quarterly-average test, reduced by the \$20x of Distributing debt assumed by Controlled in the contribution). See paragraph (d)(1) of this section.

(4) *Example 4: Amount of distributing corporation debt under revolving credit agreement—(i) Facts.* Distributing is the debtor under a revolving credit agreement entered into before the earliest applicable date with an unrelated creditor that is a qualifying creditor. The revolving credit agreement does not expire until after the date of the contribution, and the agreement is identified in the plan of reorganization for the separation. Distributing's credit limit under the agreement is \$100x. As of the earliest applicable date, Distributing's outstanding balance under the agreement is \$50x. After that date, but prior to the control

distribution date, Distributing's outstanding balance under the agreement decreases to \$40x and then subsequently increases to \$80x.

(ii) *Analysis.* The revolving credit agreement qualifies as historical distributing corporation debt because Distributing entered into the agreement before the earliest applicable date, the agreement does not expire until after the date of the contribution, and the agreement is identified in the plan of reorganization for the separation. See paragraph (c)(2)(iii) of this section. Although Distributing's credit limit under the revolving credit agreement is \$100x, the maximum amount under the agreement that Distributing can satisfy with section 361 consideration is \$40x (that is, the lesser of the outstanding balance as of the earliest applicable date (\$50x) and the lowest balance under the agreement beginning on the earliest applicable date and ending on the control distribution date (\$40x). See paragraph (c)(3)(ii)(C) of this section.

(5) *Example 5: Effect of offsetting debts on amount of historical distributing corporation debt—(i) Facts.* As of the earliest applicable date, Distributing has an outstanding \$100x debt owed to an unrelated creditor (Creditor) that is a qualifying creditor (Distributing debt). The Distributing debt is historical Distributing debt under paragraph (c)(2)(i) of this section, and therefore qualifies as Distributing debt eligible to be satisfied with section 361 consideration under paragraph (a)(2) of this section. See paragraphs (c)(1) and (2) of this section. As of the earliest applicable date, Creditor also has an outstanding \$50x debt owed to Distributing (Creditor debt).

(ii) *Analysis.* In determining the aggregate amount of eligible Distributing debt under paragraph (c)(3) of this section, the amount of eligible Distributing debt must be reduced by the aggregate principal amount of any debt for which Distributing is a creditor and the debtor is the Creditor with respect to that Distributing debt. See paragraph (c)(3)(iii) of this section (requiring offsetting debts to be taken into account). Accordingly, the aggregate amount of eligible Distributing debt is \$50x (that is, the \$100x of Distributing debt reduced by the \$50x of Creditor debt).

(6) *Example 6: Qualifying original creditor exchange—(i) Facts.* The section 361 consideration received by Distributing in the contribution consists of Controlled stock and \$100x of Controlled securities. As of the earliest applicable date, Distributing has an outstanding \$100x debt owed to an unrelated creditor (Creditor) that is a

qualifying creditor (Distributing debt). The Distributing debt has an original term that ends after the date of the contribution and is identified in the plan of reorganization. The maximum amount of Distributing debt determined under paragraph (d) of this section that can be satisfied with section 361 consideration is \$100x. Pursuant to the plan of reorganization for the separation, Distributing transfers the \$100x of Controlled securities received from Controlled directly to Creditor in satisfaction of the Distributing debt. This transfer does not qualify as a qualifying intermediated exchange under paragraph (e)(3) of this section or as a qualifying direct issuance transaction under paragraph (e)(4) of this section.

(ii) *Analysis.* The Distributing debt qualifies as historical distributing corporation debt because Distributing incurred the debt before the earliest applicable date and that debt has an original term that ends after the date of the contribution and is identified in the plan of reorganization. *See* paragraph (c)(2)(i) of this section. Creditor is a qualifying creditor because Creditor holds historical distributing corporation debt and does not run afoul of the related-creditor prohibition under paragraph (b)(2)(i) of this section. *See* paragraph (b)(1) of this section. The amount of Distributing debt satisfied in the transaction (that is, \$100x) does not exceed the maximum amount determined under paragraph (d) of this section (that is, \$100x). Distributing's transfer of the \$100x of Controlled securities directly to Creditor in satisfaction of Distributing debt is a qualifying original creditorexchange, and therefore is a qualifying debt elimination transaction. *See* paragraph (e)(2) of this section. Accordingly, the transfer of \$100x of Controlled securities to Creditor in satisfaction of Distributing debt is treated as a distribution by Distributing to its shareholders pursuant to the plan of reorganization. *See* paragraph (a) of this section.

(7) *Example 7: Not a qualifying direct issuance transaction—(i) Facts.* The facts are the same as in paragraph (g)(6)(i) of this section (*Example 6*), except for the following. In anticipation of the divisive reorganization, Distributing intends to issue new debt to Creditor and use the proceeds to satisfy historical Distributing debt on a date following the contribution date. Accordingly, after the earliest applicable date, and as part of a prearranged, integrated plan with Creditor, Distributing carries out the following transactions. First, Distributing directly

issues new debt to Creditor (new Distributing debt) in exchange for \$100x. Distributing intends to transfer to Creditor the Controlled securities Distributing receives in the contribution to satisfy the new Distributing debt (collectively, the direct issuance transaction). On a date following the contribution, Distributing uses the \$100x of proceeds from the new Distributing debt to repay the historical Distributing debt. Also following the date of the contribution, Distributing transfers the Controlled securities to Creditor in exchange for the refinanced Distributing debt (securities-for-debt exchange).

(ii) *Analysis.* The securities-for-debt exchange is not carried out through a qualifying debt elimination transaction. Distributing incurred the refinanced Distributing debt after the earliest applicable date and does not satisfy the requirements for the refinancing exception in paragraph (c)(2)(ii) of this section. The direct issuance transaction fails to qualify for the safe harbor for qualifying direct issuance transactions under paragraph (e)(4)(iii) of this section because Distributing had dominion and control over the direct issuance proceeds. *See* paragraph (e)(4)(iii)(A) of this section. In addition, the dominion and control that Distributing had over the direct issuance proceeds provides substantial evidence that the direct issuance transaction fails to qualify as a qualifying debt elimination transaction under the facts-and-circumstances test set forth in paragraph (e)(4)(ii) of this section. *See* paragraph (e)(4)(ii)(B)(4) of this section. In addition, the securities-for-debt exchange was carried out pursuant to an arrangement that comprises part of a prearranged, integrated plan, and therefore also provides substantial evidence that the direct issuance transaction fails to qualify as a qualifying debt elimination transaction. *See* paragraph (e)(4)(ii)(B)(1) of this section. Accordingly, the exchange with Creditor is not a qualifying original creditorexchange, a qualifying intermediated exchange, or a qualifying direct issuance transaction. *See* paragraphs (e)(2), (3), and (4) of this section. As a result, Distributing's transfer of the Controlled securities to Creditor is not treated as a distribution to its shareholders pursuant to the plan of reorganization under § 1.361–4(a)(2)(ii). *See* paragraph (a) of this section.

(8) *Example 8: Qualifying intermediated exchange—(i) Facts—(A) Historical Distributing debt.* The section 361 consideration received by Distributing in the contribution consists

of Controlled stock and \$100x of Controlled securities. As of the earliest applicable date, Distributing has outstanding debt of \$100x owed to an unrelated creditor that is a qualifying creditor (Distributing debt). Furthermore, that debt has an original term that ends after the date of the contribution and is identified in the plan of reorganization.

(B) *Intermediated exchange.* Pursuant to the plan of reorganization for the separation, Distributing engages an intermediary to facilitate the transfer of the \$100x of Controlled securities in satisfaction of the Distributing debt (intermediated exchange). As described in the plan of reorganization, the intermediary will acquire the \$100x of Distributing debt directly from the creditor (and not from Distributing, Controlled, or any Distributing related person or Controlled related person). The intermediary will not hold that debt for the benefit of Distributing, Controlled, or any Distributing related person or Controlled related person. All exchanges of Controlled securities for Distributing debt between Distributing and the intermediary are effectuated based on terms and conditions arrived at by the parties bargaining at arm's length. None of Distributing, Controlled, or any Distributing related person or Controlled related person participates in any profit gained by the intermediary upon an exchange of Controlled securities or limits by agreement or other arrangement any such profit. The intermediary acts for its own account with regard to all components of the intermediated exchange, bears the risk of loss with respect to the Distributing debt and any subsequent sale or other disposition of the Controlled securities, and does not enter into a variable pricing or similar agreement with Distributing, Controlled, or any Distributing related person or Controlled related person with regard to the Controlled securities. The intermediary holds the Distributing debt for a period of not less than 30 days ending on the distribution date. All applicable requirements set forth in paragraphs (b) through (d) of this section are satisfied.

(ii) *Analysis.* The intermediated exchange satisfies all requirements set forth in paragraph (e)(3) of this section to qualify as a qualifying debt elimination transaction. *See* paragraphs (b) through (d) and (e)(3) of this section.

§ 1.361–6 Applicability date.

(a) *Applicability date.* The rules of §§ 1.361–1 through 1.361–5 apply to transactions intended to qualify under section 361 of the Code for which the

earliest of the following dates occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER]:

(1) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(2) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(3) The date of approval of the transaction by the board of directors of the taxpayer.

(4) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(5) The date a ruling request for the transaction is submitted to the IRS.

■ **Par. 14.** Section 1.368–1 is amended by revising paragraph (c) to read as follows:

§ 1.368–1 Purpose and scope of exception of reorganization exchanges.

* * * * *

(c) *Scope of exception for reorganization exchanges*—(1)

Overview. The reorganization provisions of part III of subchapter C of chapter 1 of the Code (part III) consist of the following categories of rules:

(i) *Definitional provisions* (as described in paragraph (c)(2)(i) of this section), the satisfaction of which qualify persons for potential nonrecognition treatment under the Code. The purpose of these definitional provisions is to limit the scope of transactions, and therefore the parties to such transactions (and other relevant persons, such as shareholders of a party to a reorganization), to which certain operative provisions apply.

(ii) *Operative provisions* (certain of which are described in greater detail in paragraph (c)(2)(ii) of this section), the satisfaction of which qualify a party for partial or complete nonrecognition treatment under part III. The purpose of these operative provisions is to further limit the scope of transactions, and therefore the parties to such transactions (and other relevant persons, such as shareholders of a party to a reorganization), that qualify for nonrecognition treatment (in whole or in part) under part III.

(2) *Definitional and operative provisions.* The definitional and operative provisions referred to in paragraph (c)(1) of this section include the following:

(i) *Definitional provision.* Section 368(a)(1) limits the definition of the term *reorganization* to seven types of transactions (including triangular

reorganizations, which are variants of such transactions). All transactions and series of transactions that do not satisfy any of the definitional provisions under section 368(a)(1) are excluded from treatment as a reorganization under part III.

(ii) *Operative provisions for transactions that qualify as reorganizations*—(A) *Section 354.*

Section 354 generally provides that a shareholder or security holder of a target corporation recognizes no gain or loss if the target corporation is a party to a reorganization and the shareholder or security holder exchanges solely stock or securities of the target corporation for the stock or securities of an acquiring corporation pursuant to the plan of reorganization.

(B) *Section 355.* Section 355 generally provides that, if all requirements are satisfied, shareholders and security holders of a distributing corporation recognize no gain or loss (and do not include any amount in income) on the receipt of controlled corporation stock or securities with respect to, or in exchange for, their distributing corporation stock.

(C) *Section 356.* Section 356 of the Code generally provides that, if a shareholder of a target corporation receives stock or securities of the corporation in an exchange to which section 354 or 355 otherwise would apply, and also receives money or other property, then that shareholder recognizes gain or income (as determined pursuant to the gain calculation and characterization rules under section 356).

(D) *Section 357.* Section 357 of the Code generally provides that an assumption by an acquiring corporation of a liability of a target corporation is not treated as money received by the target corporation (and, therefore, the target corporation recognizes no gain or loss as a result of the liability assumption).

(E) *Section 361(a) and (b)—Transfers of stock or securities.* Section 361(a) and (b) of the Code generally provide that a target corporation recognizes no gain or loss if that corporation is a party to a reorganization and exchanges property, pursuant to the plan of reorganization, solely for stock or securities in an acquiring corporation that is a party to the reorganization.

(F) *Section 361(c)—Distributions of qualified property by target corporation.* Section 361(c) generally provides that a target corporation recognizes no gain or loss on the distribution to its shareholders or transfer to its creditors of qualified property (as defined in

section 361(c)(2)(B)) pursuant to the plan of reorganization.

(3) *Applicability date.* This paragraph (c) applies to transactions intended to qualify under section 368 of the Code for which the earliest of the following dates occurs after [DATE OF PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER]:

(i) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(ii) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(iii) The date of approval of the transaction by the board of directors of the taxpayer.

(iv) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(v) The date a ruling request for the transaction is submitted to the IRS.

* * * * *

■ **Par. 15.** Section 1.368–2 is amended by revising paragraphs (f) and (g) to read as follows:

§ 1.368–2 Definitions of terms and operative rules.

* * * * *

(f) *Party to a reorganization*—(1)

Overview. The provisions described in § 1.368–1(c)(2)(i) and (ii) apply solely to a transaction that is carried out by, between, or among one or more parties to a reorganization.

(2) *Scope of party to a reorganization.* For purposes of determining the scope of the transaction or series of transactions to which the provisions described in § 1.368–1(c)(2)(i) and (ii) apply, the term *party to a reorganization* is limited solely to a corporation that—

(i) Is described in paragraph (f)(3) of this section; and

(ii) Is determined to be a party to a reorganization pursuant to paragraph (f)(4) of this section.

(3) *Definition*—(i) *In general.* The term *party to a reorganization* includes—

(A) A corporation resulting from a transaction that qualifies as a reorganization;

(B) Both corporations, in a transaction that qualifies as a reorganization in which one corporation acquires stock or properties of another corporation; and

(C) A corporation controlling an acquiring corporation in a transaction that qualifies as a triangular reorganization (as defined in § 1.358–6(b)(2)) if stock of the controlling corporation is used in the acquisition of stock or properties.

(ii) *Certain transfers of assets or stock in reorganizations*—(A) *In general.* If a transaction otherwise qualifies as a reorganization, a corporation remains a party to the reorganization even though stock or assets acquired by the acquiring corporation pursuant to the plan of reorganization are transferred in a transaction described in paragraph (k) of this section. For example, a corporation does not cease to be a party to the reorganization solely because part or all of the assets acquired pursuant to the plan of reorganization are transferred to a partnership in which the transferor is a partner, so long as the continuity of business enterprise requirement is satisfied. See § 1.368–1(d).

(B) *Triangular reorganizations.* If a transaction otherwise qualifies as a reorganization under section 368(a)(1)(B) or as a reverse triangular merger (as defined in § 1.358–6(b)(2)(iii)), the target corporation (in the case of a transaction that otherwise qualifies as a reorganization under section 368(a)(1)(B)) or the surviving corporation (in the case of a transaction that otherwise qualifies as a reverse triangular merger) remains a party to the reorganization even though its stock or assets acquired pursuant to the plan of reorganization are transferred in a transaction described in paragraph (k) of this section. If a transaction otherwise qualifies as a forward triangular merger (as defined in § 1.358–6(b)(2)(i)), a triangular B reorganization (as defined in § 1.358–6(b)(2)(iv)), a triangular C reorganization (as defined in § 1.358–6(b)(2)(ii)), or a reorganization under section 368(a)(1)(G) by reason of section 368(a)(2)(D), the acquiring corporation remains a party to the reorganization even though its stock is transferred in a transaction described in paragraph (k) of this section.

(4) *Determination of party to the reorganization*—(i) *Status generally based on plan of reorganization.* Subject to paragraph (f)(4)(ii) of this section, the status of a corporation as a party to a reorganization is established solely by the inclusion and identification of that corporation as a party to the reorganization in a plan of reorganization (as defined in § 1.368–4) that is filed with the IRS pursuant to § 1.368–3(a)(5).

(ii) *Status determined by Commissioner based on Federal income tax principles.* Notwithstanding the inclusion or omission of a corporation as a party to a reorganization in a plan of reorganization filed by the taxpayer with the IRS pursuant to § 1.368–3(a)(5), the status of a corporation as a party to the reorganization may be determined by the Commissioner based on the

correction of that plan of reorganization in accordance with § 1.368–4(c)(2), taking into account—

(A) All facts and circumstances regarding the transaction or series of transactions; and

(B) All relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine.

(5) *Examples.* The following examples illustrate the application of the rules of this paragraph (f).

(i) *Example 1: Statutory merger*—(A) *Facts.* Pursuant to State law, Corporation A merges into Corporation B in a transaction qualifying as a reorganization under section 368(a)(1)(A). A plan of reorganization is filed with the IRS pursuant to § 1.368–3(a)(5) that identifies A and B as parties to the reorganization.

(B) *Analysis.* A and B are both described in paragraph (f)(3)(i)(B) of this section. Further, the status of both A and B as parties to the reorganization is established by their identification in the plan of reorganization. See paragraph (f)(4)(i) of this section. Accordingly, each of A and B is a party to a reorganization for purposes of determining the scope of the transactions to which the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply. See paragraph (f)(2) of this section.

(ii) *Example 2: B reorganization*—(A) *Facts.* Corporation C owns all the stock of Corporation D. D acquires all the stock of Corporation E solely in exchange for voting stock of D in a transaction qualifying as a reorganization under section 368(a)(1)(B). A plan of reorganization is filed with the IRS pursuant to § 1.368–3(a)(5) that identifies D and E as parties to the reorganization.

(B) *Analysis.* With respect to D and E, the analysis is the same as in paragraph (f)(5)(i)(B) of this section (*Example 1*). C is not described in paragraph (f)(3) of this section. Accordingly, C is not a party to the reorganization.

(iii) *Example 3: Triangular C reorganization*—(A) *Facts.* The facts are the same as in paragraph (f)(5)(ii)(A) of this section (*Example 2*), except that D acquires all the assets of E solely in exchange for voting stock of C, and E distributes the stock of C received in the exchange to E's shareholders, in a transaction that qualifies as a reorganization under section 368(a)(1)(C). A plan of reorganization is filed with the IRS pursuant to § 1.368–3(a)(5) that identifies C, D, and E as parties to the reorganization.

(B) *Analysis.* With respect to D and E, the analysis is the same as in paragraph

(f)(5)(i)(B) of this section (*Example 1*). C is described in paragraph (f)(3)(i)(C) of this section and is identified as a party to the reorganization in the plan of reorganization. Accordingly, C also is a party to a reorganization for purposes of determining the scope of the transactions to which the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply. See paragraph (f)(2) of this section.

(iv) *Example 4: Transfer of assets acquired in a reorganization*—(A) *Facts.* The facts are the same as in paragraph (f)(5)(iii)(A) of this section (*Example 3*), except that, after the reorganization, D transfers all the assets of E received in the exchange to a partnership in which D owns a significant interest. The partnership continues E's historic business.

(B) *Analysis.* The continuity of business enterprise requirement continues to be satisfied after D's transfer of the E assets to the partnership. See § 1.368–1(d)(4)(iii). Consequently, none of C, D, or E ceases to be a party to the reorganization. See paragraph (f)(3)(ii)(B) of this section.

(v) *Example 5: Transfer of stock acquired in a triangular reorganization.* The facts are the same as in paragraph (f)(5)(iii)(A) of this section (*Example 3*), except that E merges into D under State law solely in exchange for C stock in a transaction qualifying as a reorganization under section 368(a)(1)(A) by reason of section 368(a)(2)(D). After the reorganization, C transfers all the stock of D to newly formed Corporation G in exchange for all the stock of G.

(B) *Analysis.* The analysis is the same as in paragraph (f)(5)(iii)(B) of this section. Additionally, the continuity of business enterprise requirement continues to be satisfied after C's transfer of the D stock to G. See § 1.368–1(d)(4)(iii). Accordingly, D does not cease to be a party to the reorganization by reason of the transfer. See paragraph (f)(3)(ii) of this section.

(vi) *Example 6: Divisive reorganization*—(A) *Facts.* Pursuant to a plan of reorganization for a transaction that qualifies as a reorganization under sections 368(a)(1)(D) and 355, Corporation F transfers one of its businesses to newly formed Corporation G in exchange for all the stock of G and then distributes all the G stock to F's shareholders. The plan of reorganization, which is filed with the IRS pursuant to § 1.368–3(a)(5), identifies F and G as parties to the reorganization.

(B) *Analysis.* The analysis is the same as in paragraph (f)(5)(i)(B) of this section (*Example 1*).

(6) *Applicability date.* The rules of this paragraph (f) apply to transactions intended to qualify under section 368 of the Code for which the earliest of the following dates occurs after [date of publication of final regulations in the **Federal Register**]:

(i) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(ii) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(iii) The date of approval of the transaction by the board of directors of the taxpayer.

(iv) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(v) The date a ruling request for the transaction is submitted to the IRS.

(g) [Reserved]

* * * * *

■ **Par. 16.** Section 1.368–3 is amended by:

■ a. Revising paragraphs (a)(3)(iv) and (4);

■ b. Adding paragraph (a)(5) and

■ c. Revising paragraph (e).

The revisions and addition read as follows:

§ 1.368–3 Records to be kept and information to be filed with returns.

(a) * * *

(3) * * *

(iv) Property not described in paragraph (a)(3)(i), (ii), or (iii) of this section;

(4) The date and control number of any private letter ruling(s) issued by the Internal Revenue Service in connection with this reorganization; and

(5) A copy of the plan of reorganization satisfying the requirements set forth in § 1.368–4(d).

* * * * *

(e) *Applicability date*—(1) *In general.* This section applies to any taxable year beginning on or after May 30, 2006. However, taxpayers may apply this section to any original Federal income tax return (including any amended return filed on or before the due date (including extensions) of such original return) timely filed on or after May 30, 2006. For taxable years beginning before May 30, 2006, see § 1.368–3 as contained in 26 CFR part 1 in effect on April 1, 2006.

(2) *Paragraphs (a)(3) and (b)(3).* Paragraphs (a)(3) and (b)(3) of this section apply with respect to reorganizations occurring on or after March 28, 2016, and also with respect to reorganizations occurring before such

date as a result of an entity classification election under § 301.7701–3 of this chapter filed on or after March 28, 2016, unless such reorganization is pursuant to a binding agreement that was in effect prior to March 28, 2016 and at all times thereafter.

(3) *Paragraph (a)(5).* Paragraph (a)(5) of this section applies to transactions intended to qualify under section 368 of the Code for which the earliest of the following dates occurs after [date of publication of final regulations in the **Federal Register**]:

(i) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(ii) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(iii) The date of approval of the transaction by the board of directors of the taxpayer.

(iv) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(v) The date a ruling request for the transaction is submitted to the IRS.

■ **Par. 17.** Section 1.368–4 is added to read as follows:

§ 1.368–4 Plan of reorganization.

(a) *Plan of reorganization*—(1) *Scope and purpose.* This section sets forth requirements and procedures for the determination of a plan of reorganization, including the scope of transactions properly included within that plan. The plan of reorganization serves to identify solely those transactions to which the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply. The plan of reorganization also serves to distinguish those qualifying transactions described in § 1.368–1(c)(2)(i) and (ii) from transactions to which the general recognition provisions of the Code (such as section 1001 of the Code) apply. The plan of reorganization is not to be construed as broadening the definition of a *reorganization* as set forth in section 368(a) of the Code.

(2) *Plan of reorganization to which definitional and operative provisions apply.* The provisions described in § 1.368–1(c)(2)(i) and (ii) apply solely to a transaction that is identified in, and carried out pursuant to—

(i) A plan of reorganization of a taxpayer described in paragraph (b)(1) or an amended plan of reorganization described in paragraph (f) of this section;

(ii) A plan of reorganization of a taxpayer that is corrected by the

Commissioner under paragraph (b)(2)(i) of this section; or

(iii) A plan of reorganization that is identified by the Commissioner under paragraph (b)(2)(ii) of this section.

(3) *Failure to satisfy requirements.* The failure of a taxpayer to comply with any particular requirement or procedure set forth in this section (including the failure to file a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5)) does not, on its own, prevent a transaction or series of transactions from being considered part of the plan of reorganization, qualifying as a reorganization under a definitional provision, or qualifying for nonrecognition treatment (in whole or in part) under an operative provision.

(b) *Definition.* The term *plan of reorganization* means—

(1) A plan of reorganization of a taxpayer that—

(i) Satisfies all requirements set forth in paragraph (d) of this section; and

(ii) Is filed with the IRS pursuant to § 1.368–3(a)(5); or

(2) A plan of reorganization that results from—

(i) The Commissioner correcting a plan of reorganization of a taxpayer; or

(ii) The Commissioner identifying a plan of reorganization for a taxpayer (in the event of a failure to file a plan of reorganization with the IRS pursuant to § 1.355–5(a)(2)).

(c) *Determination of plan of reorganization*—(1) *Status generally based on plan of reorganization filed by taxpayer.* Except as provided in paragraph (c)(2) of this section, a taxpayer establishes the plan of reorganization for a transaction or series of transactions solely by—

(i) Satisfying all requirements set forth in paragraph (d) of this section; and

(ii) Filing the plan of reorganization with the IRS pursuant to § 1.368–3(a)(5).

(2) *Correction or identification of plan of reorganization due to taxpayer's failure to file a complete plan of reorganization*—(i) *In general.* If a taxpayer files a plan of reorganization with the IRS that fails to satisfy any requirement set forth in paragraph (d) of this section, or if the taxpayer fails to file any plan of reorganization with the IRS, the Commissioner may correct or identify a plan of reorganization in accordance with paragraph (c)(2)(ii) of this section.

(ii) *Status of transactions as part of a plan of reorganization.* The Commissioner may determine that a transaction or series of transactions should be included in, or excluded from, a plan of reorganization described in paragraph (c)(2)(i) of this section based on—

(A) All facts and circumstances regarding the transaction or series of transactions; and

(B) All relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine.

(d) *Requirements for a plan of reorganization.* To qualify as a plan of reorganization described in paragraph (b)(1) of this section, the taxpayer must satisfy all requirements set forth in paragraphs (d)(1) through (3) of this section. For purposes of this paragraph (d) and paragraph (e) of this section, the term *official records* includes a contract or other written agreement to which the taxpayer is a party, a resolution or other document authorized by the taxpayer's board of directors, or other document filed with the U.S. Securities and Exchange Commission (SEC) or other Federal regulatory agency.

(1) *Documentation requirement.* The plan of reorganization is provided in a single, comprehensive document that—

(i) Identifies all parties to the reorganization (as determined pursuant to § 1.368–2(f));

(ii) Identifies all transactions properly included in the plan of reorganization (as determined pursuant to paragraph (e) of this section);

(iii) Identifies all liabilities (including debt) to be assumed by the acquiring corporation and the obligees (or creditors) of those liabilities;

(iv) Identifies all debt of the target corporation that will be satisfied with section 361 consideration (as defined in § 1.361–1(b)(49)) (including all debt intended to qualify for the refinancing exception for historical distributing corporation debt under § 1.361–5(c)) and the creditors of that debt;

(v) Describes the intended Federal income tax treatment of the transactions described in paragraph (d)(1)(ii) of this section;

(vi) Describes the business purpose for each transaction described in paragraph (d)(1)(ii) of this section; and

(vii) Establishes that the readjustments involved in transactions described in paragraph (d)(1)(ii) of this section are undertaken to facilitate the continuance of the business of a corporation a party to the reorganization.

(2) *Adoption of plan of reorganization.* Prior to the first step of the reorganization, a plan of reorganization described in paragraph (b)(1)(i) of this section or an original plan of reorganization that becomes the amended plan of reorganization (within the meaning of paragraph (f) of this section), as applicable, is finalized and

adopted by the party to the reorganization, as established by—

(i) The acts of the party's respective duly authorized officers and directors; and

(ii) The official records of the party to the reorganization.

(3) *Completion of plan of reorganization—(i) Expeditious prosecution of plan of reorganization—(A) General rule.* In accordance with paragraph (d)(3)(iii) of this section, taking into account all facts and circumstances (including the one or more business purposes for the reorganization), all parties to the reorganization complete the plan of reorganization as expeditiously as practicable.

(B) *24-month presumption.* The requirement in paragraph (d)(3)(i)(A) of this section is presumed to be satisfied if, in accordance with paragraph (d)(3)(ii) of this section, all parties to the reorganization complete the plan of reorganization within the 24-month period beginning on the date of the first step of the plan of reorganization.

(ii) *Completion of entire plan of reorganization—(A) General rule.* All transactions included in a plan of reorganization must be carried out in the manner described in the plan of reorganization.

(B) *Failure to complete entire plan of reorganization.* Except as provided in paragraph (f) of this section, if the requirement of paragraph (d)(3)(ii)(A) of this section is not satisfied, the provisions described in § 1.368–1(c)(2)(i) and (ii) do not apply to the transaction (or series of transactions) unless the Commissioner determines the existence of a plan of reorganization.

(e) *Requirements for transactions to be treated as properly included in plan of reorganization.* The requirements set forth in this paragraph (e) must be satisfied for a transaction to be treated as properly included in a plan of reorganization. The existence of contingencies or conditions is not conclusive in determining whether a requirement of this paragraph (e) is satisfied.

(1) *Definite intent requirement—(i) General rule.* Prior to the first step of the plan of reorganization or an original plan of reorganization that becomes the amended plan of reorganization (within the meaning of paragraph (f) of this section), one or more parties to the reorganization evidences a definite intent to carry out the transaction through a written commitment in one or more official records of the party that substantiate the plan of reorganization.

(ii) *Section 355 transactions.* With regard to a control distribution (as

defined in § 1.355–1(a)(2)(iii)) that occurs in the next taxable year after the first distribution, the distributing corporation does not establish a definite intent under paragraph (e)(1)(i) of this section unless all distributions up to and including the control distribution are effectuated pursuant to a binding commitment of the distributing corporation. See § 1.355–2(e)(2)(ii).

(iii) *Relevancy of contemplated possibilities—(A) Contemplation irrelevant to taxpayer's determination.* The contemplation by a party that the party may carry out a transaction is not sufficient for the party to establish a definite intent to carry out that transaction, regardless of whether that contemplated transaction is included in an official record of a party.

(B) *Contemplation relevant to Commissioner's determination.* A party's contemplation of a transaction may be relevant for purposes of the correction or identification of a plan of reorganization by the Commissioner pursuant to paragraph (c)(2) of this section.

(2) *Proximate relationship requirement—(i) General rules.* Taking into account paragraphs (e)(2)(ii) and (iii) of this section:

(A) *Necessary or integral test for application of definitional provision.* A transaction is part of the plan of reorganization for a reorganization to which the provisions described in § 1.368–1(c)(2)(i) apply only if, on its own or as part of a series of transactions, the transaction is necessary to satisfy one or more requirements of a definitional provision described in § 1.368–1(c)(2)(i), or is an integral part of a series of transactions carried out to satisfy the requirements of the definitional provision intended to apply to the reorganization, as evidenced by a written commitment in one or more official records of the party to the reorganization.

(B) *But for, or integral to, test for application of operative provision.* A transaction is part of the plan of reorganization to which the provisions described in § 1.368–1(c)(2)(ii) apply only if, on its own or as part of a series of transactions, the transaction would not occur but for the reorganization that is covered by the plan of reorganization, or is an integral part of a series of transactions carried out to satisfy the requirements of the definitional provision intended to apply to the reorganization, as evidenced by a written commitment in one or more official records of the party to the reorganization.

(ii) *Existence of independent significance not determinative.* The

independent significance of a transaction (for example, the fact that the transaction has a separate business motive apart from the reorganization) does not preclude the satisfaction of the requirements under paragraph (e)(2)(i) of this section.

(iii) *Temporal proximity.* A transaction that takes place in close temporal proximity to one or more other transactions is not properly included in a plan of reorganization under paragraph (e)(2)(i) of this section unless Federal income tax principles (including the step transaction doctrine) would apply to determine that the transaction was in substance part of the plan of reorganization.

(3) *Business purpose consistency requirement.* A transaction, on its own or as part of a series of transactions is consistent with, and directly related to, one or more business purposes for the reorganization (for example, the transaction directly furthers one or more business purposes for the reorganization).

(f) *Amended plan of reorganization—*
(1) *Conditions.* If a taxpayer amends a plan of reorganization described in paragraph (b)(1) of this section (original plan of reorganization) after the first step of the original plan of reorganization (amended plan of reorganization), those amendments will not cause the taxpayer to fail to satisfy the requirements set forth in paragraph (d) of this section only if—

(i) Those amendments are in direct response to an identifiable, unexpected, and material change in market or business conditions that occurs after the date on which the original plan of reorganization is adopted by the party to the reorganization in the manner described in paragraph (d)(2) of this section;

(ii) The amendments are necessary to achieve the one or more business purposes for the reorganization; and

(iii) The amended plan of reorganization satisfies all requirements set forth in paragraph (d) of this section.

(2) *Consequences of plan of reorganization amended due to changed circumstances—*(i) *Qualifying amended plan of reorganization.* If the requirements set forth in paragraph (f)(1) of this section are satisfied, the provisions described in § 1.368–1(c)(2)(i) and (ii) will apply to transactions identified in, and carried out pursuant to, the amended plan of reorganization. That is, the Federal income tax consequences of all transactions included in the amended plan of reorganization will be determined based on that plan of

reorganization (and not on the original plan of reorganization).

(ii) *Non-qualifying amended plan of reorganization.* If an amended plan of reorganization fails to satisfy all requirements set forth in paragraph (f)(1) of this section, the Commissioner may correct or identify the amended plan of reorganization.

(g) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples, unless otherwise stated: terms defined in § 1.361–1(b) and used in these examples have the meaning given such terms in § 1.361–1(b); all transactions are completed within the 24-month period beginning on the date of the first transaction; all transactions qualify for the Federal income tax treatment intended by the taxpayers, as described in the facts of each example; and all corporations are calendar-year taxpayers.

(1) *Example 1: Creation of plan of reorganization—*(i) *Facts.* A target corporation (Target) transfers all its assets to an acquiring corporation (Acquiring) solely in exchange for stock of Acquiring and Acquiring's assumption of Target liabilities. Target distributes all the Acquiring stock to Target's shareholders. The transaction is intended to qualify as a reorganization under section 368(a)(1)(C). Target fails to file a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5).

(ii) *Analysis.* Target's failure to file a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) does not, on its own, prevent the series of transactions from qualifying as a reorganization under section 368(a)(1)(C). See paragraph (a)(3) of this section. The Commissioner may identify a plan of reorganization for the series of transactions based on all facts and circumstances and all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine. See paragraphs (b)(2)(ii) and (c)(2) of this section. The definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply to the series of transactions identified in, and carried out pursuant to, the plan of reorganization identified by the Commissioner. See paragraph (a)(2)(iii) of this section.

(2) *Example 2: Correction of taxpayer's plan of reorganization—*(i) *Facts.* An acquiring corporation (Acquiring) acquires a target corporation (Target) through the following series of transactions. Acquiring first effectuates a tender offer for 51 percent of Target stock from Target shareholders solely for Acquiring voting stock (tender offer).

A subsidiary of Acquiring (Merger Sub) then merges into Target (statutory merger) in a transaction intended to qualify as a reverse subsidiary merger under section 368(a)(2)(E). In the statutory merger, Acquiring's Merger Sub stock is converted into Target stock, and each Target shareholder holding shares of the remaining 49 percent of Target stock exchanges its shares of Target stock for a combination of consideration, two-thirds of which is Acquiring stock and one-third of which is cash. Under general principles of Federal income tax law, including the step transaction doctrine, the tender offer and the statutory merger are treated as an integrated acquisition by Acquiring of all the Target stock. Target files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) that satisfies all requirements set forth in paragraph (d) of this section, except that the plan of reorganization does not mention the tender offer.

(ii) *Analysis.* To determine whether the tender offer should be included in the plan of reorganization for the statutory merger, the Commissioner may examine all facts and circumstances regarding the series of transactions and apply all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine. See paragraph (c)(2)(ii) of this section. Because the tender offer and the statutory merger are treated as an integrated series of transactions for Federal income tax purposes, the tender offer and the statutory merger are treated as an integrated acquisition for purposes of determining whether the transaction qualifies as a reverse subsidiary merger under section 368(a)(2)(E). Accordingly, the Commissioner may correct Target's plan of reorganization by including the tender offer. See paragraph (c)(2)(i) of this section. The definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply to the transactions identified in, and carried out pursuant to, the plan of reorganization as corrected by the Commissioner. See paragraph (a)(2)(ii) of this section.

(3) *Example 3: Scope of plan of reorganization—distribution to equalize values—*(i) *Facts.* On June 30, 2025, Corporation X and Corporation Y decide to merge into newly formed Corporation Z. As reflected in a single, comprehensive document that satisfies the requirements set forth in paragraph (d)(1) of this section, the board of directors of each of X and Y approves the transaction pursuant to paragraph (d)(2) of this section, with the agreement that X and Y must be of equal value

when merged into Z. Consequently, to equalize the amount of its assets and Y's assets, and pursuant to a board resolution, X distributes \$100x in cash to its shareholders on September 30, 2025 (equalizing distribution). On October 31, 2025, X and Y consolidate under State law (X/Y consolidation) in a transaction intended to qualify as a reorganization described in section 368(a)(1)(A).

(ii) *Analysis.* The board resolution pursuant to which the equalizing distribution was made, and the single, comprehensive document that reflects the decision of both boards of directors that X and Y be of equal value when combined in the X/Y consolidation, evidence a definite intent, prior to the first step of the plan of reorganization, for X to make the equalizing distribution. *See* paragraph (e)(1) of this section. The equalizing distribution is an integral part of the X/Y consolidation because the equalizing distribution satisfies a condition identified by the boards of directors of X and Y for executing the X/Y consolidation (that is, to equalize the values of X and Y prior to the X/Y consolidation). *See* paragraph (e)(2)(i)(B) of this section. The equalizing distribution is consistent with, directly relates to, and therefore directly furthers the business purpose for the X/Y consolidation, because the X/Y consolidation is intended to effectuate a merger of equals. *See* paragraph (e)(3) of this section. Accordingly, the equalizing distribution is properly included in the plan of reorganization for the X/Y consolidation. *See* paragraph (e) of this section. Consequently, the Federal income tax consequences of the equalizing distribution and the X/Y consolidation are determined under the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii). *See* paragraph (a)(2)(i) of this section.

(4) *Example 4: Scope of plan of reorganization—pre-merger stock acquisition—(i) Facts.* Two potential acquiring corporations (X and Y) engage in competing tender offers to acquire 100 percent of the stock of a target corporation (Target). X and Y carry out the tender offers through their respective subsidiary corporations. On June 30, 2025, before acquiring any shares in Target, X subsidiary signs an agreement with Target (X/Target agreement) providing that, among other conditions (including regulatory approval and approval by the shareholders of X and Target), if X subsidiary successfully acquires at least 51 percent of Target's outstanding stock through its tender offer, X will acquire all remaining Target stock by causing

Target to merge into X subsidiary in a transaction intended to qualify as a reorganization under section 368(a)(2)(D) (subsidiary merger). As of September 30, 2025, X subsidiary has been tendered 51 percent of Target's outstanding stock. On October 15, 2025, Y subsidiary tenders to X subsidiary all of Y subsidiary's Target shares received in Y subsidiary's tender offer (30 percent of Target's outstanding stock) in exchange for X stock (Y share exchange). On November 1, 2025, pursuant to the X/Target agreement, X causes Target to merge into X subsidiary (that is, the subsidiary merger). The subsidiary merger satisfies the requirements of a definitional provision described in § 1.368–1(c)(2)(i) regardless of whether X subsidiary's tender offer (including the Y share exchange) is included in the plan of reorganization for the subsidiary merger.

(ii) *Analysis.* The X/Target agreement imposes a legal obligation on X subsidiary to carry out the subsidiary merger if X subsidiary's tender offer is successful. Therefore, this agreement evidences a definite intent, prior to the first step of the plan of reorganization, for X subsidiary to carry out both of those transactions as part of a plan of reorganization. *See* paragraph (e)(1) of this section. Satisfaction of this requirement is not affected by the fact that the subsidiary merger is subject to significant conditions, including a successful X subsidiary tender offer, regulatory approval, and X and Target shareholder approvals. *See* paragraph (e) of this section. The X/Target agreement establishes that X subsidiary's tender offer is an integral part of a series of transactions carried out to satisfy the requirements of section 368(a)(2)(D). *See* paragraph (e)(2) of this section. Satisfaction of this requirement is not affected by the fact that X subsidiary's tender offer has a degree of economic significance independent of the subsidiary merger. *See* paragraph (e)(2)(ii) of this section. X's business purpose for the merger is to acquire all the remaining outstanding stock of Target, as established through the X/Target agreement. The tender offer is consistent with, directly relates to, and therefore directly furthers that business purpose. *See* paragraph (e)(3) of this section. Accordingly, X subsidiary's tender offer and the Y share exchange are properly included in the plan of reorganization for the subsidiary merger. Consequently, the Federal income tax consequences of both X subsidiary's tender offer and the subsidiary merger are determined under the definitional and operative provisions described in

§ 1.368–1(c)(2)(i) and (ii). *See* paragraph (a)(2) of this section.

(5) *Example 5: Scope of plan of reorganization—multiple distributions of controlled corporation stock to constitute a control distribution—(i) Facts.* On June 30, 2025, a distributing corporation (Distributing) contributes property to a newly formed controlled corporation (Controlled) in exchange for Controlled stock (contribution). On September 30, 2025, Distributing distributes 57 percent of the Controlled stock to Distributing's shareholders (first distribution). On January 1, 2026, Distributing distributes the remaining 43 percent of Controlled stock to Distributing's shareholders (final distribution; together with the contribution and the first distribution, the separation). The separation and distribution agreement provides that Distributing will distribute 57 percent of Controlled stock during Distributing's 2025 taxable year, but only expresses a contemplated possibility that Distributing will distribute the remaining 43 percent of Controlled stock. Distributing files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) with its Federal income tax return for the 2025 taxable year that includes the first distribution and the final distribution as part of the plan of reorganization for the separation.

(ii) *Analysis.* If a taxpayer files a plan of reorganization with the IRS that fails to satisfy any requirement set forth in paragraph (d) of this section, the Commissioner may correct the plan of reorganization. *See* paragraph (c)(2)(i) of this section. The Commissioner may correct the plan of reorganization to exclude a transaction based on an examination of all facts and circumstances and consideration of all relevant provisions of the Code and general principles of Federal income tax law, including the step transaction doctrine. *See* paragraph (c)(2)(ii) of this section. The final distribution is properly excluded from the plan of reorganization for the separation because Distributing fails to satisfy the definite intent requirement with respect to the final distribution. *See* paragraph (e)(1)(i) and (iii) of this section. Specifically, because the distribution of control (that is, the final distribution) occurs in the next taxable year after the first distribution and is not pursuant to a binding commitment, Distributing does not establish a definite intent under paragraph (e)(1)(i) of this section. *See* paragraph (e)(1)(ii) of this section. The definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) apply solely to the transactions identified in, and carried

out pursuant to, the plan of reorganization as corrected by the Commissioner (that is, the contribution and first distribution). *See* paragraph (a)(2) of this section. Accordingly, the transaction would fail to meet the definitional requirement under section 368(a)(1)(D) because the first distribution, by itself, does not meet the requirement set forth in § 1.355–2(e)(2)(i).

(6) *Example 6: Scope of plan of reorganization—qualifying distribution of amount of controlled corporation stock constituting section 368(c) control—(i) Facts.* The facts are the same as in paragraph (g)(5)(i) of this section (*Example 5*), except for the following. First, Distributing provides in its separation and distribution agreement with Controlled that Distributing will distribute the remaining 43 percent of Controlled stock during 2026. Second, for its Federal income tax return for the 2025 taxable year, Distributing files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) that satisfies all requirements set forth in paragraph (d) of this section, including the establishment, by reference to the separation and distribution agreement, that Distributing will distribute to its shareholders pursuant to a binding commitment 57 percent of Controlled stock during 2025 and the remaining 43 percent of Controlled stock during 2026.

(ii) *Analysis.* The final distribution is properly included in the plan of reorganization for the separation because Distributing satisfies the definite intent requirement to make the final distribution. *See* paragraph (e)(1)(ii) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the contribution and both the first distribution and the final distribution are determined under the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii). *See* paragraph (a)(2)(i) of this section.

(7) *Example 7: Scope of plan of reorganization—contribution and distribution in divisive reorganization—(i) Facts.* On June 1, 2025, a distributing corporation (Distributing) contributes property to a newly formed controlled corporation (Controlled) in exchange for Controlled stock and Controlled's assumption of Distributing liabilities related to the contributed business (contribution). On September 1, 2025, Distributing distributes all Controlled stock to Distributing's shareholders (distribution; together with the contribution, the separation). A separation and distribution agreement between Distributing and Controlled,

filed by Distributing with the SEC, evidences a definite intent, prior to the first step of the separation, to carry out each of these transactions comprising the separation. Additional official records of Distributing provide that the separation is carried out to sharpen management focus on, and reduce competition for capital between, the retained and contributed businesses, which includes ensuring that earnings of each business are used to pay liabilities arising solely from that business. Distributing files a plan of reorganization with the IRS pursuant to § 1.368–3(a)(5) with its Federal income tax return for the 2025 taxable year.

(ii) *Analysis—(A) Contribution.* The contribution is properly included in the plan of reorganization for the separation. *See* paragraph (e) of this section. First, as substantiated by the separation and distribution agreement, Distributing and Controlled evidence a definite intent, prior to the first step of the plan of reorganization, to carry out the contribution. *See* paragraph (e)(1)(i) of this section. Second, the contribution is necessary to satisfy the requirements of section 368(a)(1)(D). *See* paragraph (e)(2)(i)(A) of this section. Lastly, the contribution is consistent with, is directly related to, and therefore directly furthers, the business purpose for the reorganization. *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the contribution are determined under a definitional provision described in § 1.368–1(c)(2)(i) (that is, section 368(a)(1)(D)). *See* paragraph (a)(2) of this section.

(B) *Controlled liability assumption.* Controlled's liability assumption is properly included in the plan of reorganization for the separation. *See* paragraph (e) of this section. First, as substantiated by the separation and distribution agreement, Distributing and Controlled evidence a definite intent, prior to the first step of the plan of reorganization, for the liability assumption to occur. *See* paragraph (e)(1)(i) of this section. Second, the liability assumption would not have occurred but for, and is integral to, the separation, because the assumption ensures that the respective liabilities of the retained and contributed businesses continue to be associated with those businesses. *See* paragraph (e)(2)(i)(B) of this section. Lastly, the Controlled liability assumption is consistent with, is directly related to, and therefore directly furthers the business purpose for the reorganization by ensuring that the earnings of each business are used to

pay liabilities arising solely from that business (in other words, furthering Distributing's fit-and-focus corporate business purpose). *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the liability assumption are determined under an operative provision described in § 1.368–1(c)(2)(ii) (that is, section 357). *See* paragraph (a)(2) of this section.

(C) *Distribution.* The distribution is properly included in the plan of reorganization for the separation. *See* paragraph (e) of this section. First, as substantiated by the separation and distribution agreement, Distributing and Controlled evidence a definite intent, prior to the first step of the plan of reorganization, for Distributing to make the distribution. *See* paragraph (e)(1)(i) of this section. Second, the distribution is necessary to satisfy the requirements of section 368(a)(1)(D). *See* paragraph (e)(2)(i)(A) of this section. Lastly, the distribution is consistent with, is directly related to, and therefore directly furthers, the fit-and-focus corporate business purpose for the reorganization. *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the distribution are determined under the definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii) (that is, sections 355 and 368(a)(1)(D)). *See* paragraph (a)(2) of this section.

(8) *Example 8: Scope of plan of reorganization—boot purge through special dividend—(i) Facts.* The facts are the same as in paragraph (g)(7)(i) of this section (*Example 7*), except for the following. As part of the contribution, Distributing receives cash from Controlled in partial exchange for the assets contributed by Distributing to Controlled. Distributing distributes that cash to its shareholders pursuant to a special dividend declared by Distributing's board of directors (special dividend boot purge) that is intended to facilitate an appropriate post-separation capital structure for the retained and contributed businesses. The separation and distribution agreement, a resolution adopted by Distributing's board of directors, and other official records of Distributing collectively evidence a definite intent, prior to the first step of the separation, to carry out the transactions comprising the separation (including the special dividend boot purge). In particular, those documents provide that the special dividend is in addition to any regularly occurring

dividends distributed to Distributing's shareholders pursuant to Distributing's dividend payment policy (as reflected in documents filed by Distributing with the SEC).

(ii) *Analysis.* The special dividend boot purge is properly included in the plan of reorganization for the separation. See paragraph (e) of this section. First, as substantiated by the separation and distribution agreement and other official records of Distributing, Distributing and Controlled evidence a definite intent, prior to the first step of the plan of reorganization, for Distributing to make the special dividend boot purge. See paragraph (e)(1)(i) of this section. Second, the special dividend boot purge would not occur but for the separation, as evidenced by the separation and distribution agreement and other official records of Distributing, and by the fact that the special dividend is in addition to any regularly occurring dividends made pursuant to Distributing's dividend payment policy. See paragraph (e)(2)(i)(B) of this section. Lastly, the special dividend boot purge is consistent with, directly relates to, and therefore directly furthers the business purpose for the separation because the special dividend boot purge facilitates an appropriate post-separation capital structure for the retained and contributed businesses (thereby facilitating Distributing's fit-and-focus corporate business purpose). See paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the special dividend boot purge are determined under an operative provision described in § 1.368–1(c)(2)(ii) (that is, section 361). See paragraph (a)(2) of this section.

(9) *Example 9: Scope of plan of reorganization—boot purge through special stock repurchase—(i) Facts.* The facts are the same as in paragraph (g)(8)(i) of this section (*Example 8*), except that Distributing uses the Controlled cash to fund a special repurchase of Distributing stock (and, accordingly, is not part of an existing stock repurchase program approved by Distributing's board of directors).

(ii) *Analysis.* The analysis is the same as in paragraph (g)(8)(ii) of this section (*Example 8*).

(10) *Example 10: Scope of plan of reorganization—boot purge through ordinary course dividend—(i) Facts.* The facts are the same as in paragraph (g)(8)(i) of this section (*Example 8*), except for the following. Distributing provides in the separation and

distribution agreement, or other official records of Distributing, that Distributing will distribute the Controlled cash to Distributing's shareholders through an ordinary course dividend made pursuant to Distributing's dividend payment policy. After the distribution date, Distributing pays an ordinary course dividend that is funded with the cash received from Controlled in the contribution (that is, the Controlled cash).

(ii) *Analysis.* The ordinary course dividend is properly excluded from the plan of reorganization for the separation because the dividend would have occurred regardless of the separation. Therefore, the ordinary course dividend fails the “but for, or integral to, test” for application of operative provision. See paragraph (e)(2)(i)(B) of this section. Accordingly, the Federal income tax consequences of the ordinary course dividend are determined under section 301 of the Code, not an operative provision described in § 1.368–1(c)(2)(ii). See paragraph (a)(2) of this section.

(11) *Example 11: Scope of plan of reorganization—boot purge through existing stock repurchase program—(i) Facts.* The facts are the same as in paragraph (g)(10)(i) of this section (*Example 10*), except that Distributing uses the Controlled cash to fund a repurchase of Distributing stock pursuant to an existing stock repurchase program approved by Distributing's board of directors.

(ii) *Analysis.* The analysis is the same as in paragraph (g)(10)(ii) of this section (*Example 10*). Accordingly, the Federal income tax consequences of the ordinary course stock repurchase are determined under section 301 or 302 of the Code, and not an operative provision described in § 1.368–1(c)(2)(ii). See paragraph (a)(2) of this section.

(12) *Example 12: Scope of plan of reorganization—securities-for-debt exchange—(i) Facts.* The facts are the same as in paragraph (g)(7)(i) of this section (*Example 7*), except for the following. As part of the contribution, Distributing receives securities from Controlled in partial exchange for the assets contributed by Distributing to Controlled. Distributing transfers those Controlled securities to a creditor of Distributing in a series of transactions that satisfies all the requirements set forth in § 1.361–5(a) (securities-for-debt exchange). The separation and distribution agreement, a resolution adopted by Distributing's board of directors, and other official records of Distributing, collectively evidence a definite intent, prior to the first step of

the separation, to carry out each of the transactions comprising the securities-for-debt exchange. Consistent with the requirements set forth in §§ 1.361–5(a) and 1.368–3(a)(5), Distributing identifies the historical Distributing debt and the qualifying creditor with regard to that historical Distributing debt, prior to the first step of the plan of reorganization that includes the separation.

(ii) *Analysis.* The securities-for-debt exchange is properly included in the plan of reorganization for the separation because the exchange satisfies all conditions required by paragraph (e) of this section. First, as substantiated by the separation and distribution agreement and other official records of Distributing, Distributing evidences a definite intent, prior to the first step of the plan of reorganization, to carry out the securities-for-debt exchange. See paragraph (e)(1)(i) of this section. Second, the securities-for-debt exchange would not occur but for the separation, as evidenced by the separation and distribution agreement and other official records of Distributing. See paragraph (e)(2)(i)(B) of this section. Lastly, the securities-for-debt exchange is consistent with, and directly relates to, the fit-and-focus corporate business purpose for the separation, because it facilitates the elimination of competition for capital between the retained and contributed businesses through the establishment of an appropriate post-separation capital structure for each of those businesses. See paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the securities-for-debt exchange are determined under an operative provision described in § 1.368–1(c)(2)(ii). See paragraph (a)(2) of this section.

(13) *Example 13: Scope of plan of reorganization—dispositions of retained stock—(i) Facts.* The facts are the same as in paragraph (g)(7)(i) of this section (*Example 7*), except for the following. On September 30, 2025, Distributing distributes to its shareholders 80 percent of the outstanding Controlled stock, constituting a control distribution. With regard to the retained stock, the separation and distribution agreement and other official records of Distributing provide that Distributing will transfer the retained stock to a creditor of Distributing in a stock-for-debt exchange that satisfies the requirements set forth in §§ 1.361–5(a) and 1.368–3(a)(5) (stock-for-debt exchange). The separation and distribution agreement and those other

official records also provide that, to the extent the retained stock is not disposed of in the stock-for-debt exchange, Distributing will distribute that retained stock to Distributing's shareholders (follow-on spin-off). Lastly, the separation and distribution agreement provides that, to the extent the retained stock is not disposed of after Distributing succeeds or fails in completing the stock-for-debt exchange and follow-on spin-off, Distributing will sell the retained stock on the open market by not later than five years after the first distribution date (open-market sale). Distributing describes these contingent commitments in its plan of reorganization filed with the IRS pursuant to § 1.368–3(a)(5).

(ii) *Analysis*—(A) *Stock-for-debt exchange*. The stock-for-debt exchange is properly included in the plan of reorganization for the separation because the exchange satisfies all conditions required by paragraph (e) of this section. First, as substantiated in the separation and distribution agreement, in which Distributing expresses that it will carry out the stock-for-debt exchange, Distributing evidences a definite intent, prior to the first step of the plan of reorganization, to carry out the stock-for-debt exchange. *See* paragraph (e)(1) of this section. The satisfaction of this requirement is not affected by the fact that Distributing might engage in the follow-on spin-off or the open-market sale to dispose of all the retained stock in the event that the stock-for-debt exchange does not result in a total disposition of that stock, because Distributing is committed in writing in one or more of its official records to attempt to complete the exchange. *See* paragraph (e) of this section. Second, the stock-for-debt exchange would not occur but for the separation, as evidenced by the separation and distribution agreement. *See* paragraph (e)(2)(i)(B) of this section. Lastly, the stock-for-debt exchange is consistent with, and directly relates to, the fit-and-focus corporate business purpose for the separation, because it facilitates the elimination of competition for capital between the retained and contributed businesses through the establishment of an appropriate post-separation capital structure for each of those businesses. *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the securities-for-debt exchange are determined under an operative provision described in § 1.368–

1(c)(2)(ii). *See* paragraph (a)(2) of this section.

(B) *Follow-on spin-off*. The follow-on spin-off is properly included in the plan of reorganization for the separation because that distribution satisfies all conditions required by paragraph (e) of this section. First, as substantiated by the separation and distribution agreement, in which Distributing expresses that it will carry out the follow-on spin-off, Distributing evidences a definite intent, prior to the first step of the plan of reorganization, to carry out the follow-on spin-off. *See* paragraph (e)(1) of this section. The satisfaction of this requirement is not affected by the contingency arising from the fact that Distributing commits to first attempt to carry out the stock-for-debt exchange, because Distributing commits in writing in one or more of its official records to carry out the follow-on spin-off in the event that the stock-for-debt exchange does not occur or does not result in the disposition by Distributing of all the retained stock. *See* paragraph (e) of this section. For the same reason, the satisfaction of this requirement is not affected by the fact that Distributing ultimately might engage in the open-market sale to dispose of all the retained stock, in the event that the follow-on spin-off does not result in a total disposition of that stock. *See* paragraph (e) of this section. In addition, the follow-on spin-off would not occur but for the separation, as evidenced by the separation and distribution agreement. *See* paragraph (e)(2)(i) of this section. Lastly, the follow-on spin-off is consistent with, and directly relates to, the fit-and-focus corporate business purpose for the separation because it would further the separation of the retained and contributed businesses. *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the Federal income tax consequences of the follow-on spin-off are determined under an operative provision described in § 1.368–1(c)(2)(ii) (that is, section 361). *See* paragraph (a)(2) of this section.

(C) *Open-market sale*. The open-market sale is properly included in the plan of reorganization for the separation because that sale satisfies all conditions required by paragraph (e) of this section. First, as evidenced by the separation and distribution agreement and other official records of Distributing, in which Distributing expresses that it will carry out the open-market sale, Distributing evidences a definite intent, prior to the first step of the plan of reorganization, to carry out the open-market sale. *See*

paragraph (e)(1) of this section. The satisfaction of this requirement is not affected by the contingency that Distributing commits to first attempt to carry out the stock-for-debt exchange and then the follow-on spin-off, because Distributing commits in writing in one or more of its official records to carry out the open-market sale in the event that the stock-for-debt exchange and the follow-on spin-off, taken together or on their own, do not occur or do not result in the disposition by Distributing of all the retained stock. *See* paragraph (e) of this section. In addition, the open-market sale is necessary to satisfy one or more of the requirements of a definitional provision described in § 1.368–1(c)(2)(i) intended to apply to the reorganization. *See* paragraph (e)(2)(i)(A) of this section. Lastly, the open-market sale is consistent with, and directly relates to, the fit-and-focus corporate business purpose for the separation because it would further the separation of the retained and contributed businesses. *See* paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the open-market sale is taken into account along with the contribution and distribution for determining the Federal income tax consequences of the separation under sections 355 and 368(a)(1)(D) (that is, the relevant definitional and operative provisions described in § 1.368–1(c)(2)(i) and (ii)). *See* paragraph (a)(2) of this section.

(14) *Example 14: Scope of plan of reorganization—dispositions of retained stock*—(i) *Facts*. The facts are the same as in paragraph (g)(13)(i) of this section (*Example 13*), except for the following. With regard to the retained stock, the separation and distribution agreement and other official records of Distributing provide that Distributing might transfer the retained stock to a creditor of Distributing in a stock-for-debt exchange that satisfies the requirements set forth in §§ 1.361–5(a) and 1.368–3(a)(5) (stock-for-debt exchange). The separation and distribution agreement and other official records of Distributing also provide that Distributing might distribute that retained stock to Distributing's shareholders (follow-on spin-off). Lastly, those documents provide that, to the extent the retained stock is not disposed of after Distributing succeeds or fails in completing the stock-for-debt exchange and follow-on spin-off, Distributing will sell the retained stock on the open market by not later than five years after the first distribution date (open-market sale). Distributing describes these

contemplated possibilities of carrying out the stock-for-debt exchange and follow-on spin-off, as well as its written commitment to carry out the open-market sale, in its plan of reorganization filed with the IRS pursuant to § 1.368–3(a)(5).

(ii) *Analysis*—(A) *Stock-for-debt exchange*. The stock-for-debt exchange is properly excluded from the plan of reorganization for the separation because the exchange fails to satisfy all conditions required by paragraph (e) of this section. Specifically, as evidenced by the separation and distribution agreement and other official records of Distributing, Distributing treats the occurrence of the stock-for-debt exchange as a contemplated possibility, thereby failing to evidence a definite intent to carry out the transaction. See paragraph (e)(1)(iii) of this section. Accordingly, as corrected by the Commissioner, the securities-for-debt exchange is excluded from the taxpayer's plan of reorganization (and therefore section 361(c), the otherwise relevant operative provision described in § 1.368–1(c)(2)(ii), does not apply). See paragraph (a)(2)(ii) of this section.

(B) *Follow-on spin-off*. The analysis is the same as in paragraph (g)(14)(ii)(A) of this section (*Example 14*). Therefore section 361(c), the otherwise relevant operative provision described in § 1.368–1(c)(2)(ii), does not apply.

(C) *Open-market sale*. The open-market sale is properly included in the plan of reorganization for the separation because the sale satisfies all conditions required by paragraph (e) of this section. First, as substantiated by the separation and distribution agreement, in which Distributing expresses that it will carry out the open-market sale, Distributing evidences a definite intent, prior to the first step of the plan of reorganization, to carry out the open-market sale. See paragraph (e)(1) of this section. The satisfaction of this requirement is not affected by the contingency created by Distributing's contemplation of carrying

out the stock-for-debt exchange and the follow-on spin-off, because Distributing commits in writing in one or more of its official records to carry out the open-market sale in the event that the stock-for-debt exchange and the follow-on spin-off, taken together or on their own, do not occur or do not result in the disposition by Distributing of all the retained stock. See paragraph (e) of this section. In addition, the open-market sale is necessary to satisfy one or more of the requirements of a definitional provision described in § 1.368–1(c)(2)(i) intended to apply to the reorganization. See paragraph (e)(2)(i)(A) of this section. Lastly, the open-market sale is consistent with, and directly relates to, the fit-and-focus corporate business purpose for the separation because it would further the separation of the retained and contributed businesses. See paragraph (e)(3) of this section. Accordingly, based on the correct and properly filed plan of reorganization pursuant to § 1.368–3(a)(5), the open-market sale is taken into account along with the contribution and distribution for determining the Federal income tax consequences of the separation under the relevant definitional provisions described in § 1.368–1(c)(2)(i). See paragraph (a)(2) of this section.

(15) *Example 15: Scope of plan of reorganization—dispositions of retained stock*—(i) *Facts*. The facts are the same as in paragraph (g)(14)(i) of this section (*Example 14*), except for the following. With regard to the retained stock, the separation and distribution agreement and other official records of Distributing provide that the open-market sale also is a contemplated possibility, rather than subject to a written commitment by Distributing.

(ii) *Analysis*—(A) *Stock-for-debt exchange*. The analysis is the same as in paragraph (g)(14)(ii)(A) of this section (*Example 14*).

(B) *Follow-on spin-off*. The analysis is the same as in paragraph (g)(14)(ii)(B) of this section (*Example 14*).

(C) *Open-market sale*. The open-market sale is properly excluded from the plan of reorganization for the separation because the open-market sale fails to satisfy all conditions required by paragraph (e) of this section. Specifically, as evidenced by the separation and distribution agreement and other official records of Distributing, Distributing treats the occurrence of the open-market sale as a contemplated possibility, thereby failing to evidence a definite intent to carry out the transaction. See paragraph (e)(1)(iii) of this section. Accordingly, the open-market sale is not taken into account for purposes of satisfying the relevant definitional provision described in § 1.368–1(c)(2)(i), pursuant to a plan of reorganization corrected by the Commissioner. See paragraph (a)(2)(ii) of this section.

(h) *Applicability date*. This section applies to transactions intended to qualify under section 368 of the Code for which the earliest of the following dates occurs after [date of publication of final regulations in the **Federal Register**]:

(1) The date of the first public announcement (as defined in § 1.355–7(h)(10)) of the transaction.

(2) The date of entry by the taxpayer into a written agreement to engage in the transaction.

(3) The date of approval of the transaction by the board of directors of the taxpayer.

(4) The date of a court order (or a plan confirmed, or a sale approved, by order of a court) in a title 11 or similar case (as defined in section 368(a)(3)(A) of the Code), but only if the taxpayer was a debtor in a case before such court.

(5) The date a ruling request for the transaction is submitted to the IRS.

Douglas W. O'Donnell,

Deputy Commissioner.

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Part VIII

Department of Commerce

Bureau of Industry and Security

15 CFR Parts 734, 736, 740, et al.

Implementation of Additional Due Diligence Measures for Advanced Computing Integrated Circuits; Amendments and Clarifications; and Extension of Comment Period; Interim Final Rule

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 736, 740, 742, 743, 744, 748, 762, 772, and 774

[Docket No. 250108–0013]

RIN 0694–AJ98

Implementation of Additional Due Diligence Measures for Advanced Computing Integrated Circuits; Amendments and Clarifications; and Extension of Comment Period

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Interim final rule, with request for comment.

SUMMARY: BIS is revising the Export Administration Regulations (EAR) in response to requests from the public to provide additional due diligence procedures regarding advanced computing integrated circuits (ICs). This interim final rule (IFR) will protect the national security of the United States and assist foundries and Outsourced Semiconductor Assembly and Test (“OSATs”) companies in complying with provisions of the EAR pertaining to advanced computing ICs in the supply chain. This IFR also revises the EAR to make amendments and clarifications to the EAR for changes made to the EAR in an IFR released by BIS on December 2, 2024, “Foreign-Produced Direct Product Rule Additions, and Refinements to Controls for Advanced Computing and Semiconductor Manufacturing Items,” (FDP IFR), including extending the deadline for written comments for the FDP IFR to March 14, 2025.

DATES:

- *Effective date:* The effective date of this rule is January 16, 2025.
- *Compliance date:* Although this rule is effective January 16, 2025, exporters, reexporters, and transferors (in-country) are not required to comply with the new requirements of this rule until January 31, 2025. This compliance date only applies to EAR text that this rule revises, and does not otherwise impact any provision that was in effect prior to January 16, 2025 or added to the EAR through other rules. For example, under Export Control Classification Number (ECCN) 3A090, this IFR adds new Note 1 to 3A090.a, which, as new text, is subject to this compliance date. This IFR also revises ECCN 3A090.a. Only the new changes to ECCN 3A090.a in this particular rule are eligible for this compliance date.

- *Comment date:* Comments on this IFR must be received by BIS no later than March 14, 2025.

- *Extension of comment period for FDP IFR:* The comment period for the FDP IFR published December 5, 2024, at 89 FR 96790, is extended. Comments must be received on the FDP IFR by BIS no later than March 14, 2025.

ADDRESSES: Comments on this IFR, including the amendments and clarifications made for the FDP IFR described under section III.G of this IFR, may be submitted to the Federal rulemaking portal at: www.regulations.gov. The www.regulations.gov ID for this IFR is BIS–2024–0055. Please refer to RIN 0694–AJ98 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” Any submissions with file names that do not begin with either a “BC” or a “P” will be assumed to be public and will be made publicly available at: <https://www.regulations.gov>. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT:

- For general questions, contact Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at 202–482–2440 or by email: RPD2@bis.doc.gov.

- For Category 3 technical questions, contact Carlos Monroy at 202–482–3246 or by email: Carlos.Monroy@bis.doc.gov.

- For Category 5 technical questions, contact Aaron Amundson at 202–482–0707 or RPD2@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 7, 2022, BIS issued the first of a series of rules that restricted the ability of the People’s Republic of China (PRC) and other countries of concern to obtain certain advanced computing ICs (*i.e.*, ICs exceeding specified performance thresholds) and related items (October 7 IFR). The controls in the October 7 IFR and the controls in the subsequent related rules were designed to prevent malicious state and non-state actors in the PRC and elsewhere from obtaining critical technology that they could use to threaten U.S. national security and foreign policy objectives. Today, through this IFR, BIS is updating the EAR to enhance the effectiveness of these controls. This IFR aims to address a common request from public comments on the October 7 IFR controls and subsequent related rules for more detailed guidance on how to conduct due diligence to confirm that an IC does not exceed the performance thresholds specified in EAR controls. In particular, this IFR focuses on providing “front-end fabricators” with objective, bright-line rules designed to assist in better identifying transactions with potential risk for diversion in a manner contrary to U.S. national security and foreign policy interests; enhancing due diligence procedures to ensure that new customers are appropriately vetted by “front-end fabricators” prior to providing ICs that may meet the advanced computing control levels; and improving reporting for transactions involving newer customers who may pose a heightened risk of diversion.

A. Semiconductors Are Central to the PRC’s Technological and Military Ambitions

The PRC seeks to use advanced computing ICs and supercomputing capacity in the development and deployment of advanced computing systems and artificial intelligence (AI) models to further its goal of surpassing the military capabilities of the United States and its allies. Advanced or frontier AI capabilities such as large AI foundation models can lead to improved design and execution of weapons of mass destruction (WMDs), autonomous weapons, and advanced conventional weapons. Military decision-making aided by these AI models can improve

speed, accuracy, planning, and logistics. Advanced computing ICs are necessary for the development of these capabilities, because of the high processing power needed.

The use of advanced computing ICs in development and deployment of PRC AI models would further the PRC's goals of surpassing the military capability of the United States and its allies, a goal noted in the February 6, 2023, Annual Threat Assessment of the U.S. Intelligence Community (see <https://www.dni.gov/files/ODNI/documents/assessments/ATA-2023-Unclassified-Report.pdf>). That same report indicated that the PRC "is rapidly expanding and improving its artificial intelligence (AI) and big data analytics capabilities, which could expand beyond domestic use," including to export its digital authoritarian ecosystem to assist in surveillance and to facilitate its transnational repression overseas.

Such activities by the PRC are contrary to U.S. national security and foreign policy interests as set forth in the Export Control Reform Act of 2018 (ECRA) (codified, as amended, at 50 U.S.C. 4801–4852), which directs BIS to control items subject to the jurisdiction of the United States when those items could be used in "military programs that pose a threat to the security of the United States or its allies," could lead to "the proliferation of weapons of mass destruction or of conventional weapons," or could undermine the "foreign policy of the United States, including the protection of human rights and the promotion of democracy" (50 U.S.C. 4811(2)).

B. Export Controls on Advanced Computing ICs

Accordingly, on October 7, 2022, BIS released the IFR, "Implementation of Additional Export Controls: Certain Advanced Computing and Semiconductor Manufacturing Items; Supercomputer and Semiconductor End Use; Entity List Modification" (October 7 IFR) (October 13, 2022, 87 FR 62186), which amended the EAR to implement controls on certain ICs, computer commodities that contain such ICs, and certain semiconductor manufacturing items, and to make other EAR changes to implement appropriate related controls, including on certain "U.S. person" activities. The October 7 IFR explained that these controls were aimed at limiting the PRC's ability to engage in activities that would pose significant threats to U.S. national security and foreign policy. BIS determined that advanced computing ICs and related computing items—many of which originated in the United States

or were produced with U.S. technology, software, or tools—could enable the PRC to develop certain enhanced data processing and analysis capabilities, including through AI applications because of the high processing power of the advanced computing ICs and related computing items.

Specifically, the October 7 IFR required a license for the export or reexport to the PRC of ICs and related items above a certain performance threshold (e.g., those specified in Export Control Classification Number (ECCN) 3A090) that are the "direct product" of certain technology or software that is subject to the EAR or are produced by a plant or major component of a plant that is the direct product of such technology or software. That rule also imposed a license requirement for the export to certain entities on the Entity List of any items subject to the EAR that are the "direct product" of certain technology or software that is subject to the EAR or are produced by a plant or major component of a plant that is the direct product of such technology or software. This requirement significantly limited access to "advanced-node integrated circuits (ICs)" for the PRC, as production of "advanced-node ICs" requires U.S. technology, software, and tools. Exceeding the control thresholds for advanced computing ICs that were set in the October 7 IFR is extremely challenging without the use of U.S. technology, software, and tools, so controlling these items significantly reduced the PRC's ability to indigenously produce advanced computing ICs.

On October 25, 2023, BIS updated the controls imposed by the October 7 IFR to address advances in technology and ensure the controls remained effective. In particular, BIS learned that certain additional ICs could provide nearly comparable AI model training capability as those controlled in the October 7 IFR, and so further restricted those ICs. As such, the IFR, "Implementation of Additional Export Controls: Certain Advanced Computing Items; Supercomputer and Semiconductor End Use; Updates and Corrections" (AC/S IFR) (88 FR 73458, October 25, 2023), adjusted parameters for advanced computing ICs that are critical for advanced computing and AI applications, and imposed new measures to address the risk of circumvention of the controls, including expanding the license requirement for advanced computing ICs to apply to Country Groups D:1, D:4, and D:5.

In addition to the imposition of licensing requirements for advanced computing ICs and related items (e.g.,

those specified in ECCN 3A090) to the PRC and elsewhere, BIS provided guidance through the AC/S IFR to help ensure that semiconductor foundries do not inadvertently violate the controls that are based on performance thresholds. Specifically, the AC/S IFR imposed a license requirement, including for transactions involving foreign produced items subject to the EAR pursuant to § 734.9(e)(2) (footnote 4), on 13 PRC entities involved in the development of advanced computing ICs by adding them to the Entity List. In addition, the AC/S IFR provided additional Red Flags and due diligence requirements to help "front-end fabricators" (i.e., manufacturers of ICs designed by another party) identify whether IC designs meet the specified performance thresholds and thus require a license when destined for countries of concern. These Red Flags were designed to assist "front-end fabricators" to evaluate information provided by IC designers as to IC performance capabilities and assess whether foreign parties are attempting to circumvent controls by illicitly fabricating restricted ICs. In particular, Red Flag 19 gave producers of advanced ICs specific factors to identify a potential advanced computing IC regardless of a customer's assertion of an item's technical parameters. Specifically, it explained that if the item that would be produced is an IC, or a computer, "electronic assembly," or "component" that incorporates more than 50 billion transistors and high bandwidth memory (HBM), it raises a Red Flag that there is a high degree of likelihood that a license is required under the EAR. Under standard BIS practice, when Red Flags are raised, the exporter, reexporter, or transferor (in-country) is required to investigate the circumstances and inquire about the end use, end user, or ultimate country of destination to resolve the Red Flag. If the Red Flag is not sufficiently resolved, then the exporter, reexporter, or transferor (in-country) should seek guidance from BIS by submitting an advisory opinion request to BIS or by submitting a license application to BIS.

On December 2, 2024, BIS released another IFR, "Foreign-Produced Direct Product Rule Additions, and Refinements to Controls for Advanced Computing and Semiconductor Manufacturing Items," (FDP IFR) (89 FR 96790, December 5, 2024), that made changes to the EAR controls for certain advanced computing items, supercomputers, and semiconductor manufacturing equipment, which includes adding new controls for certain

semiconductor manufacturing equipment and related items, creating new Foreign Direct Product (FDP) rules for certain commodities to impair the capability of certain destination or entities of concern to produce “advanced-node ICs”, adding new controls for certain high bandwidth memory (HBM) important for advanced computing, and clarifying controls on certain software keys that allow for the use of items such as software tools. The FDP IFR published concurrently with another BIS final rule entitled, “Additions and Modifications to the Entity List; and Removals from the Validated End-User (VEU) Program” (Entity List rule) (89 FR 96830, December 5, 2024) that added to and modified the Entity List to ensure appropriate EAR controls are in place for certain critical technologies and to minimize the risk of diversion to entities of concern.

On January 13, 2025, BIS filed for public inspection, a rule related to this IFR, the “Framework for Artificial Intelligence Diffusion” IFR (AI Diffusion IFR) which imposed a worldwide regional stability (RS) license requirement for the export, reexport, or transfer (in-country) of advanced computing ICs classified under ECCNs 3A090.a, 4A090.a, and related .z items in § 742.6(a)(6)(iii)(A), and created several exceptions and pathways to authorization to facilitate transactions that pose a low risk of diversion or would otherwise advance U.S. national security or foreign policy interests, including U.S. technological leadership. Additionally, in January 2025, BIS filed for public inspection, a final rule related to this IFR, “Additions to the Entity List” (Foundry Entity List rule) which amends the EAR by adding 16 entities to the Entity List, under the destinations of China, People’s Republic of (China) (14) and Singapore (2).

C. National Security Basis for Additional Controls Related to “Applicable Advanced Logic Integrated Circuits (ICs)”

Following the implementation of the October 7 IFR in 2022, BIS has continued to study and assess the effectiveness of its controls in protecting U.S. national security and foreign policy interests. In so doing, BIS has relied on open-source reporting, public comments, industry analysis, and other sources of information available to the U.S. Government.

Over the past year, BIS determined that modifications to existing controls are warranted. BIS assessed that relevant Entity List entries, Red Flag requirements and technical guidance

have not fully ensured that foundries producing ICs for IC designers and other related companies in the IC supply chain are able to definitively determine whether those ICs meet or exceed the ECCN 3A090 control parameters. As noted above, the EAR provides a series of Red Flag indicators that foundries can use to assess an IC’s performance level. However, BIS has assessed that entities seeking to divert ICs that meet the control parameters of ECCN 3A090 to unauthorized end uses and end users may misrepresent the performance capabilities of their ICs in a manner that would make it difficult for a foundry to adequately verify the performance of such items. As an initial matter, BIS has assessed that ICs with a transistor count below that specified in current Red Flag 19 (50 billion) can meet the performance threshold specified in ECCN 3A090. The Red Flag thus provides no guidance to foundries that receive orders for ICs with transistor counts below 50 billion in verifying their customers’ assertions that those ICs do or do not fall within ECCN 3A090.

Furthermore, these technical challenges in assessing the performance of an IC can emerge at multiple stages of the IC production process. In cases where a foundry does not control the final packaging of an IC, ICs are at risk of being diverted and later packaged into products that exceed the performance thresholds set out in ECCN 3A090. For example, a customer may request an IC with a transistor count just below the current transistor count Red Flag threshold, and contract with an OSAT company to incorporate that IC into a packaged item that exceeds the performance thresholds specified in ECCN 3A090. Such challenges in assessing the ultimate performance capabilities of an IC create a heightened risk that a foundry will fail to detect efforts by third parties to evade BIS controls.

Even in cases where a foundry retains control over a wafer through packaging and testing, BIS has identified challenges in ensuring compliance with advanced computing IC controls. BIS understands that contractual arrangements could prohibit foundries from analyzing certain business confidential information (e.g., a design file) that would give greater clarity into an IC’s ultimate usage and performance capabilities. Additionally, it can be challenging to assess the performance of an IC based on a design file. This lack of visibility into IC performance means such ICs may exceed ECCN 3A090 performance thresholds and ultimately be diverted to the PRC and other destinations of national security

concern or prohibited entities for use in advanced AI applications. BIS has therefore assessed that controls would be more effective with verifiable technical metrics such as node, which is immediately verifiable by the foundry, and transistor count, which is verifiable through communication between foundry and OSAT.

The risk that an IC designer might misrepresent the ECCN of “applicable advanced logic ICs” that meet the control parameters of ECCN 3A090 and divert these ICs to unauthorized end uses or end users is not hypothetical. BIS has observed persistent efforts to evade the controls on “advanced computing ICs,” as well as restrictions imposed through the Entity List, by the PRC and other entities through intermediaries and/or shell companies. Open-source reporting described PRC companies using foreign subsidiaries or other means to purchase ICs subject to EAR controls. To counter these efforts, as well as PRC operations inside and outside of the PRC (including the Hong Kong and Macau Special Administrative Regions as specified in the EAR) seeking to acquire advanced computing ICs through transshipment, diversion, and accessing datacenters with advanced computing ICs in destinations across the world, the AC/S IFR and the AI Diffusion IFR expanded the scope of destinations for which a license is required to export, reexport, or transfer (in-country) advanced computing ICs.

Although BIS’s controls have been effective, they have not entirely prevented the diversion of advanced computing ICs to the PRC and other destinations and entities of concern. Accordingly, BIS has determined that further restrictions on these ICs are warranted to ensure that advanced computing ICs are only exported to customers with low risk of diversion to restricted entities. While certain IC designers and/or OSATs have a long history of compliance with export controls, more safeguards are needed to ensure that the PRC and other entities cannot access advanced computing ICs through diversion from third parties.

To that end, this IFR imposes a broader license requirement for “front-end fabricators” and “OSAT” companies seeking to export, reexport, or transfer (in-country) certain “applicable advanced logic integrated circuits” under ECCN 3A090.a to or within any destination worldwide (see § 742.6(a)(6)(iii)(A) of the EAR, which works in conjunction with new Note 1 to 3A090), unless the license requirement is overcome in any of the three ways outlined in paragraphs a. through c. of Note 1 to 3A090. To

exclude the substantial number of low-risk transactions potentially captured within this expanded scope, the rule provides three ways to overcome the license requirement and creates lists of reliable sources to verify technical parameters of “applicable advanced logic ICs:”

- (i) Approved IC designers (listed in supplement no. 6 to part 740),
- (ii) Approved “OSAT” companies (listed in supplement no. 7 to part 740), as well as
- (iii) A method of identifying authorized IC designers with criteria included in Note 1 to 3A090.a.

Approved listed entities are those that submit requests to BIS to be added to a list and are approved through the End-user Review Committee (ERC) to be added to the relevant list. (see section III.D for the description of the criteria used in making such decision as specified in § 748.16(a)(4) and section III.B).

Authorized IC designers are those that meet the criteria under new Note 1 to 3A090.a. Prior to April 13, 2026, authorized IC designers include all IC designers that are headquartered in Taiwan or a destination specified in Country Group A:1 or A:5, that are neither located in nor have an ultimate parent headquartered in Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR; and that have agreed to submit applicable information described in § 743.9(b) to the “front-end fabricator,” which the “front-end fabricator” must then report to BIS. After April 13, 2026, authorized IC designers include any IC designer that both meets those criteria and has submitted an application to become an approved IC designer. However, any company deemed an authorized IC designer after April 13, 2026, will cease to be an authorized IC designer 180 days after the submission of its application to become an approved IC designer.

This rule also modifies License Exceptions Artificial Intelligence Authorization (AIA) and Advanced Compute Manufacturing (ACM) so that certain exceptions are only available for items designed by approved IC designers who are likely to accurately report the ECCN of the items they request advanced foundries to fabricate.

II. Overview of This Interim Final Rule

In this IFR, BIS makes changes to EAR controls in seven categories. The six categories of changes implemented by this IFR are described in section III as follows:

A. Revises License Exceptions AIA and ACM;

B. New supplement nos. 6 and 7 to part 740, including lists of approved IC designers and approved “OSAT” companies, as well as authorized IC designers in specified destinations;

C. New reporting requirements for “front-end fabricators” producing advanced computing ICs for authorized IC, as well as a new “Know Your Customer” (KYC) vetting form;

D. Application process for additions, modifications, and removals from the approved IC designer and approved “OSAT” company lists;

E. New Definitions;

F. Revisions to ECCNs to clarify scope of ECCN 3A090; and

G. Amendments and clarifications to the EAR as set forth in the FDP IFR.

III. Changes to the EAR

A. Revisions to License Exceptions Artificial Intelligence Authorization (AIA) and Advanced Compute Manufacturing (ACM)

This IFR revises the items within the scope of two license exceptions: License Exception AIA (§ 740.27) and License Exception ACM (§ 740.28). License Exception AIA authorizes the export, reexport, and transfer (in-country) of the items identified in paragraphs (a)(1) and (a)(2) to entities located within destinations listed in paragraph (a) of supplement no. 5 to part 740, unless the entity is headquartered outside of, or has an ultimate parent company headquartered outside of, a destination specified in paragraph (a) of supplement no. 5 to part 740, with an expanded authorization for certain model weights in paragraph (a)(3), subject to additional conditions. License Exception ACM authorizes the export, reexport, and transfer (in-country) of eligible items (ECCNs 3A090, 4A090, and related .z commodities, software, and technology) to a ‘private sector end user’ that is located in a destination not listed in Country Group D:5 or Macau, provided it is not headquartered in and does not have an ultimate parent company headquartered in Macau or a destination specified in Country Group D:5, if the ultimate end use is the “development,” “production” or storage (in a warehouse or other similar facility) of such eligible items.

This IFR amends License Exception AIA by adding a requirement for three of the eligible commodities for this exception: ECCNs 3A090.a; 5A002.z.1.a, z.2.a, z.3.a, z.4.a, z.5.a; and 5A992.z.1. The requirement for those three ECCNs provides that those ECCNs are eligible for this license exception only if they are designed by an approved or authorized IC designer, as described in

supplement no. 6 to part 740 and Note 1 to ECCN 3A090.a, respectively. This requirement is intended to ensure that foundries and other entities seeking to use this exception can do so only if the items have been designed by an entity that presents a low risk of diversion. As provided in Note 1 to ECCN 3A090.a, authorized IC designers are those that are (i) in Taiwan or a location specified in Country Group A:1 or A:5, that are neither headquartered nor have an ultimate parent headquartered in Macau or a location specified in Country Group D:5 of supplement no. 1 to part 740 and (ii) for whom transactions are subject to the reporting requirements in § 743.9 of the EAR.

This IFR similarly revises License Exception ACM. Paragraph (b) is revised by adding a requirement for three of the eligible commodities for this exception: ECCNs 3A090.a; 5A002.z.1.a, z.2.a, z.3.a, z.4.a, z.5.a; and 5A992.z.1. The requirement for those three ECCNs provides that those ECCNs are eligible for this license exception only if designed by an approved or authorized IC designer, as described in supplement no. 6 to part 740 and Note 1 to ECCN 3A090.a, respectively. As with the new requirement for License Exception AIA, this requirement is intended to ensure that foundries and other entities seeking to use License Exception ACM can do so only if they are working with entities that pose a low risk of diversion.

These revisions ensure License Exceptions ACM and AIA authorization for these three ECCNs are only available when designed by approved or authorized IC designers, which supports the more secure supply chain. The EAR still requires “front-end fabricators” to conduct continuous technical and KYC due diligence for authorized and approved IC designers and report their results to BIS. This ensures BIS has up-to-date information on these entities, enabling BIS to act on any concerning information reported. The factors used to designate authorized and approved IC designers are discussed in more detail below, but entities determined to have a strong history of export control compliance and that have been vetted by the U.S. government are likely to be trustworthy IC designers. Additionally, these exceptions are available for items designed by authorized IC designers headquartered in countries A:1, A:5, and Taiwan, which are destinations that are members of multilateral export control regimes (e.g., the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-use Goods and Technologies), have the authority to control key items of concern, or otherwise have incentive to ensure

compliance with these additional requirements. These destinations share the U.S. government's interest in countering diversion or misuse of advanced node ICs and promoting mutual security, and companies in such destinations will generally have a lower likelihood of misrepresenting the technical specifications of their items to advanced foundries.

Based on the changes in this IFR, these amended license exceptions will facilitate low-risk trade while allowing the U.S. government to vet prospective approved entities for such advanced ICs in the first instance, rather than relying solely on foundry due diligence to identify potential diversion risks. The reporting requirements associated with authorized IC designers will also allow the U.S. government visibility into the verification process between these entities and the advanced foundries to assure that it is operating as envisioned. It will therefore become much more difficult for entities headquartered in Macau or destinations specified in Country Group D:5 to obtain advanced computing ICs subject to the EAR by attempting to place orders through entities that might misrepresent the technical specifications of their items and then divert advanced computing ICs to restricted destinations.

B. New Supplement Nos. 6 and 7 to Part 740, Including Lists of Approved IC Designers and Approved "OSAT" Companies, as Well as Authorized IC Designers

Part 740 is amended by adding supplement nos. 6 and 7 to create two new lists of entities: approved IC designers (supplement no. 6) and approved "OSAT" companies (supplement no. 7).

In deciding which entities to initially include in these supplements, the agencies represented on the End User Review Committee (ERC) have assessed a variety of national security and foreign policy factors, including the company's record of engagement in appropriate end-use activities; the company's export licensing and related history indicating compliance with U.S. export controls and existence of other potential derogatory information related to said company (e.g., information raising questions about ownership of the company); whether the applicant has a longstanding history of advanced IC purchases; the ability of the applicant to guard against both the misuse and diversion of computing resources; the location of the company's headquarters and its principal place of operations; the volume and nature of the company's trade in ICs; and other factors as

determined by BIS to be relevant. In deciding on which entities warrant inclusion or removal from these supplements, the ERC will apply the same factors.

i. Addition of supplement no. 6 to part 740.

New supplement no. 6 to part 740, which is referenced in the Note 1 to ECCN 3A090.a, lists as approved IC designers Advanced Micro Devices, Inc., Alphabet Inc., Amazon.com, Inc., Analog Devices, Inc., Apple Inc., BAE Systems, Inc., Block, Inc., The Boeing Company, Broadcom Inc., Cerebras Systems Inc., Cisco Systems, Inc., Hewlett Packard Enterprise Company, Honeywell International, Inc., Infineon Technologies AG, Intel Corporation, International Business Machines Corporation (IBM), L3Harris Technologies, Inc., Marvell Technology, Inc., MediaTek Inc., Meta Platforms, Inc., Micron Technology, Inc., Microsoft Corporation, Mitsubishi Group, Nokia Corporation, Nvidia Corporation, NXP Semiconductors N.V., Qualcomm Incorporated, Raytheon Company, Realtek Semiconductor Corporation, Sony Group Corporation, Tesla, Inc., Texas Instruments, and Western Digital Technologies, Inc. Section 748.16 explains how to apply to be added to the list of approved IC designers. To be added to the list of approved IC designers, an IC designer with plans to produce one or more ICs classified under ECCN 3A090.a must submit to BIS a request in the form of an advisory opinion that is accompanied by certain required information, *i.e.*, the information in new supplement no. 4 to part 748. The processing of advisory opinion requests to add companies to the approved IC designer list in supplement no. 6 to part 740 will follow the interagency process for review of Validated End-User requests set forth in supplement no. 9 to part 748 of the EAR. BIS will conduct supplemental outreach to the companies initially included in supplement no. 6 to part 740 to ensure continued compliance with the EAR, including the requirements promulgated by this IFR.

ii. Addition of supplement no. 7 to part 740.

Supplement no. 7 to part 740 lists the following companies as approved "OSAT" companies, which is referenced in the Note 1 to ECCN 3A090.a: Amkor Technology, Inc., Ardentec Corporation, ASE Technology Holding Co., Ltd., Doosan Tesna Inc., Fabrinet, Giga Solution Tech. Co., Ltd., GlobalFoundries, Inc., HT Micron Semicondutores SA, Intel Corporation, International Business Machines Corporation (IBM); KESM Industries

Berhad, LB Semicon Inc. Micro Silicon Electronics Co., Ltd., Nepes Corporation, Powertech Technology Inc (PTI), QP Technologies, Raytek Semiconductor, Inc., Samsung Electronics Co. Ltd., SFA Semicon, Shinko Electric Industries Co. Ltd., Sigurd Microelectronics Corporation., Steco Co., Ltd., Taiwan Semiconductor Manufacturing Company Limited (TSMC), and United Microelectronics Corporation (UMC). To develop this list, BIS identified "OSAT" companies currently engaged in production of "applicable advanced logic ICs" headquartered outside of Macau or locations specified in Country Group D:5 in supplement no. 1 to part 740 of the EAR. BIS and the other export control agencies then vetted these entities on a case-by-case basis. Based on a review of open source and other information available to the U.S. Government, these companies have been determined to be approved. Therefore, these companies' attestations regarding the "aggregated approximated transistor count" of a final, packaged item can be used to overcome the presumption in Note 1 to ECCN 3A090.a that an "applicable advanced logic integrated circuit" is a 3A090.a item.

To apply to be added to the list of approved "OSAT" companies, § 748.16 specifies that an "OSAT" company with plans to test, assemble, or package one or more items exceeding the technical thresholds of 3A090.a designed by the approved IC designer must submit a request in the form of an advisory opinion to BIS. The processing of advisory opinion requests to add companies to the approved "OSAT" company list in supplement no. 7 to part 740 will follow the interagency process for review of Validated End-User requests set forth in supplement no. 9 to part 748 of the EAR.

BIS will conduct supplemental outreach to the companies initially included in supplement no. 7 to part 740 to ensure continued compliance with the EAR, including the requirements promulgated by this IFR.

C. Reporting Requirements for "Front-End Fabricators" Producing "Applicable Advanced Logic Integrated Circuits" for Authorized IC Designers

Section 743.9 adds new reporting requirements for "front-end fabricators" producing any IC specified in ECCN 3A090.a for authorized IC designers. Authorized IC designers are those that meet the criteria under new Note 1 to 3A090.a., including having agreed to submit applicable information described in § 743.9(b) to the "front-end fabricator," which the "front-end

fabricator” must then report to BIS and excludes these entities from some of these license requirements as described in Note 1 to 3A090.a. These new reporting requirements are designed to ensure the U.S. government has visibility into companies that are not listed on the initial approved IC designer list.

Note that BIS continuously monitors export licensing and trade data, and may take corrective action, including the imposition of reporting requirements, with respect to approved “OSAT” companies and approved IC designers should such parties present U.S. national security or foreign policy concerns.

Paragraph (a) to § 743.9 stipulates that reports must be submitted to BIS in accordance with this section by “front-end fabricators” producing ICs specified in ECCN 3A090.a for any authorized IC designers (§ 743.9(a)). Because only a small number of “front-end fabricators” are capable of producing ICs specified in ECCN 3A090.a, this allows for consolidation of reporting requirements from the smaller set of “front-end fabricators,” who can help to verify the much wider sets of IC designers and “OSAT” companies they work with. Structuring the reporting requirement for “front-end fabricators” ensures that the economic and compliance burden is minimal and placed on the companies who are best positioned to provide information that can help address potential diversion concern. Additionally, “front-end fabricators” need not provide information about exports, reexports, or transfers (in-country) to an entity that is an authorized IC designer and becomes an approved IC designer.

Paragraph (b) to § 743.9 identifies the information that must be collected by the “front-end fabricator” and included in each report to BIS regarding authorized IC designers (e.g., the name, address, and point of contact of the authorized IC designer; the end-user vetting form included in supplement no. 2 of this part; and a description of each category of IC specified or presumed to be specified under ECCN 3A090.a sold during the reporting quarter). The information in the report about the IC specified or presumed to be specified under ECCN 3A090.a should include the designer, product names, model number (if known), and quantity sold during the reporting quarter. This information provides the U.S. government visibility over the verification process.

The final three paragraphs of § 743.9 provide more information on how to submit reports, and where to submit

general information on reporting. Paragraph (c)(1) to § 743.9 establishes that reports must be submitted on a quarterly subject to the provisions of this section, and that the first report must be submitted by May 31, 2025 and the report shall cover any exports, reexports, and transfers (in-country) during the time between January 31 and April 30, 2025. Thereafter, paragraph (c)(2) states that reports for the reporting period ending April 30 must be received by BIS no later than May 31. Reports for the reporting period ending July 31 must be received by BIS no later than August 31. Reports for the reporting period ending October 31 must be received by BIS no later than November 30. Reports for the reporting period ending January 31 must be received by BIS no later than February 28. Paragraph (d) provides the email address, *EAR.Reports@bis.doc.gov*, where reports must be submitted with authorized IC designer in the subject line. Paragraph (e) notes that general information or questions about the reports can be submitted to the Office of National Security Controls, Tel. (202) 482-0092, or Email: *EAR.Reports@bis.doc.gov*.

The authorized IC designer KYC Vetting Form discussed in § 743.9 has been added through this IFR in new supplement no. 2 to part 743. This supplement contains a questionnaire that must be completed as part of the reporting requirements for authorized IC designers in § 743.9 of the EAR. Unresolved answers of “Yes” to questions in the form in supplement no. 2 to part 743 are considered a Red Flag. The “front-end fabricators” would need to conduct additional due diligence before proceeding with the transaction. The questions in the form are KYC best practices that are especially critical in this context where there is a risk of companies seeking advanced foundry services in circumvention of controls on advanced computing items. They are not an exhaustive list of due diligence requirements but provide important information that should be part of KYC screening. These questions focus on three areas: the legitimacy of the authorized IC designer; whether the authorized IC designer matches any entry on the Consolidated Screening List; and screening of any other parties to a given transaction; and general Red Flags such as whether a freight forwarding firm is listed as the final destination or whether any party appears to be overpaying for a transaction.

D. Application Process for Additions, Modifications, and Removals From the Approved IC Designer and Approved “OSAT” Company Lists

i. Changes to the advisory opinion process being used to request being added, modified, or removed from the lists of approved IC designers or approved “OSAT” companies.

In § 748.3(c) (Advisory opinions), this IFR makes revisions to account for the advisory opinion process that will be used to request a party to be added, removed, or modified from the list of approved IC designers in supplement no. 6 to part 740 or approved “OSAT” companies in supplement no. 7 to part 740. Those changes are implemented in paragraph (c)(4) of § 748.3. This IFR redesignates existing paragraph (c)(4) as paragraph (c)(5).

ii. Section 748.16: Application for additions and modification to, or removals from the list of approved IC designers and approved “OSAT” companies.

Part 748 is amended by adding new section § 748.16 for addition, removal, or modification requests for approved IC designers and approved “OSAT” companies. To be eligible to be listed in supplement no. 6 or 7 to part 740 of the EAR, § 748.16 notes that applicants must adhere to the provisions set forth in paragraphs (a) through (d) of this section. These provisions, discussed in greater detail in the paragraphs below in this section III.D.ii, establish eligibility for approved IC designer and approved “OSAT” company status, create protocols for additions, modifications, and removals from the list of approved IC designers and “OSAT” companies. Section 748.16 notes that if a request to be listed in supplement no. 6 or no. 7 to part 740 of the EAR is not granted, no new license requirement is triggered. In addition, such a result does not render the entity ineligible for license approvals from BIS, nor does it preclude the subsequent approval of a request to be listed in supplement no. 6 or 7 to part 740. These clarifications are to ensure an entity is not dissuaded from applying to be listed in this supplement.

Paragraph (a)(1) to § 748.16 states that only entities that have designed, assembled, tested, or packaged ICs, or have credible plans to do so, will be considered for addition to either list in supplement no. 6 or 7 to part 740. Entities headquartered or having an ultimate parent headquartered in Macau or a destination in Country Group D:5 are not eligible, as they are at risk of facing significant pressure to provide inaccurate information to the “front-end fabricators” in order to gain access to

advanced foundry services to make restricted advanced ICs. Meanwhile, entities that have not designed, assembled, tested, or packaged ICs and have no credible plans to do so are not eligible for inclusion on either list since they cannot attest to the performance specifications of ICs they have not designed, assembled, tested, or packaged themselves.

Paragraph (a)(2) provides a requirement to include, with a request for addition to a list, the information in supplement no. 4 to part 748. The information in this required supplement is much like the information required of Validated End User (VEU) applicants (*i.e.*, identity, ownership, methodology for recordkeeping, certification of compliance with all the provisions of § 748.16, and a statement of acknowledgement and agreement).

Paragraph (a)(3) provides an email address to send all types of requests. Requests must be submitted in the form of an advisory opinion request, as described in § 748.3(c), and requests should be marked “approved supply chain entities request” and emailed to *approved_supply_chain@bis.doc.gov*.

Paragraph (a)(4) establishes some of the factors used by the End-User Review Committee (ERC) in evaluating an applicant for eligibility to be listed as an approved IC designer or approved “OSAT” company. The factors include: (i) the applicant’s record of exclusive engagement in appropriate end-use activities; (ii) the applicant’s compliance with U.S. export controls; (iii) the need for an on-site review prior to approval; (iv) the applicant’s capability of complying with the requirements of being listed as an approved IC designer; (v) the ability of the applicant to guard against both the misuse and diversion of computing resources; and (vi) the applicant’s relationships with U.S. and foreign companies. In addition, subparagraph (a)(4) states that when evaluating the eligibility of an IC designer or “OSAT” company for approved status, the ERC will consider the status of the export controls of the country or countries where the applicant is headquartered, and these countries’ support of and adherence to multilateral export control regimes. All of these factors are relevant to assessing the risk that an applicant will adhere to all U.S. export control regulations and poses a low risk of diversion.

Next, paragraph (a)(5) notes that listings of approved IC designers, and approved “OSAT” companies are subject to revision, suspension, or revocation entirely or in part, and paragraph (a)(6) emphasizes that

information submitted in an addition or modification request is deemed to constitute continuing representations of existing facts or circumstances. Any material or substantive change relating to the authorization must be promptly reported to BIS, whether status has been granted or is still under consideration. The provisions ensure that approved IC designer status, and decision-making about whether to grant this status, is informed by the most up-to-date information.

Paragraph (b) requires the requester retain records relating to all requests submitted pursuant to § 748.16 in accordance with the recordkeeping requirements set forth in part 762 of the EAR. This is to ensure that in the event of an investigation, BIS can request access to relevant facts and representations made in the course of attaining and maintaining list status.

Paragraph (c) identifies the information that authorized IC designers are required to report to the “front-end fabricators” producing their ICs classified under ECCN 3A090.a, which the “front-end fabricators” must then report to BIS. These reporting requirements are in § 743.9 Reporting Requirements for authorized IC designers, which was discussed in section III.C.

Finally, entities listed as approved IC designers and approved “OSAT” companies may request their removal of their listing in supplement nos. 6 or 7 to part 740 of the EAR by following the instructions in paragraph (a)(2) of this section. Paragraph (d) notes that recordkeeping and reporting to the “front-end fabricator” or “front-end fabricators” must continue until the EAR has been updated to remove the entity from supplement nos. 6 or 7 to part 740 of the EAR. Any End-user Review Committee member has authority to make a proposal for an addition to, modification of, or removal of an entry from the IC Designer list and OSAT list, consistent with the authorities in supplement no. 9 to part 748 of the EAR.

E. New Definitions

Section 772.1 is amended by adding five definitions: “16/14 nanometer node,” “Aggregated approximated transistor count,” “Applicable advanced logic integrated circuits,” “Front-end fabricator,” and “Outsourced Semiconductor Assembly and Test (OSAT).” These terms are added to § 772.1 to assist the public to easily find the definition for these terms, because they are used in multiple parts of the EAR. The new definitions for “16/14 nanometer node,” “Aggregated

approximated transistor count,” and “Applicable advanced logic integrated circuits” defines these technical terms in a way that will add greater specificity under the EAR for where these terms are used. The new definitions for “Front-end fabricator,” and “Outsourced Semiconductor Assembly and Test (OSAT)” defined these types of entities for purposes of the EAR and will make it easier for exporters, reexporters, and transferors to identify these types of entities.

This IFR also revises the definition for “Advanced-node integrated circuits” by amending paragraph (3) for Dynamic Random-Access Memory (DRAM) ICs by revising the memory cell area from “less than 0.0019 μm^2 ” to read “less than 0.0026 μm^2 ” and revising the memory density from “greater than 0.288 gigabits per square millimeter” to read “greater than 0.20 gigabits per square millimeter.” In addition, this rule adds the parameter of “more than 3000 through-silicon vias per die” to ensure that all of the DRAM ICs that are intended to be captured under this definition are caught. In addition, the word “gigabytes” is changed to “gigabits” in Note 2 to the definition. See Section III.G.i.b. for more explanation about these revisions.

F. Revisions To Clarify the Scope of ECCN 3A090.a

BIS seeks to further ensure that customers of “front-end fabricators” and “OSAT” companies, including potential shell companies, cannot evade controls on advanced computing ICs by misrepresenting the performance capabilities of their IC designs. Thus, BIS has determined that it is not sufficient for “front-end fabricators” to confirm the ECCN by solely relying on the attestation of the end user or other party to the transaction. Accordingly, this IFR amends supplement no. 1 to part 774 by revising ECCN 3A090.a. This IFR adds Note 1 to ECCN 3A090.a to clarify that when a “front-end fabricator” or “OSAT” company is seeking to export, reexport, or transfer (in-country) any “applicable advanced logic integrated circuit,” there is a presumption that the item is 3A090.a and designed or marketed for datacenter. Unless this presumption is overcome, then the “front-end fabricator” or “OSAT” company must comply with all requirements applicable to items specified in 3A090.a. The presumption can be overcome in one of following three ways:

i. If the designer of the “applicable advanced logic integrated circuit” is an approved or authorized IC designer.

As discussed above, approved IC designers have been vetted by the U.S. government, while, prior to April 13, 2026, authorized IC designers include all IC designers (a) headquartered in Taiwan or a destination specified in Country Group A:1 or A:5, that are neither located in nor have an ultimate parent headquartered in Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR and (b) for whom transactions are subject to the reporting requirements in § 743.9 of the EAR. After April 13, 2026, a company will be considered an authorized IC designer for a period of 180 days if it both meets those criteria and submits an application to become an approved IC designer. Structuring the ECCN in this manner allows most IC designers—as the above destinations comprise the vast majority of “front-end fabricators”’ revenues—to proceed with transactions without a license but enhances the U.S. government’s visibility into this approved supply chain process. In particular, authorized IC designers headquartered in Taiwan or a destination specified in Country Group A:1 or A:5 may overcome the presumption if their “front-end fabricators” comply with reporting requirements for such customers. After April 13, 2026, the main way to be exempted is to become an approved IC designer (other than the 180-day route described here).

ii. If the IC die is packaged by the “front-end fabricator” at a location outside of Macau or a destination specified in Country Group D:5 in supplement no. 1 to part 740, then the attestation of the “front-end fabricator” that (a) the “aggregated approximated transistor count” of the final packaged IC is below 30 billion transistors, or (b) the final packaged IC does not contain high bandwidth memory (HBM) and that the “aggregated approximated transistor count” of the final packaged IC is below (i) 35 billion transistors for any exports, reexports, or transfers (in-country) completed in 2027; or (ii) 40 billion transistors for any exports, reexports, or transfers (in-country) completed in 2029 or thereafter, then this overcomes the presumption that the IC is specified in ECCN 3A090.a.

Packaging that is completed by the “front-end fabricator” itself at a location outside D:5 or Macau will enable that chipmaker to produce a credible, reliable assessment of the technical parameters of the chip. The “front-end fabricators” will know definitively whether the final, packaged item exceeds the applicable transistor threshold specified above if it conducts the packaging itself, and so the front-

end fabricator will not need to rely solely on the customer’s information.

iii. If the IC is packaged by an approved “OSAT” company listed in supplement no. 7 to part 740 of the EAR, then the attestation of the approved “OSAT” company that (a) the “aggregated approximated transistor count” of the final packaged IC is below 30 billion transistors, or (b) the final packaged IC does not contain high bandwidth memory (HBM) and that the “aggregated approximated transistor count” of the final packaged IC is below (i) 35 billion transistors for any exports, reexports, or transfers (in-country) completed in 2027; or (ii) 40 billion transistors for any exports, reexports, or transfers (in-country) completed in 2029 or thereafter, then this overcomes the presumption that the IC is specified in ECCN 3A090.a.

Because of their enhanced credibility, completion of the packaging by an approved “OSAT” company should produce a reliable assessment for the final item’s technical specifications, given that the U.S. government has assessed those entities to accurately report the ultimate performance of a final, packaged item. If an approved “OSAT” company can confirm that a final item does not contain more than the applicable number of transistors (as specified based on the year of the export, reexport, or in-country transfer), then it is very unlikely such item is an advanced AI IC. Any of these three conditions would suffice to enhance the credibility of a customer’s attestation as to an IC’s performance, thus enabling a potential customer to proceed without applying for a license. In the absence of an attestation of the ‘total processing performance’ and the ‘performance density’ by an approved IC designer listed in supplement no. 6 to part 740 of the EAR, any logic IC produced using the “16/14 nanometer node” or below, or using a non-planar transistor architecture and destined for an item with an “aggregated approximated transistor count” exceeding the applicable number of transistors (as specified for the year of the export, reexport, or in-country transfer) within the package, or where the “aggregated approximated transistor count” of the final, packaged item cannot be confirmed by the “front-end fabricator” or “OSAT” company as described above, is presumed to be a 3A090.a item designed or marketed for a datacenter.

Similarly, processing by an approved “OSAT” company, having been vetted by BIS and relevant interagency partners, overcomes the presumption that an “applicable advanced logic IC”

is a 3A090.a item and designed or marketed for a datacenter.

Importantly, the presumption in ECCN 3A090 does not apply to the extent an item is classified under ECCNs 4A003.z, 4A004.z, 4A005.z, or 4A090. As a result, the changes set forth under this IFR are primarily limited to circumstances in which a “front-end fabricator” seeks to export an IC to a chip designer or “OSAT” company.

Note 2 to 3A090.a provides a definition ‘approximated transistor count’ of a die, which is the ‘transistor density’ of the die multiplied by the area of the die measured in square millimeters. The ‘transistor density’ of the die is the number of transistors that can be fabricated per square millimeter for the process node used to manufacture the die.

G. Amendments to the Changes Made in the FDP IFR

i. Non-Commerce Control List (CCL) Amendments.

a. Revisions to § 744.11.

This rule amends § 744.11(a)(2)(v) to harmonize the product scope of the license requirements for exports from abroad or reexports from all countries by an entity headquartered in, or whose ultimate parent is headquartered in, Macau or a destination specified in Country Group D:5 with the product scope of the license requirements in § 744.11(a)(3)(i) by an entity that is headquartered or whose ultimate parent company is headquartered in a country not specified in supplement no. 4 to part 742. Specifically, this rule adds additional ECCNs to the scope of paragraph (a)(2)(v)(A)(1), which was ECCN 3B993, and with this IFR is now ECCNs 3B001 (except 3B001.a.4, c, d, f.1, f.5, f.6, g, h, k to n, p.2, p.4, or r), 3B002 (except 3B002.c), 3B611, 3B903, 3B991 (except 3B991.b.2.a through 3B991.b.2.b), 3B992, 3B993, or 3B994.

b. Revisions to the definition of DRAM “advanced-node integrated circuit.”

This rule updates the definition of “advanced-node integrated circuit” in § 772.1 for DRAM ICs to clarify that (1) the relevant cell area BIS intended to capture with its prior 18 nanometer (nm) half-pitch standard is 0.0026 square micrometers (μm^2); (2) the relevant memory density BIS intended to capture with its 18 nm half-pitch standard is 0.20 gigabits per square millimeter (Gb/mm²); and (3) the relevant number of through-silicon vias per die intended to be captured is a parameter of “more than 3000 through-silicon vias per die”. In October 2022, BIS defined advanced-node DRAM ICs for purposes of §§ 744.6(c)(2) and 744.23(a)(2) as those with an “18 nm

half pitch or below.” Based on the parameters specified for “18 nm half-pitch” DRAM in the International Roadmap for Devices and Systems (IRDS), this standard corresponds to a DRAM cell size of 0.00194 μm^2 and a memory density of 0.288 Gb/mm². In the FDP IFR, BIS replaced the 18 nm half-pitch standard by directly referencing these technical parameters.

However, based on further analysis of DRAM production information, BIS determined that the IRDS definition of “18 nm half-pitch” does not fully cover DRAM ICs equivalent to “18 nm half-pitch” due to the IRDS definition and actual parameters of DRAM produced by the relevant foundries. As such, it does not restrict exports, reexports and transfers (in-country) of items covered by § 744.23(a)(2) and the activities of U.S. persons § 744.6 (c)(2)(i) to high bandwidth memory and other advanced DRAM applications. Accordingly, this update revises the cell area and memory density parameters to be consistent with production standards in the DRAM industry for the 18 nm half-pitch node, rather than the IRDS definition of “18 nm half-pitch,” which is based on a theoretical model, rather than actual, physical characteristics of DRAM memory. This revision imposes end use and U.S. persons controls at DRAM facilities not previously controlled by the definition of DRAM in the December 5, 2024 FDP IFR.

c. Revisions to Footnote 5-related references to address support for the “production” of logic and DRAM “advanced-node integrated circuits.”

This rule expands the scope of end users covered by the new *De Minimis* and FDPs applicable to Footnote 5 entities to include any end-user facility where the “production” of logic and DRAM “advanced-node integrated circuits” occurs. As explained in the FDP IFR, BIS added 16 entities to the Entity List with a Footnote 5 designation because of specific national security and or foreign policy concerns described in the Entity List rule, including supporting, or having the potential to support, the PRC’s efforts to produce “advanced-node integrated circuits,” including for military end uses. These controls complement BIS’s existing controls on the “production” of “advanced-node integrated circuits” in §§ 744.6(c)(2) and 744.23(a)(2) of the EAR. The revisions in this IFR will ensure that controls apply to certain foreign produced items when there is “knowledge” that an item is destined for certain entities located at facilities of concern, whether or not they have already been added to the Entity List with a Footnote 5 designation. At this

time, BIS has determined to add extraterritorial controls on facilities where the “production” of logic and DRAM “advanced-node integrated circuits” occurs.

d. Revisions to § 734.4(a)(3) text and footnote.

This rule revises the term “a” to “this” in § 734.4(a)(3) to clarify that the relevant “commodity” for purposes of this section is equipment described in ECCN 3B993.f.1. This IFR also updates the Footnote 1 to § 734.4 to address questions from industry about which countries maintain controls on these items.

e. Revisions to § 734.9(a) to add is-informed authority.

This rule revises § 734.9(a) by adding paragraph (a)(3) to clarify BIS’s authority to notify persons that foreign-produced items located outside the United States are subject to the EAR when they meet the requirements of any FDP rule in § 734.9, which as of the effective date of this IFR consists of paragraphs (b) through (k), as well as notifying persons of any license requirements that apply to such items.

f. Correcting four note designations in § 734.9 to place them in sequential order.

In § 734.9 this IFR also redesignates four of the existing notes to place the notes in numerical order in the section for consistency with Office of Federal Register requirements for the sequential numbering of notes in a section. This IFR redesignates Note 3 to paragraph (g) as Note 4 to paragraph (g), Note 5 to paragraph (h)(2)(ii) as Note 6 to paragraph (h)(2)(ii), Note 3 to paragraph (k)(1)(ii)(B) as Note 6 to paragraph (k)(1)(ii)(B), and Note 7 to paragraph (l)(1) as Note 8 to paragraph (l)(1).

g. Addition of Note 4 to § 734.9(h)(1).

In the advanced computing FDP rule, this IFR adds Note 4 to § 734.9(h)(1) to alert fabrication facilities and “OSAT” companies that pursuant to Note 1 of ECCN 3A090 there is a presumption that the commodity is ECCN 3A090.a and designed or marketed for datacenters when the IC is an “applicable advanced logic integrated circuit,” *i.e.*, logic integrated circuits produced using the “16/14 nanometer node” or below, or using a non-planar transistor architecture.

h. Revision of product scope for Temporary General License (TGL)—Less restricted SME “parts,” “components,” or “equipment.”

In supplement no. 1 to part 736, this IFR revises the product scope under paragraph (d)(1)(i)(A) for the TGL—Less restricted SME “parts,” “components,” or “equipment” under paragraph (d)(1). This IFR removes the reference to ECCN

3A991 in paragraph (d)(1)(i)(A) and adds in its place 3B991 to correct the product scope.

ii. Commerce Control List Revisions.

a. Revision to add items for improving 3B001.f and 3B993.f lithography equipment.

This rule adds new paragraphs under 3B001.f, 3B993.f, 3D992, 3D993, 3E992, and 3E993 for commodities, “software,” and “technology” designed or modified to improve the minimum resolvable feature size and ‘dedicated chuck overlay’ of deep-ultraviolet lithography equipment specified in 3B001.f.1 and 3B993.f. These new controls cover items that would not otherwise be specified under 3B001.f.1 or 3B993.f as “specially designed” “components” or “accessories” for such equipment, or under related 3D and 3B ECCNs for “software” and “technology” “specially designed” for the “development” or “production” of such equipment.

This rule also amends various cross references in the EAR to include 3B001.f.6.

b. Revisions to ECCNs 3B993 and 3B994.

This rule amends the headings for ECCNs 3B993 and 3B994 to specify both equipment and “specially designed” “components” and “accessories” for commodities specified in these ECCNs. BIS is making these changes to harmonize the scope of ECCNs 3B993 and 3B994 with similar controls in ECCN 3B001 and 3B002.

c. Revisions to ECCNs 3D992, 3D993, 3D994, 3E992, 3E993, and 3E994.

Paragraphs 3D992.a, 3D993.a, 3E993.a are amended by adding “specially designed” for consistency with other 990 series software controls.

ECCNs 3D994 and 3E994 are amended by adding “specially designed” to the heading for consistency with other 990 series software and technology controls.

ECCN 3E992 is amended by adding “and “technology” as follows (see List of Items Controlled)” to the heading and adding paragraphs 3E992.a to control “technology” “specially designed” for the “development” or “production” of commodities specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r; or 3B002.c; and adding 3E992.b to control “technology” not specified by 3E992.a designed or modified to perform specified actions in or with deep-ultraviolet immersion photolithography equipment.

iii. Extension of comment period for FDP IFR.

This IFR extends the FDP IFR deadline for written comments to March 14, 2025. This extension is being made to allow for commenters to have additional time to review the additional

amendments and clarifications to the EAR made in the FDP IFR and to be informed by the public outreach that BIS is conducting on the FDP IFR and will be conducting for this IFR in preparing their comments. Extending the public comment period on the FDP IFR does not change that rule's effective date.

IV. Public Comments

BIS welcomes comments from the public on these additional due diligence revisions to the regulations, as well as for any of the other changes included in this IFR.

V. Savings Clauses

A. Savings Clause for the Entire IFR

For shipments of items removed from eligibility for a license exception or export, reexport, or transfer (in-country) NLR as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on January 31, 2025, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) NLR, provided the export, reexport, or transfer (in-country) is completed no later than on until March 3, 2025.

C. Savings Clause for This IFR for Certain Transactions Previously Authorized

If, in the twelve months prior to the effective date of this regulatory action, BIS exempted exports, reexports, or transfers (in-country) of an item from a licensing requirement imposed by notice issued pursuant to §§ 744.11(c) or 744.23(b), then exports, reexports, or transfers (in-country) of that item are exempt from any licensing requirement imposed by this regulatory action absent additional action taken by BIS.

VI. Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included ECRA (codified, as amended, at 50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, and as noted elsewhere, Section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, Section 1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, *inter alia*, the establishment of a list of controlled

items; the prohibition of unauthorized exports, reexports, and transfers (in-country); the requirement of licenses or other authorizations for exports, reexports, and transfers (in-country) of controlled items; apprising the public of changes in policy, regulations, and procedures; and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

VII. Rulemaking Requirements

1. Executive Orders 12866, 13563, and 14094 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects and distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. Pursuant to Executive Order 12866, as amended, this final rule has not been determined to be a “significant regulatory action.”

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number.

This rule involves the following OMB-approved collections of information subject to the PRA:

- 0694–0088, “Multi-Purpose Application,” which carries a burden hour estimate of 29.4 minutes for a manual or electronic submission;
- 0694–0096 “Five Year Records Retention Period,” which carries a burden hour estimate of less than 1 minute;
- 0694–0122, “Licensing Responsibilities and Enforcement,” which carries a burden hour estimate of 10 minutes per electronic submission;
- 0694–0137, “License Exceptions and Exclusions,” which carries a burden hour estimate of 5 minutes per electronic submission; and
- 0607–0152 “Automated Export System (AES) Program,” which carries a burden hour estimate of 3 minutes per electronic submission.

This IFR will affect the collection under control number 0694–0088, for

the multipurpose application because of the increase of 375 more license applications. BIS estimates that the changes included in this IFR will result in a net increase of 375 multi-purpose applications (*i.e.*, an increase of 375 license applications) submitted annually to BIS. However, the increase in burden falls within the existing burden estimates currently associated with these control numbers.

This IFR also involves a collection previously approved by the OMB under control number 0694–0137, “License Exceptions and Exclusions” because this rule modifies two EAR license exceptions, which now include new notification and reporting requirements. Specifically, this IFR adds two new types of requests that can be made under the existing advisory opinion process and new reporting requirements. There are two types of entities specified in Note 1 to 3A090.a that require submissions of requests to be added, modified or removed as an approved IC designer or approved “OSAT” company. These new reporting requirements related to License Exceptions ACM and AIA are specified under §§ 743.9 and new Note 1 to 3A090.a of the EAR. These changes are expected to result in an increase of 1,704 submissions related to this use of License Exceptions AIA and ACM, submitted to BIS or to other parties involved in the transaction. BIS estimates that these changes will result in an increase in burden hours of 385 hours. This collection of information fits within the scope of this information collection.

Additional information regarding these collections of information—including all background materials—can be found at: <https://www.reginfo.gov/public/do/PRAMain> by using the search function to enter either the title of the collection or the OMB Control Number.

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

4. Pursuant to Section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While Section 1762 of ECRA on its own provides sufficient authority for such an exemption, this action is also independently exempt from the same APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Nonetheless, BIS is accepting comments on this IFR.

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

List of Subjects

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Parts 736 and 772

Exports.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information, Exports, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 734, 736, 740, 742, 744, 748, 762, 772, and 774 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 1. The authority citation for part 734 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 2. Section 734.4 is amended by revising paragraphs (a)(3), (8), and (9) to read as follows:

§ 734.4 *De minimis* U.S. content.

(a) * * *

(3) There is no *de minimis* level for equipment meeting the parameters in ECCN 3B993.f.1 of the Commerce Control List in supplement no. 1 to part 774 of the EAR, when the equipment is destined for use in the “development” or “production” of “advanced-node integrated circuits” and the “advanced-node integrated circuits” meet the parameter specified in paragraph (1) of that definition in § 772.1 of the EAR, unless the country from which the foreign-made item was first exported¹ has this commodity specified on an export control list.

* * * * *

(8) There is no *de minimis* level related to the SME FDP rule for a commodity meeting the parameters in ECCNs 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, or 3B002.c of the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR, when the commodity contains a U.S.-origin integrated circuit specified under Category 3, 4, or 5 of the CCL, and the commodity is destined for Macau or a destination specified in Country Group D:5, unless excluded from the national security license requirement in § 742.4(a)(4) or the regional stability license requirement in § 742.6(a)(6) of the EAR.

(9) For items related to the Footnote 5 FDP rule, there is no *de minimis* level for an item meeting the parameters in ECCNs specified in Category 3B (except 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, or 3B002.c) of the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR, when the commodity contains a U.S.-origin integrated circuit specified under Category 3, 4, or 5 of the CCL, and the commodity is destined for an entity with a Footnote 5 designation in the license requirement column of the Entity List in supplement no. 4 to part 744 of the EAR, or to an end-user “facility” located in Macau or a destination specified in Country Group D:5 when there is “knowledge” that the commodities will be used in the “production” of logic or DRAM “advanced-node integrated circuits.”

* * * * *

¹ The Government of Japan added ArF-wet lithography equipment and other advanced semiconductor manufacturing equipment to its control list for all regions on July 23, 2023. The Government of the Kingdom of the Netherlands added this equipment to its

control list for all regions on September 9, 2024.

■ 3. Section 734.9 is amended by:

■ a. Revising the paragraph heading of paragraph (a) and adding paragraph (a)(3);

■ b. Revising paragraphs (e)(3) introductory text, (e)(3)(i) introductory text; and (e)(3)(ii);

■ c. Redesignating Note 3 to paragraph (g) as Note 4 to paragraph (g), Note 5 to paragraph (h)(2)(ii) as Note 6 to paragraph (h)(2)(ii), Note 3 to paragraph (k)(1)(ii)(B) as Note 7 to paragraph (k)(1)(ii)(B) and Note 7 to paragraph (l)(1) as Note 8 to paragraph (l)(1);

■ d. Adding Note 5 to paragraph (h)(1); and

■ e. Revising paragraph (k)(1) introductory text.

The additions and revisions read as follows:

§ 734.9 Foreign-Direct Product (FDP) Rules.

* * * * *

(a) Definitions, model certification, and is-informed authority—

* * * * *

(3) *Jurisdiction and license requirements for persons informed by BIS.* BIS may inform persons, either individually by specific notice or through amendment to the EAR, that foreign-produced items located outside the United States are subject to the EAR pursuant to § 734.9, and of any license requirements that apply to such items. Specific notice will be given only by, or at the direction of, the Principal Deputy Assistant Secretary for Strategic Trade and Technology Security or the Deputy Assistant Secretary for Strategic Trade. When such notice is provided orally, it will be followed by written notice within two working days signed by one of those officials or their designee. The absence of BIS notification does not excuse the exporter from compliance with other requirements of this section.

(e) * * *

(3) *Entity List FDP rule: Footnote 5 and “advanced-node integrated circuit” “production.”* A foreign-produced commodity is subject to the EAR if it meets both the product scope in paragraph (e)(3)(i) of this section and the end-user scope in paragraph (e)(3)(ii) of this section. See § 744.11(a)(2)(v) of the EAR for license requirements, exclusion from license requirements, and license review policy, applicable to foreign-produced commodities that are subject to the EAR pursuant to this paragraph (e)(3).

(i) *Product scope Entity List FDP rule: footnote 5 and “advanced-node integrated circuit” “Production.”* The product scope applies if a foreign-

produced commodity is specified in ECCN 3B001 (except 3B001.a.4, c, d, f.1, f.5, f.6, g, h, k to n, p.2, p.4, r), 3B002 (except 3B002.c), 3B903, 3B991 (except 3B991.b.2.a through 3B991.b.2.b), 3B992, 3B993, or 3B994, and meets the conditions of either paragraph (e)(3)(i)(A) or (B) of this section.

* * * * *

(ii) *End-user scope of the Entity List FDP rule: Footnote 5 and for entities located at “facilities” where “advanced-node integrated circuit” “production” occurs.* A foreign-produced commodity meets the end-user scope of this paragraph (e)(3)(ii) if there is “knowledge” that:

(A) *Activities involving Footnote 5 designated entities and for entities located at “facilities” where the “production” of “advanced-node integrated circuits” occurs.* The foreign-produced commodity will be incorporated into any “part,” “component,” or “equipment” produced, purchased, or ordered by any entity with a Footnote 5 designation in the license requirement column of the Entity List in supplement no. 4 to part 744 of the EAR or by an entity located at a “facility” in Macau or a destination specified in Country Group D:5 where the “production” of logic or DRAM “advanced-node integrated circuits” occurs; or

(B) *Footnote 5 designated entities and for “advanced-node integrated circuits” “production” “facilities” as transaction parties.* Any entity with a Footnote 5 designation in the license requirement column of the Entity List in supplement no. 4 to part 744 of the EAR or an entity located at a “facility” located in Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 where the “production” of logic or DRAM “advanced-node integrated circuits” occurs is a party to any transaction involving the foreign-produced commodity (e.g., as a “purchaser,” “intermediate consignee,” “ultimate consignee,” or “end-user”).

* * * * *

(h) * * *

(1) * * *

Note 5 to paragraph (h)(1): See Note 1 to ECCN 3A090, because when a “front-end fabricator” or “OSAT” company is seeking to export, reexport, or transfer (in-country) an “applicable advanced logic integrated circuit,” there is a presumption that the commodity is 3A090.a and designed or marketed for datacenters.

* * * * *

(k) * * *

(1) *Product scope.* The product scope applies to a foreign-produced commodity specified in ECCN

3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, or 3B002.c that meets the conditions of either paragraph (k)(1)(i) or (ii) of this section.

PART 736—GENERAL PROHIBITIONS

■ 4. The authority citation for part 736 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of May 8, 2024, 89 FR 40355 (May 9, 2024); Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 5. Supplement no. 1 to part 736 is amended by revising paragraphs (d)(1)(i)(A) to read as follows:

Supplement No. 1 to Part 736—General Orders

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) ECCNs that are designated as controlled on the CCL only for AT reasons (3BA991, 3B992, and associated “software” and “technology”); or

* * * * *

PART 740—LICENSE EXCEPTIONS

■ 6. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 7. Section 740.2 is amended by revising paragraph (a)(9)(i) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

(a) * * *

(9) * * *

(i) The item is controlled under ECCN 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, 3B002.c, 3B993, 3B994, or associated software and technology in ECCN 3D001, 3D002, 3D003, 3D992, 3D993, 3D994, 3E001, 3E992, 3E993, or 3E994 and is being exported, exported from abroad, reexported, or transferred (in-country) to or within either Macau or a destination specified in Country Group D:5 of supplement no. 1 to this part, and the license exception is other than License Exception GOV, restricted to eligibility under the provisions of § 740.11(b).

* * * * *

■ 8. Section 740.26 is amended by revising paragraph (c)(1) to read as follows:

§ 740.26 License Exception Restricted Fabrication “Facility” (RFF)

* * * * *

(c) * * *

(1) Items may not be used for the operation, installation, maintenance, repair, overhaul, or refurbishing of items specified in ECCNs 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, 3B002.c, 3B993, or 3B994 at a ‘restricted fabrication facility’.

* * * * *

■ 9. Section 740.27 is amended by revising paragraph (a)(1) to read as follows:

§ 740.27 License Exception Artificial Intelligence Authorization (AIA).

(a) * * *

(1) Eligible commodities for this exception are those specified in ECCNs 3A001.z.1.a, z.2.a, z.3.a, z.4.a; 3A090.a, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a; 4A003.z.1.a, z.2.a; 4A004.z.1; 4A005.z.1; 4A090.a; 5A002.z.1.a, z.2.a, z.3.a, z.4.a, z.5.a, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a; 5A004.z.1.a, z.2.a; and 5A992.z.1, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a.

* * * * *

■ 10. Section 740.28 is amended by revising paragraph (b) to read as follows:

§ 740.28 License Exception Advanced Compute Manufacturing (ACM).

* * * * *

(b) *Eligible commodities, software, and technology.* Commodities, “software,” and “technology” eligible for License Exception ACM are as follows: Items specified by ECCNs 3A001.z; 3A090.a, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a; 3A090.b and c; 3D001 (for “software” for commodities controlled by 3A001.z or 3A090); 3E001 (for “technology” for commodities controlled by 3A001.z or 3A090); 4A003.z; 4A004.z; 4A005.z; 4A090; 4D001 (for “software” for commodities controlled by 4A003.z, 4A004.z, and 4A005.z); 4D090 (for “software” for commodities controlled by 4A090); 4E001 (for commodities controlled by 4A003.z, 4A004.z, 4A005.z, 4A090 or “software” specified by 4D001 (for 4A003.z, 4A004.z, or 4A005.z), or 4D090 (for “software” for commodities controlled by 4A090)); 5A002.z.1.a,

z.2.a, z.3.a, z.4.a, z.5.a, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a; 5A002.z.2; 5A004.z.2; and 5A992.z.2; 5A004.z; 5A992.z.1, if designed by an approved or authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a 5A992.z.2; 5D002.z; 5D992.z; 5E002 (for “technology” for commodities controlled by 5A002.z or 5A004.z or “software” specified by 5D002 (for 5A002.z or 5A004.z commodities)); or 5E992 (for “technology” for commodities controlled by 5A992.z or “software” controlled by 5D992.z).

* * * * *

- 11. Supplements no. 6 and 7 are added to read as follows:

**Supplement No. 6 to Part 740—
Approved Integrated Circuit Designers**

Note: See Note 1 to ECCN 3A090.a.

Advanced Micro Devices, Inc.;
Alphabet, Inc.;
Amazon.com, Inc.;
Analog Devices, Inc.;
Apple, Inc.;
BAE Systems, Inc.;
Block, Inc.;
The Boeing Company;
Broadcom, Inc.;
Cerebras Systems, Inc.;
Cisco Systems, Inc.;
Hewlett Packard Enterprise Company;
Honeywell International, Inc.;
Infineon Technologies AG;
Intel Corporation;
International Business Machines Corporation (IBM);
L3Harris Technologies, Inc.;
Marvell Technology, Inc.;
MediaTek, Inc.;
Meta Platforms, Inc.;
Micron Technology, Inc.;
Microsoft Corporation;
Mitsubishi Group;
Nokia Corporation;
Nvidia Corporation;
NXP Semiconductors NV;
Qualcomm, Inc.;
Raytheon Company;
Realtek Semiconductor Corporation;
Sony Group Corporation;
Tesla, Inc.;
Texas Instruments; and
Western Digital Technologies, Inc.

**Supplement No. 7 to Part 740—
Approved “OSAT” Companies**

Note: See Note 1 to ECCN 3A090.a.

Amkor Technology, Inc.;
Ardentec Corporation;
ASE Technology Holding Co., Ltd.;
Doosan Tesna, Inc.;
Fabrinet;
Giga Solution Tech. Co., Ltd.;
GlobalFoundries, Inc.;
HT Micron Semicondutores SA;
Intel Corporation;
International Business Machines Corporation (IBM);
KESM Industries Berhad;

LB Semicon, Inc.;
Micro Silicon Electronics Co., Ltd.;
Nepes Corporation;
Powertech Technology, Inc. (PTI);
QP Technologies;
Raytek Semiconductor, Inc.;
Samsung Electronics Co. Ltd.;
SFA Semicon Co., Ltd.;
Shinko Electric Industries Co. Ltd.;
Sigurd Microelectronics Corporation;
Steco Co., Ltd.;
Taiwan Semiconductor Manufacturing Company Limited (TSMC); and
United Microelectronics Corporation (UMC).

**PART 742—CONTROL POLICY—CCL
BASED CONTROLS**

- 12. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

- 13. Section 742.4 is amended by revising paragraph (a)(4)(i) to read as follows:

§ 742.4 National Security.

(a) * * *

(4) * * *

(i) *Scope.* A license is required for exports, reexports, exports from abroad, and transfers (in-country) to or within either Macau or a destination specified in Country Group D:5 in supplement no. 1 to part 740 of the EAR of items specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, 3B002.c, 3D992, or 3E992.

* * * * *

- 14. Section 742.6 is amended by revising paragraph (a)(6)(i)(A)(1) to read as follows:

§ 742.6 Regional Stability.

(a) * * *

(6) * * *

(i) * * *

(A) * * *

(1) *Scope.* A license is required for exports, reexports, and transfers (in-country) to or within either Macau or a destination specified in Country Group D:5 in supplement no. 1 to part 740 of the EAR of items specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, 3B002.c, 3D992, or 3E992.

* * * * *

PART 743—SPECIAL REPORTING AND NOTIFICATION

- 15. The authority citation for part 743 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; 78 FR 16129.

- 16. Section 743.9 is added to read as follows:

§ 743.9 Reporting requirements for “front-end fabricators” producing “applicable advanced logic integrated circuits” for authorized integrated circuit designers.

(a) *Requirement.* “Front-end fabricators” producing any integrated circuit specified under ECCN 3A090.a or presumed to be specified under ECCN 3A090.a by Note 1 to 3A090 for any authorized integrated circuit designer must submit reports to BIS in accordance with this section. Reports need not, however, include information about exports, reexports, or in-country transfers to an entity that is both an approved integrated circuit designer listed in supplement no. 6 to part 740 of the EAR and an authorized integrated circuit designer, as described in Note 1 to ECCN 3A090.a.

(b) *Information to be included in the reports.* The following information must be collected by the “front-end fabricator” and included in each report to BIS:

(1) The name, address, and point of contact of the authorized integrated circuit designer;

(2) The “front-end fabricator’s” name and address must appear at the top of each page;

(3) The end-user Know Your Customer (KYC) vetting form included in supplement no. 2 of this part;

(4) Description of each category of integrated circuit classified under ECCN 3A090.a sold by the “front-end fabricator” to the authorized integrated circuit designer during the reporting quarter, including all of the following:
(i) Designer of the integrated circuit classified under ECCN 3A090.a;
(ii) Product names associated with the integrated circuit specified or presumed to be specified under ECCN 3A090.a, including model number (if known); and
(iii) Quantity of the integrated circuits classified under ECCN 3A090.a sold by the “front-end fabricator” to the integrated circuit designer during the reporting quarter.

(c) *Quarterly reporting requirement.*
(1) You must submit the first report by May 31, 2025. The report shall cover any exports, reexports, or transfers (in-

country) of integrated circuits classified under ECCN 3A090.a during the time between January 15, 2025 and April 30, 2025. Thereafter, reports are due according to the provisions of paragraph (c)(2) of this section.

(2)(i) After May 31, 2025, you must submit a report for each reporting period. There are four reporting periods:

- (A) May 1 to July 31;
- (B) August 1 to October 31;
- (C) November 1 to January 31; and
- (D) February 1 to April 30.

(ii) The report for a given period shall cover any exports, reexports, or transfers (in-country) of integrated circuits classified under ECCN 3A090.a during

that period. Each report is due no later than 30 days after the end of the relevant reporting period.

(d) *Where to submit reports required under this section.* Reports may be emailed to *EAR.Reports@bis.doc.gov* and must specify “Authorized integrated circuit designer” in the subject line.

(e) *Contacts.* General information or questions about these reports can be directed to the Office of National Security Controls, Tel. (202) 482–0092, or Email: *EAR.Reports@bis.doc.gov*.

■ 17. Supplement no. 2 is added to read as follows:

Supplement No. 2 to Part 743 Authorized Integrated Circuit Designer Know Your Customer (KYC) Vetting Form

This supplement contains a questionnaire that must be completed as part of the reporting requirements for authorized integrated circuit designers in § 743.9 of the EAR. The questions in the form are KYC best practices that are especially critical in this context where there is a risk of companies seeking advanced foundry services in circumvention of controls on advanced computing items. They are not an exhaustive list of due diligence requirements but provide important information that should be part of KYC screening.

VETTING FOR AUTHORIZED INTEGRATED CIRCUIT DESIGNER

	Yes/no	If yes, insert how you resolved column 2
<i>Section 1: Legitimacy of the authorized integrated circuit designer:</i> 1.A. Does the entity lack a website? 1.B. Does the entity's website IP address correspond to a different geographical region than the entity's physical address? 1.C. Is the country code of the entity's phone number different than the entity's physical address? 1.D. Does the entity's email address <i>not</i> contain the company domain name? 1.E. Is the entity's physical address invalid? 1.F. Is the entity purportedly a civil end user but its address is co-located with a military “facility”? 1.G. Do publicly available corporate records contradict the entity's assertions regarding its business (e.g., entity claims to be a large enterprise, but filings show only a small number of employees)? <i>Section 2: Screening:</i> 2.A. Does the entity's name match an entry in the Consolidated Screening List? 2.B. Does the entity's address match an entry in the Consolidated Screening List? 2.C. Does the customer's senior management or technical leadership (e.g., process engineers that are team leaders or otherwise leading development or production activities) overlap with an entity on the Consolidated Screening List? <i>Section 3: Additional Party Screening:</i> 3.A. Are any companies within the entity's corporate hierarchy (i.e., parent, subsidiary, ultimate beneficial owner) headquartered in Macau or Country Group D:5 in supplement no. 1 to part 740 of the EAR? 3.B. Do any companies within the entity's corporate hierarchy (i.e., parent, subsidiary, ultimate beneficial owner) match an entry or address in the Consolidated Screening List? 3.C. Are any other parties to the transaction (e.g., parties described in § 748.5 of the EAR) located or headquartered in Macau or Country Group D:5 in supplement no. 1 to part 740 of the EAR? <i>Section 4: General Red Flags:</i> 4.A. Is the entity's stated end use inconsistent with the nature of their business? 4.B. Is the requested quantity inconsistent with the entity's size? 4.C. Is a freight forwarding firm listed as the final destination? 4.D. Does the transaction involve multiple freight forwarders located in third countries? 4.E. Has the entity refused to answer questions about the end users and end uses of the product? 4.F. Do supporting documents such as commercial invoices list parties that are not the entity? 4.G. Is the entity overpaying for a product based on known market prices? 4.H. Does the transaction involve payments from entities in third countries not otherwise involved in the transaction?		

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 18. The authority citation for part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3

CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2024, 89 FR 77011 (September 20, 2024); Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 19. Section 744.6 is amended by revising paragraph (c)(2)(iii) to read as follows:

§ 744.6 Restrictions on specific activities of “U.S. Persons.”

* * * * *

(c) * * *

(2) * * *

(iii) *Semiconductor manufacturing equipment.* To or within either Macau or a destination specified in Country Group D:5, any item not subject to the EAR and meeting the parameters of ECCNs 3B001.a.4, c, d, f.1, f.5, f.6, k to

n, p.2, p.4, r, 3B002.c, 3D992, or 3E992 regardless of end use or end user.

* * * * *

■ 20. Section 744.11 is amended by revising paragraph (a)(2)(v) paragraph heading, paragraphs (a)(2)(v)(A) introductory text, and (a)(2)(v)(A)(1), to read as follows:

§ 744.11 License requirements that apply to entities acting or at significant risk of acting contrary to the national security or foreign policy interests of the United States.

* * * * *

(a) * * *

(2) * * *

(v) *Footnote 5 entities and end-user facilities where the “production” of logic or DRAM “advanced-node integrated circuits” occurs.*

(A) *License requirement.* You may not, without a license, reexport, export from abroad, or transfer (in-country) to or within any destination or to any end user or party any foreign-produced item subject to the EAR pursuant to §§ 734.4(a)(9) or 734.9(e)(3), for each of the following paragraphs (A)(1) through (A)(4):

(1) *Exports from abroad or reexports from all countries.* A license is required for commodities specified in ECCNs 3B001 (except 3B001.a.4, c, d, f.1, f.5, f.6, g, h, k to n, p.2, p.4, or r), 3B002 (except 3B002.c), 3B611, 3B903, 3B991 (except 3B991.b.2.a through 3B991.b.2.b), 3B992, 3B993, or 3B994 when exported from abroad or reexported by an entity headquartered in, or whose ultimate parent company is headquartered in, Macau or a destination specified in Country Group D:5.

* * * * *

PART 748—APPLICATIONS (CLASSIFICATION, ADVISORY, AND LICENSE) AND DOCUMENTATION

■ 21. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 13, 2024, 8 FR 66187 (August 15, 2024).

■ 22. Section 748.3 is amended by:

■ a. Redesignating paragraph (c)(4) as paragraph (c)(5); and

■ b. Adding a new paragraph (c)(4).
The addition reads as follows:

§ 748.3 Classification requests and advisory opinions.

* * * * *

(c) * * *

(4) To request an addition or modification to or removal from the

approved integrated circuit designers list in supplement no. 6 to part 740 of the EAR or the approved “OSAT” companies list in supplement no. 7 to part 740 of the EAR, see § 748.16 of this part.

* * * * *

■ 23. Section 748.16 is added to read as follows:

§ 748.16 Approved integrated circuit designers list and approved “OSAT” companies list, addition, removal, or modification requests.

You must submit an advisory opinion, in accordance with § 748.3 of this part and the provisions in this section, to request an addition or modification to or removal from the approved integrated circuit designers list in supplement no. 6 to part 740 of the EAR, or the approved “OSAT” companies list in supplement no. 7 to part 740 of the EAR. The advisory opinion request must adhere to the provisions in paragraphs (a) through (d) of this section. Denied requests do not result in new license requirements or render the applicant ineligible for license approvals from BIS, nor does a denied request preclude a company from submitting a subsequent request.

(a)(1) *Requests to be added.* Only entities not headquartered or having an ultimate parent headquartered in Macau or a destination specified in Country Group D:5 in supplement no. 1 to part 740 will be considered for addition to either list. Only entities that have designed, assembled, tested, or packaged integrated circuits, or have credible plans to do so, will be considered for addition to either list. To ensure a thorough review, requests to be added to either list must include the information in supplement no. 4 to this part.

(2) *Requests for removal or modification.* Any listed party may request to be removed from a list or have their listing modified. If a listed entity’s legal status changes (e.g., is dissolved), then they must request to be removed from the appropriate list. If control of the listed entity changes or the name changes, then the company must submit a modification request. If the company can no longer abide by the provisions of the EAR that pertain to approved entities, then they must request removal from the relevant list.

(3) *Submission of requests.* All requests should be emailed to approved_supply_chain@bis.doc.gov with a subject line stating, “Approved supply chain entities request.”

(4) *Review of requests for addition, modification, or removal.* The End-user Review Committee (ERC) will review all

requests (additions, modifications, and removals) to both lists.

(i) The ERC will consider a range of information for requests to be added to a list, potentially including but not limited to such factors as:

(A) the applicant’s record of exclusive engagement in appropriate end-use activities;

(B) the applicant’s compliance with U.S. export controls;

(C) the need for an on-site review prior to approval;

(D) the applicant’s capability of complying with the requirements of being added to the approved integrated circuit designers list or approved “OSAT” companies list;

(E) the ability of the applicant to guard against both the misuse and diversion of computing resources; and

(F) the applicant’s relationships with U.S. and foreign companies. In addition, when evaluating the application, the ERC will consider the status of the export controls of the country or countries where the applicant is headquartered, and these countries’ support of and adherence to multilateral export control regimes.

(ii) Requests to modify a listing due to a change in ownership or other substantive change to the listed entity will be considered in light of all of the criteria listed above. Requests to modify a listing to correct clerical errors or non-substantive changes to the listed entity’s information will typically be approved.

(iii) In reviewing requests to be removed from a list, BIS will consider facts regarding the entity’s compliance with the requirements of its status and the entity’s rationale for removing its status. In general, requests to be removed from a list will be approved.

(5) *Approval status.* Approved integrated circuit designer and approved “OSAT” company status (i.e., listing) is subject to revision, suspension, or revocation entirely or in part.

(6) *Continuing representations.* Information submitted in an addition or modification request is deemed to constitute continuing representations of existing facts or circumstances. Any material or substantive change relating to the request must be promptly reported to the ERC, whether approved or still under consideration.

(b) *Recordkeeping.* Records relating to all requests must be retained by the requester in accordance with the recordkeeping requirements set forth in part 762 of the EAR.

(c) *Reporting requirements.*

Authorized integrated circuit designers, to be eligible for that status consistent with Note 1 to ECCN 3A090.a, are required to submit certain information

to the “front-end fabricator,” which the “front-end fabricator” must then report to BIS. See § 743.9 of the EAR.

(d) *Termination of reporting requirements.* Approved integrated circuit designers and approved “OSAT” companies may request to be removed from a relevant list, however, the recordkeeping requirements in paragraph (b) of this section and the reporting requirements in paragraph (c) of this section must be adhered to until the listing is removed from the relevant list.

■ 24. Supplement no. 4 is added to read as follows:

**Supplement No. 4 to Part 748—
Information Required To Be Submitted
With a § 748.16 Request**

The following information is required to be submitted with a request to be added to either supplement no. 6 to part 740—Approved Integrated Circuit Designer list or supplement no. 7 to part 740—Approved “OSAT” company list, as described in § 748.16. The prospective added integrated circuit designer and prospective approved “OSAT” company are referred to as the candidate in this supplement.

(a) *Identity.* Name of the candidate, including all names under which the candidate conducts business; complete company physical address (simply listing a post office box is insufficient); telephone number; fax number; email address; company website; and name of individual who should be contacted if BIS has any questions. If the entity submitting the request is different from the candidate identified in the request, this information must be submitted for both entities. If the candidate has multiple locations, all physical addresses must be listed.

(b) *Ownership.* Provide an overview of the structure, ownership and business of the candidate. Include a description of the entity, including type of business activity, ownership, subsidiaries, and joint-venture projects, as well as an overview of any business activity or corporate relationship that the entity has with either government or military organizations.

(c) *“Applicable advanced logic integrated circuits.”* List any “applicable advanced logic integrated circuits” the candidate expects to design, assemble, test, or package, and the end use and any known intended end uses of these commodities. Include a description of the commodities; the ECCN for all commodities, classified to the subparagraph level, as appropriate; and technical parameters for the commodities including performance specifications.

(d) *Recordkeeping.* Specify how the candidate’s record keeping system will allow compliance with the recordkeeping requirements set forth in § 748.16(b) and part 762 of the EAR.

(e) *Certification.* Include an original statement on letterhead of the candidate, signed and dated by a person who has authority to legally bind the candidate,

certifying that the candidate will comply with all the provisions of § 748.16.

(f) *Statement of acknowledgement and agreement.* The candidate must include this statement of acknowledgement and agreement with the request, that the candidate:

(1) Acknowledges that they have been informed of and understand that the item(s) to be produced by the “front-end fabricator” have been exported in accordance with the EAR and that use or diversion of such items contrary to the EAR is prohibited, particularly the license requirements of §§ 742.6(a)(6)(iii) and 744.23(a)(3) of the EAR;

(2) Agrees to comply with the recordkeeping requirements in § 748.16(b) and part 762 of the EAR; and

(3) Agrees to allow on-site reviews by U.S. Government officials to verify compliance with the EAR.

PART 762—RECORDKEEPING

■ 25. The authority citation for part 762 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 26. Section 762.2 is amended by adding paragraphs (b)(61) and (b)(62), to read as follows:

§ 762.2 Records to be retained.

* * * * *

(b) * * *

(61) § 748.16(b), all records relating to requests for addition or modifications to or deletion from supplement no. 6 or supplement no. 7 to part 740.

(62) Supplement No. 2 to Part 743 Authorized Integrated Circuit Designer Vetting Form.

* * * * *

PART 772—DEFINITIONS OF TERMS

■ 27. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 28. Section 772.1 is amended by:

■ a. Adding, in alphabetical order, the definitions for “16/14 nanometer node;”

■ b. Revising the definition for “Advanced-Node Integrated Circuits;”

■ c. Adding, in alphabetical order, the definitions for “Aggregated approximated transistor count”, “Applicable advanced logic integrated circuits”, “Front-end fabricator”, and “Outsourced Semiconductor Assembly and Test (OSAT)” to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

16/14 nanometer node (16/14 nm node) is indicated in the Logic Industry “Node Range” figure described in the International Roadmap for Devices and Systems, 2016 edition (“More Moore” White Paper), available at: https://irds.ieee.org/images/files/pdf/2016_MM.pdf.

* * * * *

Advanced-Node Integrated Circuits (Advanced-Node IC). For parts 734 and 744 of the EAR, “advanced-node integrated circuits” include integrated circuits that meet any of the following criteria:

(1) Logic integrated circuits using a non-planar transistor architecture or with a “production” ‘technology node’ of 16/14 nanometers or less;

(2) NOT AND (NAND) memory integrated circuits with 128 layers or more; or

(3) Dynamic random-access memory (DRAM) integrated circuits having:

(i) A memory cell area of less than 0.0026 μm^2 ;

(ii) A memory density greater than 0.20 gigabits per square millimeter; or

(iii) More than 3000 through-silicon vias per die.

Note 1 to definition of “Advanced-Node Integrated Circuits”: For the purposes of paragraph (1) of this definition, the term *technology node* refers to the Logic Industry “Node Range” figure described in the International Roadmap for Devices and Systems, 2016 edition (“More Moore” White Paper), available at: https://irds.ieee.org/images/files/pdf/2016_MM.pdf.

Note 2 to definition of “Advanced-Node Integrated Circuits”: For the purposes of paragraph (3) of this definition, the term *memory density* refers to the capacity of the monolithic die, package, or stack comprising the DRAM integrated circuit measured in gigabits divided by the relevant area. For a monolithic die, the relevant area is the area of the die. For package or stack, the relevant area is the footprint of the package or stack measured in square millimeters. In the case where a stack is contained in a package, use the area of the package. Cell area is defined as Wordline*Bitline (which takes into consideration both transistor and capacitor dimensions).

* * * * *

Aggregated approximated transistor count means the sum of the ‘approximated transistor counts,’ as defined in Note 1 to 3A090.a, of each “applicable advanced logic integrated circuit” die within the final package fabricated using a “16/14 nanometer node” or below, or using a non-planar transistor architecture.

* * * * *

Applicable advanced logic integrated circuits are logic integrated circuits produced using the “16/14 nanometer

node” or below, or using a non-planar transistor architecture.

* * * * *

Front-end fabricator is the company that provides front-end fabrication services to produce an integrated circuit, creating circuits on the surface of a wafer through processes such as photolithography, etch, and deposition.

* * * * *

Outsourced Semiconductor Assembly and Test (OSAT) is a company that provides third-party manufacturing and testing services to semiconductor businesses. OSAT companies are responsible for assembling, packaging, and testing integrated circuits and other semiconductor devices.

* * * * *

PART 774—THE COMMERCE CONTROL LIST

■ 29. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 30. Supplement no. 1 to part 774 is amended by revising ECCN 3A090, 3B001, 3B993 and 3B994, 3D992, 3D993, 3D994, 3E992, 3E993, and 3E994, to read as follows:

Supplement No. 1 To Part 774—The Commerce Control List

* * * * *

3A090 Integrated circuits as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry, except 3A090.a.	To or within any destination worldwide, see § 742.6(a)(6)(iii)(A) of the EAR.
RS applies to 3A090.b ...	To or within destinations specified in Country Groups D:1, D:4, and D:5 of supplement no. 1 to part 740 of the EAR, excluding any destination also specified in Country Groups A:5 or A:6. See § 742.6(a)(6)(iii)(B) of the EAR.
RS applies to 3A090.c ...	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(6)(i)(B) of the EAR.

Control(s) *Country chart
(see Supp. No. 1
to part 738)*

AT applies to entire entry AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

NAC/ACA: Yes, for 3A090.a, if the item is not designed or marketed for use in datacenters and has a ‘total processing performance’ of 4800 or more; yes, for 3A090.b, if the item is designed or marketed for use in datacenters. N/A for 3A090.c.

HBM: Yes, for 3A090.c. See § 740.25 of the EAR.

AIA: Yes, for 3A090.a.

ACM: Yes

LPP: Yes for 3A090.a.

List of Items Controlled

Related Controls: (1) See ECCNs 3D001, 3E001, 5D002.z, and 5D992.z for associated technology and software controls. (2) See ECCNs 3A001.z, 5A002.z, 5A004.z, and 5A992.z.

Related Definitions: N/A

Items:

a. Integrated circuits having one or more digital processing units having either of the following:

a.1. A ‘total processing performance’ of 4800 or more; or

a.2. A ‘total processing performance’ of 1600 or more and a ‘performance density’ of 5.92 or more.

Note 1 to 3A090.a: When a “front-end fabricator” or “OSAT” company is seeking to export, reexport, or transfer (in-country) an “applicable advanced logic integrated circuit,” there is a presumption that the item is 3A090.a and designed or marketed for datacenters. If the “front-end fabricator” or “OSAT” company cannot overcome this presumption, then it must comply with all license requirements applicable to items specified in 3A090.a. However, this presumption does not apply to any entity other than the “front-end fabricator” or “OSAT” company. A “front-end fabricator” or “OSAT” company can overcome this presumption in any of the following three ways outlined in paragraphs a. through c. of this Note 1.

a. If the designer of the “applicable advanced logic integrated circuit” is an approved or authorized integrated circuit designer, then a datasheet or other attestation of the ‘total processing performance’ and the ‘performance density’ from the approved or authorized integrated circuit designer indicating that the IC is not specified in 3A090.a will overcome the presumption for the “front-end fabricator” or “OSAT” company that the IC is specified in ECCN 3A090.a.

(1) Approved integrated circuit designers are listed in supplement no. 6 to this part of the EAR;

(2) Prior to April 13, 2026, authorized integrated circuit designers include all integrated circuit designers:

(i) Headquartered in Taiwan or a destination specified in Country Group A:1 or A:5, that are neither located in nor have an

ultimate parent headquartered in Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR; and

(ii) That have agreed to submit applicable information described in § 743.9(b) to the “front-end fabricator,” which the “front-end fabricator” must then report to BIS.

(3) After April 13, 2026, authorized integrated circuit designers include any integrated circuit designer that both meets the criteria specified in subparagraph (2) and has submitted an application to become an approved integrated circuit designer. However, any company deemed an authorized IC designer after April 13, 2026, will cease to be an authorized IC designer 180 days after the submission of its application to become an approved IC designer.

b. If the integrated circuit die is packaged by the “front-end fabricator” at a location outside of Macau or a destination specified in Country Group D:5 in supplement no. 1 to part 740, then the attestation of the “front-end fabricator” that (a) the “aggregated approximated transistor count” of the final packaged IC is below 30 billion transistors, or (b) the final packaged IC does not contain high-bandwidth memory and that the “aggregated approximated transistor count” of the final packaged IC is below (i) 35 billion transistors for any exports, reexports, or transfers (in-country) completed in 2027; or (ii) 40 billion transistors for any exports, reexports, or transfers (in-country) completed in 2029 or thereafter, then this overcomes the presumption by the “front-end fabricator” or “OSAT” company that the IC is specified in ECCN 3A090.a.

c. If the integrated circuit is packaged by an approved “OSAT” company listed in supplement no. 7 to part 740 of the EAR, then the attestation of the approved “OSAT” company that (a) the “aggregated approximated transistor count” of the final packaged IC is below 30 billion transistors, or (b) the final packaged IC does not contain high-bandwidth memory and that the “aggregated approximated transistor count” of the final packaged IC is below (i) 35 billion transistors for any exports, reexports, or transfers (in-country) completed in 2027; or (ii) 40 billion transistors for any exports, reexports, or transfers (in-country) completed in 2029 or thereafter, then this overcomes the presumption by the “front-end fabricator” or “OSAT” company that the IC is specified in ECCN 3A090.a.

d. It is not sufficient for the “front-end fabricator” or “OSAT” company to confirm the ECCN by relying on the attestation of the end user or other party to the transaction, except under one of the three ways enumerated in paragraphs a. through c. of this note. In the absence of an attestation of the ‘total processing performance’ and the ‘performance density’ by an approved integrated circuit designer listed in supplement no. 6 to part 740 of the EAR, the “front-end fabricator” or “OSAT” company must presume that any logic integrated circuit produced using the “16/14 nanometer node” or below, or using a non-planar transistor architecture and destined for a commodity with an (a) “aggregated

approximated transistor count” of the final packaged IC is below 30 billion transistors, or (b) the final packaged IC does not contain high-bandwidth memory and that the “aggregated approximated transistor count” of the final packaged IC is below (i) 35 billion transistors for any exports, reexports, or transfers (in-country) completed in 2027; or (ii) 40 billion transistors for any exports, reexports, or transfers (in-country) completed in 2029 or thereafter, or where the “aggregated approximated transistor count,” of the final, packaged integrated circuit cannot be confirmed by the “front-end fabricator,” or an approved “OSAT” company listed in supplement no. 7 to part 740 of the EAR, is specified in ECCN 3A090.a and designed or marketed for a datacenter.

Technical Note 1 to 3A090.a: The ‘approximated transistor count’ of a die is the ‘transistor density’ of the die multiplied by the area of the die measured in square millimeters. The ‘transistor density’ of the die is the number of transistors that can be fabricated per square millimeter for the process node used to manufacture the die. To calculate the number of ‘approximated transistor count’ of a die, a “front end fabricator” or “OSAT” company has two options. First, the “front end fabricator” or “OSAT” company may take the transistor density of the process node used to manufacture the die and multiply this density by the area of the die. This number may be significantly higher than the true transistor count, but if the result is below the relevant transistor threshold, then the “front end fabricator” or “OSAT” company can be confident that the die in question will not exceed that threshold. Second, to adjudicate edge cases, the “front end fabricator” or “OSAT” company may use standard design verification tools to estimate the number of (both active and passive) transistors on the die using the GDS file.

b. Integrated circuits having one or more digital processing units having either of the following:

b.1. A ‘total processing performance’ of 2400 or more and less than 4800 and a ‘performance density’ of 1.6 or more and less than 5.92, or

b.2. A ‘total processing performance’ of 1600 or more and a ‘performance density’ of 3.2 or more and less than 5.92.

Note 2 to 3A090.a and 3A090.b: 3A090.a and 3A090.b do not apply to items that are not designed or marketed for use in datacenters and do not have a ‘total processing performance’ of 4800 or more. For 3A090.a and 3A090.b items that are not designed or marketed for use in datacenters and that have a ‘total processing performance’ of 4800 or more, see license exceptions NAC and ACA.

Note 3 to 3A090.a and 3A090.b: Integrated circuits specified by 3A090 include graphical processing units (GPUs), tensor processing units (TPUs), neural processors, in-memory processors, vision processors, text processors, co-processors/accelerators, adaptive processors, field-programmable logic devices (FPLDs), and application-specific integrated circuits (ASICs). Examples of integrated circuits are in the Note to 3A001.a.

Note 4 to 3A090.a and 3A090.b: For integrated circuits that are excluded from

ECCN 3A090 under Note 2 or 3 to 3A090, those ICs are also not applicable for classifications made under ECCNs 3A001.z, 4A003.z, 4A004.z, 4A005.z, 4A090, 5A002.z, 5A004.z, 5A992.z, 5D002.z, or 5D992.z because those other CCL classifications are based on the incorporation of an integrated circuit that meets the control parameters under ECCN 3A090 or otherwise meets or exceeds the control parameters or ECCNs 3A090 or 4A090. The performance parameters under ECCN 3A090.c are not used for determining whether an item is classified in a .z ECCN. See the Related Controls paragraphs of ECCNs 3A001.z, 4A003.z, 4A004.z, 4A005.z, 4A090, 5A002.z, 5A004.z, 5A992.z, 5D002.z, or 5D992.z.

Technical Note 2 to 3A090.a and 3A090.b: 1. ‘Total processing performance’ (‘TPP’) is $2 \times \text{MacTOPS} \times \text{‘bit length of the operation’}$, aggregated over all processing units on the integrated circuit.

a. For purposes of 3A090, ‘MacTOPS’ is the theoretical peak number of Tera (10^{12}) operations per second for multiply-accumulate computation ($D = A \times B + C$).

b. The 2 in the ‘TPP’ formula is based on industry convention of counting one multiply-accumulate computation, $D = A \times B + C$, as 2 operations for purpose of datasheets. Therefore, $2 \times \text{MacTOPS}$ may correspond to the reported TOPS or FLOPS on a datasheet.

c. For purposes of 3A090, ‘bit length of the operation’ for a multiply-accumulate computation is the largest bit-length of the inputs to the multiply operation.

d. Aggregate the TPPs for each processing unit on the integrated circuit to arrive at a total. ‘TPP’ = $\text{TPP}_1 + \text{TPP}_2 + \dots + \text{TPP}_n$ (where n is the number or processing units on the integrated circuit).

2. The rate of ‘MacTOPS’ is to be calculated at its maximum value theoretically possible. The rate of ‘MacTOPS’ is assumed to be the highest value the manufacturer claims in annual or brochure for the integrated circuit. For example, the ‘TPP’ threshold of 4800 can be met with 600 tera integer operations (or 2×300 ‘MacTOPS’) at 8 bits or 300 tera FLOPS (or 2×150 ‘MacTOPS’) at 16 bits. If the integrated circuit is designed for MAC computation with multiple bit lengths that achieve different ‘TPP’ values, the highest ‘TPP’ value should be evaluated against parameters in 3A090.

3. For integrated circuits specified by 3A090 that provide processing of both sparse and dense matrices, the ‘TPP’ values are the values for processing of dense matrices (e.g., without sparsity).

4. ‘Performance density’ is ‘TPP’ divided by ‘applicable die area’. For purposes of 3A090, ‘applicable die area’ is measured in millimeters squared and includes all die area of logic dies manufactured with a process node that uses a non-planar transistor architecture.

c. High bandwidth memory (HBM) having a ‘memory bandwidth density’ greater than 2 gigabytes per second per square millimeter.

Technical Note 1 to 3A090.c: ‘Memory bandwidth density’ is the memory bandwidth measured in gigabytes per second divided by the area of the package or stack measured in

square millimeters. In the case where a stack is contained in a package, use the memory bandwidth of the packaged device and the area of the package. High bandwidth memory (HBM) includes dynamic random access memory integrated circuits, regardless of whether they conform to the JEDEC standards for high bandwidth memory (HBM), provided they have a ‘memory bandwidth density’ greater than 2 gigabytes per second per square millimeter. This control does not cover co-packaged integrated circuits with both HBM and logic integrated circuit where the dominant function of the co-packaged integrated circuit is processing. It does include HBM permanently affixed to a logic integrated circuit designed as a control interface and incorporating a physical layer (PHY) function.

* * * * *

3B001 Equipment for the manufacturing of semiconductor devices, materials, or related equipment, as follows (see List of Items Controlled) and “specially designed” “components” and “accessories” therefor.

License Requirements

Reason for Control: NS, RS, AT

Control(s)	Country chart (see Supp. No. 1 to part 738)
NS applies to 3B001.c.1.a, 3B001.c.1.c, and 3B001.q.	Worldwide control. See § 742.4(a)(5) and (b)(10) of the EAR.
RS applies to 3B001.c.1.a, 3B001.c.1.c, and 3B001.q.	Worldwide control. See § 742.6(a)(10) and (b)(11) of the EAR.
NS applies to 3B001.a.1 to a.3, b, e, f.2 to f.4, g to j.	NS Column 2.
NS applies to 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.4(a)(4) of the EAR.
RS applies to 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(6) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: \$500, except semiconductor manufacturing equipment specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r.

GBS: Yes, except a.3 (molecular beam epitaxial growth equipment using gas sources), c.1.a (Equipment designed or modified for isotropic dry etching), c.1.c (Equipment designed or modified for anisotropic dry etching), .e (automatic loading multi-chamber central wafer handling systems *only* if connected to equipment controlled by 3B001.a.3, or .f), .f (lithography equipment) and .q (“EUV” masks and reticles designed for integrated circuits, not specified by 3B001.g, and

having a mask “substrate blank” specified by 3B001.j).

IEC: Yes, for 3B001.c.1.a, c.1.c, and .j, see § 740.2(a)(22) and § 740.24 of the EAR.

Special Conditions for STA

STA: License Exception STA may not be used to ship 3B001.c.1.a, c.1.c, and .j to any of the destinations listed in Country Group A:5 or A:6 (See supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 3B903 and 3B991. See ECCNs 3D001, 3D992, 3E001, and 3E992 for related “software” and “technology” controls.

Related Definitions: N/A

Items:

a. Equipment designed for epitaxial growth as follows:

a.1. Equipment designed or modified to produce a layer of any material other than silicon with a thickness uniform to less than $\pm 2.5\%$ across a distance of 75 mm or more;

Note: 3B001.a.1 includes atomic layer epitaxy (ALE) equipment.

a.2. Metal Organic Chemical Vapor Deposition (MOCVD) reactors designed for compound semiconductor epitaxial growth of material having two or more of the following elements: aluminum, gallium, indium, arsenic, phosphorus, antimony, oxygen, or nitrogen;

a.3. Molecular beam epitaxial growth equipment using gas or solid sources;

a.4. Equipment designed for epitaxial growth of silicon (Si) or silicon germanium (SiGe), and having all of the following:

a.4.a. At least one preclean chamber designed to provide a surface preparation means to clean the surface of the wafer; and

a.4.b. An epitaxial deposition chamber designed to operate at a temperature equal to or below 958 K (685 °C).

b. Semiconductor wafer fabrication equipment designed for ion implantation and having any of the following:

b.1. [Reserved]

b.2. Being designed and optimized to operate at a beam energy of 20 keV or more and a beam current of 10 mA or more for hydrogen, deuterium, or helium implant;

b.3. Direct write capability;

b.4. A beam energy of 65 keV or more and a beam current of 45 mA or more for high energy oxygen implant into a heated semiconductor material “substrate”; or

b.5. Being designed and optimized to operate at beam energy of 20 keV or more and a beam current of 10 mA or more for silicon implant into a semiconductor material “substrate” heated to 600 °C or greater;

c. Etch equipment.

c.1. Equipment designed for dry etching as follows:

c.1.a. Equipment designed or modified for isotropic dry etching, having a largest ‘silicon germanium-to-silicon (SiGe:Si) etch selectivity’ of greater than or equal to 100:1; or

c.1.b. [Reserved]

c.1.c. Equipment designed or modified for anisotropic dry etching, having all of the following:

c.1.c.1. Radio Frequency (RF) power source(s) with at least one pulsed RF output;

c.1.c.2. One or more fast gas switching valve(s) with switching time less than 300 milliseconds; and

c.1.c.3. Electrostatic chuck with twenty or more individually controllable variable temperature elements;

c.2. Equipment designed for wet chemical processing and having a largest ‘silicon germanium-to-silicon (SiGe:Si) etch selectivity’ of greater than or equal to 100:1;

c.3. Equipment designed for anisotropic dry etching having all of the following:

c.3.a Two or more RF independent sources;

c.3.b Two or more independent gas sources;

c.3.c ‘Process uniformity tuning’ for wafer thickness variation compensation; and

c.3.d Through Silicon Via (TSV) reveal Endpoint Detection (EPD);

c.4. Equipment designed for Through Silicon Via (TSV) etch having all of the following:

c.4.a. Silicon etch rate greater than 7 microns per minute;

c.4.b. Within wafer (WIW) etch depth non-uniformity of less than or equal to 2 percent; and

c.4.c. A Through Silicon Via (TSV) aspect ratio greater than or equal to 10:1.

Note 1: 3B001.c includes etching by ‘radicals’, ions, sequential reactions, or non-sequential reaction.

Note 2: 3B001.c.1.c includes etching using RF pulse excited plasma, pulsed duty cycle excited plasma, pulsed voltage on electrodes modified plasma, cyclic injection and purging of gases combined with a plasma, plasma atomic layer etching, or plasma quasi-atomic layer etching.

Technical Notes:

1. For the purposes of 3B001.c, ‘silicon germanium-to-silicon (SiGe:Si) etch selectivity’ is measured for a Ge concentration of greater than or equal to 30% ($\text{Si}_{0.70}\text{Ge}_{0.30}$).

2. For the purposes of 3B001.c Note 1 and 3B001.d.14, ‘radical’ is defined as an atom, molecule, or ion that has an unpaired electron in an open electron shell configuration.

3. For the purposes of 3B001.c.3, ‘process uniformity tuning’ is the process of compensating for incoming wafer thickness variations after grinding.

d. Semiconductor manufacturing deposition equipment, as follows:

d.1. Equipment designed for cobalt (Co) electroplating or cobalt electroless-plating deposition processes;

Note: 3B001.d.1 controls semiconductor wafer processing equipment.

d.2. Equipment designed for:

d.2.a. Chemical vapor deposition of cobalt (Co) fill metal; or

d.2.b. Selective bottom-up chemical vapor deposition of tungsten (W) fill metal;

d.3. Semiconductor manufacturing equipment designed to fabricate a metal contact by multistep processing within a single chamber by performing all of the following:

d.3.a. Deposition of a tungsten layer, using an organometallic compound, while maintaining the wafer substrate temperature greater than 100 °C and less than 500 °C; and

d.3.b. Surface treatment plasma process using hydrogen (H_2), hydrogen and nitrogen (H_2+N_2), or ammonia (NH_3).

d.4. Equipment or systems designed for multistep processing in multiple chambers or stations, as follows:

d.4.a. Equipment designed to fabricate a metal contact by performing all of the following processes:

d.4.a.1. Surface treatment plasma process using hydrogen (H_2), including hydrogen and nitrogen ($\text{H}_2 + \text{N}_2$) or ammonia (NH_3), while maintaining the wafer substrate at a temperature greater than 100 °C and less than 500 °C;

d.4.a.2. Surface treatment plasma process using oxygen (O_2) or ozone (O_3), while maintaining the wafer substrate at a temperature greater than 40 °C and less than 500 °C; and

d.4.a.3. Deposition of a tungsten (W) layer while maintaining the wafer substrate temperature greater than 100 °C and less than 500 °C;

d.4.b. Equipment designed to fabricate a metal contact by performing all of the following processes:

d.4.b.1. Surface treatment process using a remote plasma generator and an ion filter; and

d.4.b.2. Deposition of a cobalt (Co) layer selectively onto copper (Cu) using an organometallic compound;

Note: This control does not apply to equipment that is non-selective.

d.4.c. Equipment designed to fabricate a metal contact by performing all the following processes:

d.4.c.1. Deposition of a titanium nitride (TiN) or tungsten carbide (WC) layer, using an organometallic compound, while maintaining the wafer substrate at a temperature greater than 20 °C and less than 500 °C;

d.4.c.2. Deposition of a cobalt (Co) layer using a physical sputter deposition technique and having a process pressure greater than 133.3 mPa and less than 13.33 Pa, while maintaining the wafer substrate at a temperature below 500 °C; and

d.4.c.3. Deposition of a cobalt (Co) layer using an organometallic compound and having a process pressure greater than 133.3 Pa and less than 13.33 kPa, while maintaining the wafer substrate at a temperature greater than 20 °C and less than 500 °C;

d.4.d. Equipment designed to fabricate copper (Cu) interconnects by performing all of the following processes:

d.4.d.1. Deposition of a cobalt (Co) or ruthenium (Ru) layer using an organometallic compound and having a process pressure greater than 133.3 Pa and less than 13.33 kPa, while maintaining the wafer substrate at a temperature greater than 20 °C and less than 500 °C; and

d.4.d.2. Deposition of a copper layer using a physical vapor deposition technique and having a process pressure greater than 133.3 mPa and less than 13.33 Pa, while maintaining the wafer substrate at a temperature below 500 °C;

d.5. Equipment designed for plasma enhanced chemical vapor deposition of carbon hard masks more than 2 μm thick and with density of greater than 1.7g/cc;

d.6. Atomic Layer Deposition (ALD) equipment designed for area selective deposition of a barrier or liner using an organometallic compound;

Note: 3B001.d.6 includes equipment capable of area selective deposition of a barrier layer to enable fill metal contact to an underlying electrical conductor without a barrier layer at the fill metal via interface to an underlying electrical conductor.

d.7. Equipment designed for Atomic Layer Deposition (ALD) of tungsten (W) to fill an entire interconnect or in a channel less than 40 nm wide, while maintaining the wafer substrate at a temperature less than 500 °C.

d.8. Equipment designed for Atomic Layer Deposition (ALD) of 'work function metal' having all of the following:

d.8.a. More than one metal source of which one is designed for an aluminum (Al) precursor;

d.8.b. Precursor vessel designed and enabled to operate at a temperature greater than 30 °C; and

d.8.c. Designed for depositing a 'work function metal' having all of the following:

d.8.c.1. Deposition of titanium-aluminum carbide (TiAlC); and

d.8.c.2. Enabling a work function greater than 4.0 eV;

Technical Note: For the purposes of 3B001.d.8, 'work function metal' is a material that controls the threshold voltage of a transistor.

d.9. Spatial Atomic Layer Deposition (ALD) equipment having a wafer support platform that rotates around an axis having any of the following:

d.9.a. A spatial plasma enhanced atomic layer deposition mode of operation;

d.9.b. A plasma source; or

d.9.c. A plasma shield or means to confine the plasma to the plasma exposure process region;

d.10. Equipment designed for Atomic Layer Deposition (ALD) or Chemical Vapor Deposition (CVD) of plasma enhanced of low fluorine tungsten (FW) (fluorine (F) concentration less than 10^{19} atoms/cm³) films;

d.11. [Reserved]

d.12. Equipment designed for depositing a metal layer, and having any of the following:

d.12.a. Selective tungsten (W) growth without a barrier; or

d.12.b. Selective molybdenum (Mo) growth without a barrier;

d.13. Equipment designed for depositing a ruthenium layer (Ru) using an organometallic

compound, while maintaining the wafer substrate at a temperature greater than 20 °C and less than 500 °C;

d.14. Equipment designed for deposition assisted by remotely generated 'radicals', enabling the fabrication of a silicon (Si) and carbon (C) containing film, and having all of the following properties of the deposited film:

d.14.a. A dielectric constant (k) of less than 4.4;

d.14.b. In features with an aspect ratio greater than 5:1 with lateral openings of less than 35 nm; and

d.14.c. A feature-to-feature pitch of less than 45 nm;

d.15. Equipment designed for void free plasma enhanced deposition of a low-k dielectric layer in gaps between metal lines less than 25 nm and having an aspect ratio greater than or equal to 1:1 with a less than 3.3 dielectric constant;

d.16. [Reserved]

d.17. Equipment designed for plasma enhanced chemical vapor deposition (PECVD) or radical assisted chemical vapor deposition and UV curing in a single platform of a dielectric film, while maintaining a substrate temperature below 500 °C, having all of the following:

d.17.a. A thickness of more than 6 nm and less than 20 nm on metal features having less than 24 nm pitch and having an aspect ratio equal to or greater than 1:1.8; and

d.17.b. A dielectric constant less than 3.0;

d.18. Equipment designed or modified for Atomic Layer Deposition (ALD) of molybdenum (Mo), ruthenium (Ru), or combinations Mo or Ru, and having all of the following:

d.18.a. A metal precursor source designed or modified to operate at a temperature greater than 75 °C; and

d.18.b. A process chamber (module) using a reducing agent containing hydrogen (H) at a pressure greater than or equal to 30 Torr (4 kPa).

Note: For the purposes of paragraph d.18.a, the metal precursor source need not be integrated with the equipment. The metal precursor could be delivered by an on-tool source or from a sub-fab source.

d.19. Deposition equipment having direct-liquid injection of more than two metal precursors, designed or modified to deposit a conformal dielectric film with a dielectric constant (K) greater than 40 in features with aspect ratio greater than 200:1 in a single deposition chamber.

d.20. Physical vapor deposition equipment having electromagnets for ion flux guidance, and "specially designed" to deposit tungsten (W) metal into features having an aspect ratio of 3:1 or greater.

e. Automatic loading multi-chamber central wafer handling systems having all of the following:

e.1. Interfaces for wafer input and output, to which more than two functionally different 'semiconductor process tools' controlled by 3B001.a, .b., .c, and .d are designed to be connected; and

e.2. Designed to form an integrated system in a vacuum environment for 'sequential multiple wafer processing';

Note: 3B001.e does not control automatic robotic wafer handling systems "specially designed" for parallel wafer processing.

Technical Notes:

1. For the purposes of 3B001.e, 'semiconductor process tools' refers to modular tools that provide physical processes for semiconductor "production" that are functionally different, such as deposition, implant or thermal processing.

2. For the purposes of 3B001.e, 'sequential multiple wafer processing' means the capability to process each wafer in different 'semiconductor process tools', such as by transferring each wafer from one tool to a second tool and on to a third tool with the automatic loading multi-chamber central wafer handling systems.

f. Lithography commodities as follows:

f.1. Align and expose step and repeat (direct step on wafer) or step and scan (scanner) equipment for wafer processing using photo-optical or X-ray methods and having any of the following:

f.1.a. A light source wavelength shorter than 193 nm; or

f.1.b. A light source wavelength equal to or longer than 193 nm and having all of the following:

f.1.b.1. The capability to produce a pattern with a "Minimum Resolvable Feature size" (MRF) of 45 nm or less; and

f.1.b.2. A maximum 'dedicated chuck overlay' value of less than or equal to 1.50 nm;

Technical Notes: For the purposes of 3B001.f.1.b:

1. The 'Minimum Resolvable Feature size' (MRF) (i.e., resolution) is calculated by the following formula:

$$(an\ exposure\ light\ source\ wavelength\ in\ nm) \times (K\ factor)$$

MRF

maximum numerical aperture

where, for the purposes of 3B001.f.1.b, the K factor = 0.25 ‘MRF’ is also known as resolution.

2. ‘Dedicated chuck overlay’ is the alignment accuracy of a new pattern to an existing pattern printed on a wafer by the same lithographic system. ‘Dedicated chuck overlay’ is also known as single machine overlay.

f.2. Imprint lithography equipment capable of production features of 45 nm or less;

Note: 3B001.f.2 includes:

—Micro contact printing tools

—Hot embossing tools

—Nano-imprint lithography tools

—Step and flash imprint lithography (S-FIL) tools

f.3. Equipment “specially designed” for mask making having all of the following:

f.3.a. A deflected focused electron beam, ion beam or “laser” beam; and

f.3.b. Having any of the following:

f.3.b.1. A Full-Width Half-Maximum (FWHM) spot size smaller than 65 nm and an image placement less than 17 nm (mean + 3 sigma); or

f.3.b.2. [Reserved]

f.3.b.3. A second-layer overlay error of less than 23 nm (mean + 3 sigma) on the mask;

f.4. Equipment designed for device processing using direct writing methods, having all of the following:

f.4.a. A deflected focused electron beam; and

f.4.b. Having any of the following:

f.4.b.1. A minimum beam size equal to or smaller than 15 nm; or

f.4.b.2. An overlay error less than 27 nm (mean + 3 sigma);

f.5. Imprint lithography equipment having an overlay accuracy less (better) than 1.5;

f.6. Commodities not specified by 3B001.f.1, designed or modified to perform all of the following in or with deep-ultraviolet immersion photolithography equipment:

f.6.a. Decrease the minimum resolvable feature specified by 3B001.f.1.b; and

f.6.b. Decrease the maximum ‘dedicated chuck overlay’ of a deep-ultraviolet immersion lithography tool below or equal to 1.5 nm.

g. Masks and reticles, designed for integrated circuits controlled by 3A001;

h. Multi-layer masks with a phase shift layer not specified by 3B001.g and designed to be used by lithography equipment having a light source wavelength less than 245 nm;

Note: 3B001.h does not control multi-layer masks with a phase shift layer designed for the fabrication of memory devices not controlled by 3A001.

N.B.: For masks and reticles, “specially designed” for optical sensors, see 6B002.

i. Imprint lithography templates designed for integrated circuits by 3A001;

j. Mask “substrate blanks” with multilayer reflector structure consisting of molybdenum and silicon, and having all of the following:

j.1. “Specially designed” for “Extreme Ultraviolet” (“EUV”) lithography; and

j.2. Compliant with SEMI Standard P37;

k. Equipment designed for ion beam deposition or physical vapor deposition of a multi-layer reflector for “EUV” masks;

l. “EUV” pellicles;

m. Equipment for manufacturing “EUV” pellicles;

n. Equipment designed for coating, depositing, baking, or developing photoresist formulated for “EUV” lithography;

o. [Reserved]

p. Removal and cleaning equipment as follows:

p.1. [Reserved]

p.2. Single wafer wet cleaning equipment with surface modification drying; or

p.3. [Reserved]

p.4. Equipment designed for single wafer cleaning using supercritical CO₂ or sublimation drying;

q. “EUV” masks and “EUV” reticles, designed for integrated circuits, not specified by 3B001.g, and having a mask “substrate blank” specified by 3B001.j; or

Technical Notes: For the purposes of 3B001.q, masks or reticles with a mounted pellicle are considered masks and reticles.

r. Equipment designed for EUV ‘pattern shaping.’

Technical Note: For the purposes of 3B001.r, ‘pattern shaping’ is a deposition or removal process used to improve overall patterning by reshaping or trimming patterns produced using EUV lithography with non-vertical directed particles including ions, neutral particles, clusters, radicals, or light.

* * * * *

3B993 Specified semiconductor manufacturing equipment as follows (see list of items controls), and “specially designed” “components” and “accessories” therefor.

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) See ECCNs 3D993 and 3E993 for associated “software” and “technology” controls. (2) For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and § 744.23(a)(4) of the EAR.

Related Definitions: N/A

Items:

a. [Reserved]

b. Semiconductor wafer fabrication equipment for 300 mm wafers designed for ion implantation and having any of the following:

b.1. Equipment designed for plasma doping, having all of the following:

b.1.a. One or more Radio Frequency (RF) power source(s);

b.1.b. One or more pulsed DC Power Source; and

b.1.c. One or more n-type or p-type dopant implants.

b.2 [Reserved]

c. Etch equipment as follows:

c.1. Equipment designed or modified for anisotropic etching of dielectric materials and enabling the fabrication of high aspect ratio features with aspect ratio greater than 30:1 and a lateral dimension on the top surface of less than 100 nm, and having all of the following:

c.1.a. Radio Frequency (RF) power source(s) with at least one pulsed RF output; and

c.1.b. One or more fast gas switching valve(s) with switching time less than 300 milliseconds.

Note: 3B993.c.1 includes etching by ‘radicals’, ions, sequential reactions, or non-sequential reaction.

Technical Note: For the purposes of the Note to 3B993.c.1, ‘radical’ is defined as an atom, molecule, or ion that has an unpaired electron in an open electron shell configuration.

c.2. Equipment, not specified by 3B993.c.1, designed for anisotropic etching of dielectric material and enabling the fabrication of high aspect ratio features having all of the following:

c.2.a. An aspect ratio greater than 30:1; and

c.2.b. A lateral dimension on the top surface of less than 40 nm.

Note: 3B993.c.2 does not apply to equipment designed for wafer diameters less than 300 mm.

c.3. Equipment, not specified by 3B001.c.1.c, designed or modified for anisotropic dry etching, having all of the following:

c.3.a. Radio Frequency (RF) power source(s) with at least one pulsed RF output;

c.3.b. One or more fast gas switching valve(s) with switching time less than 500 milliseconds; and

c.3.c. Electrostatic chuck with greater than or equal to 10 individually controllable variable temperature elements.

d. Semiconductor manufacturing deposition equipment as follows:

d.1. Equipment designed, not specified by 3B001.d.14, for deposition assisted by remotely generated ‘radicals’, enabling the fabrication of a silicon (Si) and carbon (C) containing film, and having all of the following properties of the deposited film:

d.1.a. A dielectric constant (k) of less than 5.3;

d.1.b. In features with an aspect ratio greater than 5:1 with lateral openings of less than 70 nm; and

d.1.c. A feature-to-feature pitch of less than 100 nm.

d.2. Equipment designed for deposition of a film, containing silicon and carbon, and having a dielectric constant (k) of less than 5.3, into lateral openings having widths of less than 70 nm and aspect ratios greater than 5:1 (depth: width) and a feature-to-feature pitch of less than 100 nm, while maintaining the wafer substrate at a temperature greater than 400 °C and less than 650 °C, and having all of the following:

d.2.a. Boat designed to hold multiple vertically stacked wafers;

d.2.b. Two or more vertical injectors; and

d.2.c. A silicon source and propene are introduced to a different injector than a nitrogen source or an oxygen source.

d.3. Equipment designed for chemical vapor deposition of a carbon material layer with a density more than 1.6 g/cm³.

d.4. Deposition equipment, not specified by 3B001.d.19, having direct-liquid injection of more than two metal precursors, designed or modified to deposit a conformal dielectric film with a dielectric constant (K) greater than 35 in features with aspect ratio greater than 50:1 in a single deposition chamber.

e. [Reserved]

f. Lithography commodities as follows:

f.1. Align and expose step and repeat (direct step on wafer) or step and scan (scanner) lithography equipment for wafer processing using photo-optical or X-ray methods and having all of the following:

f.1.a. [Reserved]

f.1.b. A light source wavelength equal to or longer than 193 nm and having all of the following:

f.1.b.1 The capability to produce a pattern with a 'Minimum Resolvable Feature size' ('MRF') of 45 nm or less; and

f.1.b.2. A maximum 'dedicated chuck overlay' value greater than 1.50 nm and less than or equal to 2.40 nm.

Technical Notes for paragraph 3B993.f.1:

1. The 'Minimum Resolvable Feature size' ('MRF') is calculated by the following formula:

$(\text{an exposure light source wavelength in nm}) \times (K \text{ factor})$

$'MRF' = \frac{\text{maximum numerical aperture}}{\text{maximum numerical aperture}}$

maximum numerical aperture

where, for the purposes of 3B993.f.1, the K factor = 0.25.

'MRF' is also known as resolution.

2. 'Dedicated chuck overlay' is the alignment accuracy of a new pattern to an existing pattern printed on a wafer by the same lithographic system. 'Dedicated chuck overlay' is also known as single machine overlay.

f.2. Imprint lithography equipment having an overlay accuracy above 1.5 nm and less (better) than or equal to 4.0 nm.

f.3. Commodities designed or modified to increase the number of wafers processed per hour, averaged over any time interval, by greater than 1%, of equipment specified in 3B001.f.1 or 3B993.f.1.

f.4. Commodities not specified by 3B993.f.1 designed or modified to perform all of the following in or with deep-ultraviolet immersion photolithography equipment:

f.4.a. Decrease the minimum resolvable feature specified by 3B993.f.1.b.1; and

f.4.b. Decrease the maximum 'dedicated chuck overlay' of deep-ultraviolet immersion lithography equipment above 1.5 nm and below or equal to 2.4 nm.

g. through n. [Reserved]

o. Annealing equipment designed for 300 mm wafers as follows:

o.1 Annealing equipment, operating in a vacuum (equal to or less than 0.01 Pa) environment, performing any of the following:

o.1.a Reflow of copper (Cu) to minimize or eliminate voids or seams in copper (Cu) metal interconnects; or

o.1.b Reflow of cobalt (Co) or tungsten (W) fill metal to minimize or eliminate voids or seams;

o.2. Equipment designed to heat a semiconductor wafer to a temperature greater than 1000 °C (1832 °F) for a 'duration' less than 2 ms.

Technical Note: For the purposes of 3B993.o.2, 'duration' is the period above stated temperature.

p. Removal and cleaning equipment as follows:

p.1. Equipment designed for removing polymeric residue and copper oxide (CuO) film and enabling deposition of copper (Cu) metal in a vacuum (equal to or less than 0.01 Pa) environment.

p.2. [Reserved]

p.3. Equipment designed for dry surface oxide removal preclean or dry surface decontamination.

Note to 3B993.p.1 and p.3: These controls do not apply to deposition equipment.

q. Inspection and metrology equipment as follows:

q.1. Patterned wafer defect metrology or patterned wafer defect inspection equipment, designed or modified to accept wafers greater than or equal to 300 mm in diameter, and having all of the following:

q.1.a. Designed or modified to detect defects having a size equal to or less than 21 nm; and

q.1.b. Having any of the following:

q.1.b.1. A light source with an optical wavelength less than 400 nm;

q.1.b.2. An electron-beam source with a resolution less (better) than or equal to 1.65 nm;

q.1.b.3. A Cold Field Emission (CFE) electron-beam source; or

q.1.b.4. Two or more electron-beam sources.

q.2. Metrology equipment as follows:

q.2.a. Stand-alone equipment designed to measure wafer shape parameters prior to lithography exposure and utilize measurements to improve overlay or focus of a deep ultraviolet (DUV) lithography system having an immersion lens having a numerical aperture more than 1.3 or an Extreme Ultraviolet lithography (EUV) system; or

q.2.b. Metrology equipment designed to measure focus or overlay after resist development or after etch on product wafers using image-based overlay or diffraction-based measurements techniques, with an overlay measurement accuracy less (better) than or equal to 0.5 nm having any of the following:

q.2.b.1 designed for integration to a 'track'; or

q.2.b.2 'fast wavelength switching functionality';

Technical Notes:

1. For the purposes of 3B993.q.2, a 'track' is equipment designed for coating and developing photoresist formulated for lithography.

2. For the purposes of 3B993.q.2, 'fast wavelength switching functionality' is

defined as having the ability to change the measurement wavelength and acquire a measurement in less than 25 ms.

* * * * *

3B994 Semiconductor manufacturing equipment that enables "advanced-node integrated circuit" production, as follows (see list of items controls), and "specially designed" "components" and "accessories" therefor.

License Requirements

Reason for Control: RS, AT

Control(s)	Country chart (see Supp. No. 1 to part 738)
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit commodities specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (See supplement no.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: (1) See ECCNs 3D994 and 3E994 for associated software and technology controls. (2) For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and § 744.23(a)(4) of the EAR.

Related Definitions: N/A

Items:

Note for 3B994: Equipment specified in this ECCN 3B994 are limited to equipment designed for volume production, such as equipment designed to accept a SEMI standard wafer carrier such as a 200 mm or larger Front Opening Unified Pod or be connected to a multi-chamber wafer handling system.

a. [Reserved]

b. Semiconductor wafer fabrication equipment designed for ion implantation of 300mm wafers as follows:

- b.1. [Reserved]
- b.2. Ion implantation equipment as follows:
 - b.2.a. Having all of the following:
 - b.2.a.1. Beam current greater than 1uA and less than 5mA; *and*
 - b.2.a.2. Beam energy greater than 5 keV and less than 300 keV; *or*
 - b.2.b. Having all of the following:
 - b.2.b.1. Beam current greater than 5 mA; *and*
 - b.2.b.2. Beam energy less than 5 keV; *or*
 - b.2.c. Having angular accuracy equal to or less (better) than 0.1 degrees.
- c. through p. [Reserved]
- q. Inspection and metrology equipment as follows:
 - q.1. and q.2. [Reserved]
 - q.3. Optical thin film metrology equipment or optical critical dimension metrology equipment designed for 300mm wafers and containing software designed for measuring non-planar transistors.

* * * * *

3D992 “Software” for the “development” or “production” of commodities specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, or 3B002.c and “software” as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
NS applies to the entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.4(a)(4) of the EAR.
RS applies to the entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(6)(i) of the EAR.
NS applies to “software” for equipment controlled by 3B001.c.1.a or c.1.c.	Worldwide control. See § 742.4(a)(5) and (b)(10) of the EAR.
RS applies to “software” for equipment controlled by 3B001.c.1.a or c.1.c.	Worldwide control. See § 742.6(a)(10) and (b)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

IEC: Yes, for “software” for equipment controlled by 3B001.c.1.a and 3B001.c.1.c, see § 740.2(a)(22) and § 740.24 of the EAR.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “software” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (See supplement no.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and (a)(3) and § 744.23(a)(4)(iii) of the EAR.

Related Definitions: N/A

Items:

- a. “Software” “specially designed” for the “development” or “production,” of commodities specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r, or 3B002.c.
- b. ‘Electronic Computer-Aided Design’ (‘ECAD’) “software” designed for the integration of multiple dies into a ‘multi-chip’ integrated circuit, and having all of the following:
 - b.1. Floor planning; *and*
 - b.2. Co-design or co-simulation of die and package.

Technical Note: *For the purposes of 3D992.b, ‘multi-chip’ includes multi-die and multi-chiplet.*

- c. “Software” not specified by 3D992.a designed or modified to perform all of the following in or with deep-ultraviolet immersion photolithography equipment:
 - c.1. Decrease the minimum resolvable feature specified by 3B001.f.1.b; *and*
 - c.2. Decrease the maximum ‘dedicated chuck overlay’ of deep-ultraviolet immersion lithography equipment below or equal to 1.5 nm.

3D993 “Software” for the “development” or “production” of commodities specified in 3B993 and “software” as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “software” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (see supplement no.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and (a)(3) and § 744.23(a)(4)(iii) of the EAR.

Related Definitions: N/A

Items:

- a. “Software” “specially designed” for the “development” or “production” of commodities specified in 3B993.
- b. ‘Electronic Computer-Aided Design’ (‘ECAD’) “software” designed or modified for the “development” or “production” of integrated circuits using multipatterning.
- c. ‘Computational lithography’ “software” designed or modified for the “development” or “production” of patterns on DUV lithography masks or reticles.

Technical Note: *For the purposes of 3D993, ‘computational lithography’ is the use of computer modelling to predict, correct, optimize and verify imaging performance of the lithography process over a range of patterns, processes, and system conditions.*

- d. “Software” designed or modified to increase the number of wafers processed per hour, averaged over any time interval, by greater than 1%, of equipment specified in 3B001.f.1 or 3B993.f.1.

e. “Software” not specified by 3D993.a designed or modified to perform all of the following in or with deep-ultraviolet immersion photolithography equipment:

- e.1. Decrease the minimum resolvable feature specified by 3B993.f.1.b.1; *and*
- e.2. Decrease the maximum ‘dedicated chuck overlay’ of deep-ultraviolet immersion lithography equipment above 1.5 nm and below or equal to 2.4 nm.

3D994 “Software” “specially designed” for the “development” or “production” of commodities specified in 3B994 and “software” as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “software” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (see supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and (a)(3) and § 744.23(a)(4)(iii) of the EAR.

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

3E992 “Technology” for the “production” or “development” of commodities specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r; and 3B002.c; and “technology” as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
NS applies to the entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.4(a)(4) of the EAR.
RS applies to the entire entry.	To or within Macau or a destination specified in Country Group D:5 of supplement no. 1 to part 740 of the EAR. See § 742.6(a)(6)(i) of the EAR.
NS applies to “software” for equipment controlled by 3B001.c.1.a or c.1.c.	Worldwide control. See § 742.4(a)(5) and (b)(10) of the EAR.
RS applies to “software” for equipment controlled by 3B001.c.1.a or c.1.c.	Worldwide control. See § 742.6(a)(10) and (b)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

IEC: Yes, for “technology” for equipment controlled by 3B001.c.1.a, and 3B001.c.1.c, see § 740.2(a)(22) and § 740.24 of the EAR.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “technology” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (see supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items:

a. “Technology” “specially designed” for the “development” or “production” of commodities specified in 3B001.a.4, c, d, f.1, f.5, f.6, k to n, p.2, p.4, r; or 3B002.c.

b. “Technology” not specified by 3E992.a designed or modified to perform all of the following in or with deep-ultraviolet immersion photolithography equipment:

b.1. Decrease the minimum resolvable feature specified by 3B001.f.1.b; and
b.2. Decrease the maximum ‘dedicated chuck overlay’ of deep-ultraviolet immersion lithography equipment below or equal to 1.5 nm.

3E993 “Technology” for the “development” or “production” of commodities specified in 3B993; and “technology” as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “technology” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (see supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and (a)(3) and § 744.23(a)(4)(iii) of the EAR.

Related Definitions: N/A

Items:

a. “Technology” “specially designed” for the “development” or “production” of commodities specified by 3B993.

b. “Technology” designed or modified to increase the number of wafers processed per hour, averaged over any time interval, by greater than 1%, of equipment specified in 3B001.f.1 or 3B993.f.1.

c. “Technology” not specified by 3E993.a designed or modified to perform all of the

following in or with deep-ultraviolet immersion photolithography equipment:

c.1. Decrease the minimum resolvable feature specified by 3B993.f.1.b.1; and
c.2. Decrease the maximum ‘dedicated chuck overlay’ of a deep-ultraviolet immersion lithography equipment above 1.5 nm and below or equal to 2.4 nm.

3E994 “Technology” “specially designed” for the “development” or “production” of commodities specified in 3B994 and “technology” as follows (see List of Items Controlled).

License Requirements

Reason for Control: RS, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
RS applies to entire entry.	See § 742.6(a)(11) of the EAR.
AT applies to entire entry	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit “technology” specified in this ECCN to any of the destinations listed in Country Group A:5 or A:6 (see supplement no. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: For additional controls that apply to this ECCN, see also § 744.11(a)(2)(v) and (a)(3) and § 744.23(a)(4)(iii) of the EAR.

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

Matthew S. Borman,

Principal Deputy Assistant Secretary for Strategic Trade and Technology Security.

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Part IX

Department of Veterans Affairs

38 CFR Part 21

Post-9/11 Improvements, Fry Scholarship, and Interval Payments
Amendments; Final Rule

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900-AQ88

Post-9/11 Improvements, Fry Scholarship, and Interval Payments Amendments

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations that govern VA's administration of educational assistance programs to implement the provisions of the Post-9/11 Veterans Educational Assistance Improvements Act of 2010, which modified the manner in which payments of educational assistance are determined and expanded the types of programs students may pursue under the Post-9/11 GI Bill; section 1002 of the Supplemental Appropriations Act, 2009, which authorized the "Marine Gunnery Sergeant John David Fry Scholarship;" and a select number of provisions of the Harry W. Colmery Veterans Educational Assistance Act of 2017.

DATES: This rule is effective March 17, 2025.

FOR FURTHER INFORMATION CONTACT:

Thomas Alphonso, Assistant Director, Policy and Procedures, Education Service, Department of Veterans Affairs, Veterans Benefits Administration (22), 810 Vermont Avenue NW, Washington, DC 20420. Telephone: (202) 461-9800. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: Under chapter 5 of title 38, United States Code (U.S.C.), the Secretary has the authority to prescribe rules and regulations which are appropriate and necessary to carry out the laws administered by VA. Accordingly, on May 24, 2023, VA published a proposed rule at 88 FR 33672 to amend its regulations to implement section 1002 of the Supplemental Appropriations Act, 2009 (Pub. L. 111-32), which amended 38 U.S.C. chapter 33 to allow surviving children of active duty Servicemembers who died on or after September 11, 2001, to receive educational assistance under the Post-9/11 GI Bill (chapter 33); the Post-9/11 Veterans Educational Assistance Improvements Act of 2010 (Pub. L. 111-377), which amended the Post-9/11 GI Bill; six sections of the Harry W. Colmery Veterans Educational Assistance Act of 2017, or Forever GI Bill (Pub. L. 115-48); and a policy change to address how VA manages

overpayments and discontinuance dates. VA provided a 60-day comment period, which ended on July 24, 2023, and received six comments on the proposed amendments. The comments are addressed below.

Eligibility for Post-9/11 GI Bill Benefits and Time Limit for Transfer of Entitlement

One commenter expressed the belief that all veterans—no matter the length of their service—should be entitled to Post-9/11 GI Bill benefits if they were not discharged early for disciplinary reasons. The commenter stated that individuals who served honorably but with less time in service than others are not afforded the same entitlement. The commenter also indicated that the rulemaking should expand the period individuals can transfer entitlement to their children.

Requirements for payment of benefits are explicitly set by statute in 38 U.S.C. 3311 and 3313. Payment of educational assistance is based on the length of an individual's service as prescribed in sections 3311(b) and 3313(c). Generally, the greater the length of service, the greater the payment. Additionally, the time period for transferring benefits is explicitly set by statute in 38 U.S.C. 3319. Under section 3319(f) an individual may transfer entitlement only while serving in the Armed Forces. VA does not have authority to change statutory requirements through regulatory action.

Accordingly, VA makes no changes to the rule based on these comments.

Expansion of Eligibility for Post-9/11 GI Bill Benefits for Individuals

Two commenters recommended that the final rulemaking include revisions to allow more individuals the opportunity to obtain Post-9/11 GI Bill educational assistance benefits. One commenter suggested that VA should make the process to obtain these benefits easier and another suggested that individuals should be eligible for Post-9/11 GI Bill benefits regardless of when they attend school. This rulemaking implements the Post-9/11 Veterans Educational Assistance Improvements Act of 2010, which among other things, greatly expanded the types of programs students may pursue under the Post-9/11 GI Bill and eligibility for these programs. The provisions also refine and enhance VA's administration of Post-9/11 GI Bill educational assistance, improving the efficiency to deliver these benefits to claimants. Implementation of these provisions, as reflected in this

rulemaking, will make provision of benefits easier and more efficient.

Furthermore, under current law, individuals who were discharged on or after January 1, 2013, may use Post 9/11 GI Bill benefits to attend school any time after discharge. Individuals who were discharged prior to that date have 15 years from the date of discharge to use their benefits. 38 U.S.C. 3321(a). We have been implementing this law and will incorporate it into our regulations in a future rulemaking.

As such, VA makes no changes to this rule based on these comments.

Enhancement of the Definition of "In-Residence Course" and of an Attendance and Participation Requirement

One commenter suggested strengthening the definition of what constitutes an "on-site course," stating that educational institutions offering "hybrid" programs with only one residential class are actually distance-learning courses and that individuals enrolled in these hybrid programs should not be eligible for the payment of a full housing allowance when the majority of classes would be online and not "on-site." (The commenter used the term "on-site course" to refer to what VA's regulations define as an "in-residence course.")

According to 38 U.S.C. 3313(c)(1)(B)(i)(I), an individual who "pursues a [degree] program of education on more than a half-time basis" is entitled to a monthly housing allowance based on "the campus of the institution of where the individual physically participates in a majority of classes." However, 38 U.S.C. 3313(c)(1)(B)(iii) expressly authorizes payment of a monthly housing allowance at half the national average of the monthly amount of the basic allowance for housing payable under 37 U.S.C. 403 for a member with dependents in pay grade E-5 (which we will refer to as "the national average") for "an individual pursuing a [degree] program of education *solely* through distance learning on more than a half-time basis." (Emphasis added.) Similarly, for an individual pursuing a non-degree program of education on a more than half-time basis, 38 U.S.C. 3313(g)(3)(A)(ii)(I)(aa) provides a monthly housing allowance based on "the campus of the institution of where the individual physically participates in a majority of classes." But 38 U.S.C. 3313(g)(3)(A)(ii)(I)(bb) authorizes payment of a monthly housing allowance at half that amount for "an individual pursuing a [non-degree] program of education through distance

learning” on more than a half-time basis without specifically requiring that pursuit be “*solely* through distance learning.” (Emphasis added.)

VA faces several challenges in interpreting these statutory provisions. First, aspects of the statutory language at 38 U.S.C. 3313(g)(3)(A)(ii)(I)(bb) are unworkable as literally drafted. That provision calculates the monthly housing allowance for individuals pursuing non-degree distance-learning programs by reference to 38 U.S.C. 3313(g)(3)(A)(ii)(I)(aa), which is based on a locality (“campus of the institution of where the individual physically participates in a majority of classes”). However, it would be impossible to apply 38 U.S.C. 3313(g)(3)(A)(ii)(I)(bb) according to its literal terms because, for students in distance learning programs, there is no campus where the individual “physically participates in a majority of classes.”

Second, although 38 U.S.C. 3313(c)(1)(B)(iii) refers to “an individual pursuing a program of education *solely* through distance learning” (emphasis added) and 38 U.S.C. 3313(g)(3)(A)(ii)(I)(bb) refers to “an individual pursuing a program of education through distance learning” (omitting the word “solely”), VA does not believe that Congress intended to attribute any significance to this omission because a strictly literal reading would have absurd and inequitable results. With respect to the specific scenario raised by the commenter, VA is concerned that it would be absurd and inequitable to pay the full housing allowance for an individual who is taking one on-site course as part of a degree program (and thus not “solely” through distance learning) but to pay only half the housing allowance for an individual who is taking one on-site course as part of a non-degree program (and thus also not “solely” through distance learning). To avoid this absurd and inequitable result, we have interpreted the language in section 3313(g)(3)(A)(ii)(I)(bb) as referring to an individual pursuing a non-degree program *solely* through distance learning, which is still consistent with the plain language of the statute, which refers to “an individual pursuing a [non-degree] program of education through distance learning.”

Taking into account both of these interpretive challenges, the VA has concluded that the best reading of the statute is reflected in § 21.9641(c)(4), which provides that “[a]fter September 30, 2011, an individual . . . , who is pursuing a program of education solely via distance learning at a rate of pursuit of greater than 50 percent, can receive

a monthly housing allowance . . . equal to 50 percent of the [national average].” The interpretation reflected in this regulatory language best avoids absurd and illogically inequitable results. See *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (“interpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available”). Consequently, *all* classes an individual takes must be online or otherwise characterized as distance learning for the individual to receive a monthly housing allowance at the rate of half the national average; otherwise, the individual would receive the full monthly housing allowance. In other words, if an individual takes only one “on-site” class, that individual could still be eligible for the full monthly housing allowance. Because this regulation reflects the best reading of the statute, it would be beyond our authority to pay less than the full monthly housing allowance for programs that include as little as one online course as it would require statutory rather than regulatory action.

We recognize that § 21.9641(c)(4) provides for a monthly housing allowance based on the national average, regardless of whether an individual is pursuing a degree or non-degree program. As noted above, Congress provided elsewhere in section 3313 for payment of the monthly housing allowance for distance learning based upon the national average. Thus, we are calculating the rate for all distance-learning programs in a manner that is administratively feasible and consistent with the statutory scheme. Also, we plan to define “resident learning” in a separate rulemaking. As such, VA makes no change based on this comment.

As for the commenter’s suggestion that the school attendance and participation requirements be enhanced, this rule makes changes that would ensure that an educational institution is not unjustly enriched by receiving payments when a student fails to attend or participate in class for which he or she is certified. Under current § 21.9695(b)(3), an educational institution is liable for overpayments when an overpayment is the result of willful or negligent false certification by the educational institution, or willful or negligent failure to certify excessive absences from a course, discontinuance of a course, or interruption of a course by the eligible individual. Revised § 21.9695(b)(3) will add that an educational institution is also liable for an overpayment of educational

assistance paid on behalf of an individual when a student never attends classes for which he or she was certified (regardless of the reason for non-attendance), or completely withdraws from all courses on or before the first day of the certified period of enrollment. These added provisions will help ensure VA is not paying for education that is not provided. Thus, an “enhanced attendance and participation requirement” is not necessary. Consequently, VA makes no changes based on this comment.

Personal Claim

One commenter referenced a personal claim and proceedings unrelated to this rulemaking. This comment is outside of the scope of this rulemaking, and VA makes no changes based on this comment.

Terminology Correction

A commenter noted that, in proposed § 21.9676(d), the usage of the term “veteran-nonveteran” is not accurate for purposes of the 85 percent requirement in 38 CFR 21.4201(a) or 38 U.S.C. 3680A(d)(1), otherwise known as the “85/15 rule.” The commenter pointed out that the 85/15 rule measures the number of students using VA or institutional funds versus those students who do not receive assistance from VA or the institution; and, therefore, the correct terminology is “supported students versus unsupported students” rather than “veteran-nonveteran.” VA concurs with this comment and replaces the term “veteran-nonveteran” with “supported students versus unsupported students” in § 21.9675(d)(5) and includes the term “supported students versus unsupported students” in new § 21.9676(d)(5).

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and

definitions governing contemporary regulatory review established in Executive Order 12866 and Executive Order 13563. The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866, section 3(f)(1), as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary of Veterans Affairs hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Although this final rule will affect some small entities, such as testing organizations or educational institutions that qualify as “small” using the most recent official revenue standards, the economic impact on them is minor. Educational institutions of all sizes voluntarily apply for approval to receive GI Bill benefits likely because tuition and fees revenue from student Veterans consists of guaranteed government funding (from U.S. taxpayer funds). However, if the cost for smaller educational institutions applying for GI Bill approval and meeting the requirements for continued approval were substantial, participating in the GI Bill program would not be financially viable. Because the policies memorialized in this final rule have been in effect for a long period of time and small institutions continue to seek and maintain GI Bill approval, likely profiting from this status, we conclude that the rules and policies in this final regulatory action do not significantly impact these entities. Furthermore, realizing that there are costs to educational institutions associated with their participation in GI Bill programs, Congress enacted Public Law 115–48, sec. 304, which increased the reporting fee payable to testing organizations and educational institutions for carrying out reporting requirements, as provided in 38 U.S.C. 3684(c)(2), consequently further minimizing the economic impact on smaller educational and testing organizations. On this basis, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act. Therefore, under 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This final rule will have no such effect on State, local, and Tribal governments, or on the private sector.

Paperwork Reduction Act of 1995

This final rule includes provisions constituting a revision to current/valid collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The revisions also require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review and approval. VA received no comments on the revised collections of information.

OMB has received the revised collections of information. OMB’s receipt of the revised collections of information is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. In accordance with 5 CFR part 1320, the revised collections of information associated with this rulemaking are not approved by OMB at this time. OMB’s approval of the revised collections of information will occur within 30 days after the Final rulemaking publishes. If OMB does not approve the new collections of information as requested, VA will immediately remove the provision containing the related new collection of information or take such other action as is directed by OMB.

The collections of information associated with this rulemaking are described immediately following this paragraph, under its respective title.

Title: Application for Approval of an Institution of Higher Learning Facility; Institution of Higher Learning—Program Submission List; Application for Approval of Org Other Than Inst of Higher Learning.

OMB Control No: 2900–0932.

CFR Provision: 38 CFR 21.4259(b).

• *Summary of collection of information:* Public Law 117–333 section 11, enacted January 5, 2023, amended 38 U.S.C. 3672, “Approval of Courses”. This law required VA to create and design two new uniform applications and any accompanying documentation for approval of courses

of educational programs, and for those forms to be available for use by October 1, 2023. These forms are completed by educational institutions, training establishments, and other organizations seeking approval of one or more programs of study for the payment of VA education benefits rendered to eligible beneficiaries. The institutions submit the forms to the State Approving Agencies (SAAs) of jurisdiction for their review. By law, each SAA has the authority to make such approvals in their respective state. VA contracts with SAAs in each state for this approval assessment work. There is some duplication of collection information found in the discontinued OMB 2900–0051 “State Approving Agency Reports and Notices” as required by 38 CFR 21.4154, 4250(b), 21.4258 and 21.4259. However, there wasn’t an official uniform application available for use by all stakeholders; educational institutions, training establishments and SAAs to ensure the information collected was the same based on the type of educational institution seeking program and course approval.

• *Description of need for information and proposed use of information:* The collection of information is necessary to ensure all entities have access to the same collection of information, thus making the approval assessment and enrollment certification process more efficient.

• *Description of likely respondents:* SAAs, educational institutions, and training establishments.

• *Estimated total number of respondents:* 8,800.

• *Estimated total number of responses:* 8,800.

• *Estimated frequency of responses:* Once.

• *Estimated average burden per response:* 8 total hours.

• *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 70,400 burden hours. Using the annual number of responses 8,800, VA estimates a total annual reporting and recordkeeping burden of 70,400 for respondents.

• *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$2,216,192 (70,400 respondents × \$31.48 *)

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Dependents’ Application for VA Education Benefits.

OMB Control No: 2900–0098.

CFR Provision: 38 CFR 21.9520(d), 21.9530(f), 21.9691(e), 21.9691(h).

- *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9520(d), 21.9530(f), 21.9691(e), and 21.9691(h) would require certain children to submit an application to establish eligibility for the Fry Scholarship, and certain individuals who must elect the Fry Scholarship or either Dependency and Indemnity Compensation (DIC) or Survivors' and Dependents' Educational Assistance (DEA) to submit an application to establish eligibility for the elected benefit.

- *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits. The information collected will be used by VA to determine an individual's eligibility for the Fry scholarship, DIC, or DEA.

- *Description of likely respondents:* Individuals.

- *Estimated total number of respondents:* 83,972.

- *Estimated frequency of responses:* Once.

- *Estimated average burden per response:* 45 minutes.

- *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 48,983 burden hours. Using the annual number of responses 83,972, VA estimates a total annual reporting and recordkeeping burden of 48,983 hours for respondents.

- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$1,982,578.92 (83,972 respondents per year $\times$ 45 minutes per application) / 60 $\times$ \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for "all occupations" of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Application for Reimbursement of a National Exam Fee.

OMB Control No: 2900–0706.

CFR Provision: 38 CFR 21.9626(a)(3), 21.9668, 21.9681(b)(5).

- *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9626(a)(3), 21.9668, 21.9681(b)(5) would require individuals to submit a claim and supporting documentation to be reimbursed for the cost of a national test for admission or a national test for credit.

- *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits. The information collected will be used by VA to determine if an individual is eligible to receive reimbursement for a claimed national test, and to determine the amount of the reimbursement.

- *Description of likely respondents:* Individuals.

- *Estimated total number of respondents:* 310.

- *Estimated frequency of responses:* Once.

- *Estimated average burden per response:* 15 minutes.

- *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 78 burden hours. Using the annual number of responses 310, VA estimates a total annual reporting and recordkeeping burden of 78 hours for respondents.

- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$2,440 (310 respondents per year $\times$ 15 minutes per application $\times$ \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for "all occupations" of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Application for Reimbursement of Licensing and Certification Fees.

OMB Control No: 2900–0695.

CFR Provision: 38 CFR 21.9667.

- *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9667 would require individuals to submit a claim to be reimbursed for the cost of licensing and certification tests.

- *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits. The information collected will be used by VA to determine if an individual is eligible to receive reimbursement for a licensing and certification test, and to determine the amount of the reimbursement.

- *Description of likely respondents:* Individuals.

- *Estimated total number of respondents:* 4,210.

- *Estimated total number of responses:* 12,630.

- *Estimated frequency of responses:* On occasion. (3 responses per year).

- *Estimated average burden per response:* 15 minutes.

- *Estimated total annual reporting and recordkeeping burden:* VA

estimates the total annual reporting and recordkeeping burden to be 3,158 burden hours. Using the annual number of responses 12,630, VA estimates a total annual reporting and recordkeeping burden of 3,158 hours for respondents.

- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$99,398 (12,630 responses per year $\times$ 15 minutes per application $\times$ \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for "all occupations" of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Monthly Certification for Flight Training.

OMB Control No: 2900–0162.

CFR Provision: 38 CFR 21.9641(b)(5).

- *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9641(b)(5) would require students pursuing flight training programs at non-IHLs to submit monthly certifications to receive payment for such pursuit.

- *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits. The information collected will be used to determine whether the individual's educational assistance should be continued without change, amended, or terminated, and to determine the effective date of such continuance, amendment, or termination.

- *Description of likely respondents:* Individuals.

- *Estimated total number of respondents:* 3,900.

- *Estimated total number of responses:* 23,400.

- *Estimated frequency of responses:* On occasion. (6 responses annually).

- *Estimated average burden per response:* 30 minutes.

- *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 11,700 burden hours. Using the annual number of responses 23,400, VA estimates a total annual reporting and recordkeeping burden of 11,700 hours for respondents.

- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$368,316 (23,400 responses per year $\times$ 30 minutes per application $\times$ \$31.48 *).

* To estimate the total information collection burden cost, VA used the

Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Certification of Lessons Completed.

OMB Control No: 2900–0353.

CFR Provision: 38 CFR 21.9641(b)(6).

• *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9641(b)(6) would require students pursuing correspondence training programs at non-IHLs to submit certification of lessons completed to receive payment for such pursuit.

• *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits, which in the case of correspondence training, are based on the number of lessons completed. The information collected will be used by VA to determine the amount of educational assistance to be paid.

• *Description of likely respondents:* Individuals.

• *Estimated total number of respondents:* 154.

• *Estimated total number of responses:* 616.

• *Estimated frequency of responses:* Quarterly.

• *Estimated average burden per response:* 10 minutes.

• *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 103 burden hours. Using the annual number of responses 616, VA estimates a total annual reporting and recordkeeping burden of 103 hours for respondents.

• *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$3,232 (616 responses per year × 10 minutes per application × \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Certification of Affirmation of Enrollment Agreement Correspondence Course.

OMB Control No: 2900–0576.

CFR Provision: 38 CFR 21.9641(b)(6).

• *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9641(b)(6) would require students pursuing correspondence training programs at non-IHLs to submit an affirmation of enrollment in a

correspondence course to receive payment for such pursuit.

• *Description of need for information and proposed use of information:* The collection of information is necessary to pay benefits. The information collected will be used by VA to ensure an individual is enrolled in a correspondence course following the signing of a contract.

• *Description of likely respondents:* Individuals.

• *Estimated total number of respondents:* 75.

• *Estimated frequency of responses:* Annually.

• *Estimated average burden per response:* 3 minutes.

• *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 4 burden hours. Using the annual number of responses 75 VA estimates a total annual reporting and recordkeeping burden of 4 hours for respondents.

• *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$118 (75 responses per year × 3 minutes per application × \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: VA Enrollment Certification.

OMB Control No: 2900–0073.

CFR Provision: 38 CFR 21.9681(b)(1) and 21.9721.

• *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9681(b)(1) and 21.9721 would require an educational institution to certify a student’s enrollment in an approved program of education (other than a student seeking reimbursement for taking an approved licensure or certification test or a national test).

• *Description of need for information and proposed use of information:* The collection of information is necessary to ensure a student is properly enrolled in an approved program of education before making any payments of educational assistance benefits. VA will use the information collected on VA Form 22–1999 to determine the amount of educational benefits payable to an individual during a period of enrollment or training.

• *Description of likely respondents:* Individuals.

• *Estimated total number of respondents:* 1,266,616.

• *Estimated total number of responses:* 3,799,847.

• *Estimated frequency of responses:* On occasion. (3 responses per year).

• *Estimated average burden per response:* 10 minutes.

• *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 633,307 burden hours. Using the annual number of responses 3,799,847, VA estimates a total annual reporting and recordkeeping burden of 633,307 hours for respondents.

• *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$19,936,530 (3,799,847 responses per year × 10 minutes per application × \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Title: Yellow Ribbon Program Agreement.

OMB Control No: 2900–0718.

CFR Provision: 38 CFR 21.9700(b).

• *Summary of collection of information:* The new collection of information in proposed 38 CFR 21.9700(b) would include individuals who establish eligibility for the Fry Scholarship to receive benefits under the Yellow Ribbon Program.

• *Description of need for information and proposed use of information:* The collection of information is necessary to provide IHLs with the opportunity to indicate their participation in the Yellow Ribbon Program and to allow IHLs to indicate the maximum number of students that will receive benefits under the program. VA will use the information collected to determine which IHLs will be participating in the Yellow Ribbon Program, the maximum number of individuals for whom the IHL will make contributions in any given academic year, and the maximum dollar amount of outstanding established charges that will be waived for each student based on student status (i.e., undergraduate, graduate, doctoral) or sub-element (i.e., college or professional school).

• *Description of likely respondents:* Institutions of higher learning.

• *Estimated total number of respondents:* 5,600.

• *Estimated frequency of responses:* Once.

• *Estimated average burden per response:* 14 hours.

• *Estimated total annual reporting and recordkeeping burden:* VA

estimates the total annual reporting and recordkeeping burden to be 78,400 burden hours. Using the annual number of responses 5,600, VA estimates a total annual reporting and recordkeeping burden of 78,400 hours for respondents.

- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be \$2,468,032 (5,600 responses per year × 14 hours per application × \$31.48 *).

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) median hourly wage for “all occupations” of \$31.48 per hour. This information is available at: https://www.bls.gov/oes/current/oes_nat.htm.

Severability

The purpose of this section is to clarify the agencies’ intent with respect to the severability of provisions of this final rule. Each provision that the agency is promulgating is capable of operating independently. If any provision of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid. Likewise, if the application of any portion of this rule to a particular circumstance is determined to be invalid, the agencies intend that the rule remain applicable to all other circumstances.

Congressional Review Act

Under the Congressional Review Act, this regulatory action may result in “an annual effect on the economy of \$100,000,000 or more,” 5 U.S.C. 804(2), and so is subject to the 60-day delay in effective date under 5 U.S.C. 801(a)(3). In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this Regulation and the Regulatory Impact Analysis (RIA) associated with the Regulation.

List of Subjects in 38 CFR Part 21

Administrative practice and procedure, Armed forces, Civil rights, Claims, Colleges and universities, Conflict of interests, Defense Department, Education, Employment, Grant programs—education, Grant programs—veterans, Health care, Loan programs—education, Loan programs—veterans, Manpower training programs, Reporting and recordkeeping requirements, Schools, Travel and transportation expenses, Veterans, Vocational education, Veteran readiness.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, signed and approved this document on December 12, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

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

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 21 as follows:

PART 21—VETERAN READINESS AND EMPLOYMENT AND EDUCATION

Subpart C—Survivors’ and Dependents’ Educational Assistance Under 38 U.S.C. Chapter 35

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

Authority: 38 U.S.C. 501(a), 512, 3500–3566, and as noted in specific sections.

■ 2. Amend § 21.3022 by:

- a. In paragraph (i), removing “and”;
- b. In paragraph (j), removing the period and adding “; and” in its place; and
- c. Adding paragraph (k).

The addition reads as follows:

§ 21.3022 Nonduplication—programs administered by VA.

* * * * *

(k) Effective August 1, 2011, 10 U.S.C. 510 (National Call to Service).

* * * * *

Subpart D—Administration of Educational Assistance Programs

■ 3. The authority citation for subpart D continues to read as follows:

Authority: 10 U.S.C. 2141 note, ch. 1606; 38 U.S.C. 501(a), chs. 30, 32, 33, 34, 35, 36, and as noted in specific sections.

§ 21.4002 [Amended]

■ 4. Amend § 21.4002, in paragraph (a), by removing “(See §§ 19.192 and 19.183 of this chapter.)”.

■ 5. Amend § 21.4022 by:

- a. In paragraph (d), adding a semicolon at the end of the paragraph;
- b. In paragraph (k), removing the period and adding “; and” in its place; and
- c. Adding paragraph (l).

The addition reads as follows:

§ 21.4022 Nonduplication—programs administered by VA.

* * * * *

(l) Effective August 1, 2011, 10 U.S.C. 510 (National Call to Service).

* * * * *

■ 6. Amend § 21.4138 by:

- a. Removing the parenthetical authority citation at the end of paragraphs (a), (b), and (e);
- b. Revising the heading for paragraph (f) introductory text;
- c. Removing the parenthetical authority citation at the end of paragraphs (f)(4)(ii), (f)(5)(ii), and (f)(6)(ii)(B); and
- d. Adding paragraphs (g) and (h).

The revision and additions read as follows:

§ 21.4138 Certifications and release of payments.

* * * * *

(f) *Payment for intervals and temporary school closings before August 1, 2011.* * * *

* * * * *

(g) *Payment for temporary school closings after July 31, 2011.* (1) Subject to paragraph (g)(2) of this section, VA may authorize payment for a temporary school closing that occurs during a certified period of enrollment if the closing is due to an emergency (including a strike) or established policy based on an Executive order of the President.

(2) An individual may not receive more than 4 weeks of payment for temporary school closings in any 12-month period.

(3) The decision as to whether a school closing is permanent or temporary will be made by—

(i) The director of the VA regional processing office of jurisdiction; or

(ii) The Director, Education Service, if the emergency or established policy based on an Executive Order of the President results in the closing of schools in the jurisdiction of more than one VA regional processing office.

(4) A school that disagrees with a decision made under paragraph (g)(3) of this section may request an administrative review. The review request must be submitted in writing and received by the director of the VA regional processing office of jurisdiction, or the Director, Education Service, whoever made the decision under paragraph (g)(3) of this section, within one year of the date of VA’s letter notifying the school of the decision. A review of the decision will include the evidence of record and any other pertinent evidence the school may wish to submit. The affirmation or reversal of

the initial decision based on an administrative review is final. The review will be conducted by the—

(i) Director, Education Service, if the director of the VA regional processing office of jurisdiction made the initial decision to continue or discontinue payments.

(ii) Under Secretary for Benefits, if the Director, Education Service, made the initial decision to continue or discontinue payments.

(h) *Authority.* (1) Paragraph (a) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034, 3680(f);

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(c), 3680(f);

(3) Paragraph (e) of this section issued under the authority of 38 U.S.C. 5113, 3680(b), 3680(c), 3680(g);

(4) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3680;

(5) Paragraph (f)(5) of this section issued under the authority of 38 U.S.C. 3680(a);

(6) Paragraph (f)(6) of this section issued under the authority of 38 U.S.C. 512, 3680(a); and

(7) Paragraph (g) of this section issued under the authority of 38 U.S.C. 512, 3680(a).

* * * * *

■ 7. Amend § 21.4150 by:

■ a. Revising paragraph (c)(2) and removing the parenthetical authority citation at the end of the paragraph;

■ b. Removing the parenthetical authority citation at the end of paragraphs (d) and (e);

■ c. Revising paragraph (f) and removing the parenthetical authority citation at the end of the paragraph;

■ d. Removing the parenthetical authority citation at the end of paragraph (g); and

■ e. Adding paragraph (h).

The revisions and addition read as follows:

§ 21.4150 Designation.

* * * * *

(c) * * *

(2) When VA has approval, disapproval, or suspension authority.

* * * * *

(f)(1) The Secretary is responsible for approving programs of education offered by any agency or instrumentality of the Federal Government.

(2)(i) Effective August 1, 2011, subject to §§ 21.4201, 21.4203, 21.4251, 21.4252, and 21.4253(d)(2) and (3), the following programs of education are deemed approved—

(A) An accredited standard college degree program offered at a public or

not-for-profit proprietary institution of higher learning that is accredited by a national or regional agency or organization recognized for that purpose by the Department of Education.

(B) A flight training course approved by the Federal Aviation Administration that is offered by a certified pilot school that possesses a valid Federal Aviation Administration pilot school certificate or provisional pilot school certificate under 14 CFR part 141.

(C) An apprenticeship program registered with the Office of Apprenticeship of the Employment Training Administration of the Department of Labor or a State apprenticeship agency recognized by the Office of Apprenticeship under 29 U.S.C. 50, *et seq.*

(D) A program of education leading to a secondary school diploma offered by a secondary school approved in the State in which it is operating.

(E) A licensure test offered by a Federal, State, or local government.

(ii) [Reserved]

(h)(1) Paragraph (c)(2) of this section issued under the authority of 38 U.S.C. 3671(b)(1);

(2) Paragraph (d) of this section issued under the authority of 38 U.S.C. 512(a), 3561(b);

(3) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3672(c);

(4) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3672(b); and

(5) Paragraph (g) of this section issued under the authority of 38 U.S.C. 3689.

* * * * *

■ 8. Amend § 21.4151 by:

■ a. Removing the parenthetical authority citation at the end of paragraphs (a) and (b);

■ b. In paragraph (b)(5), removing “and” at the end of the paragraph;

■ c. Redesignating paragraph (b)(6) as paragraph (b)(7);

■ d. Adding new paragraph (b)(6);

■ e. Removing the parenthetical authority citation at the end of paragraph (c); and

■ f. Adding paragraph (d).

The additions read as follows:

§ 21.4151 Cooperation.

* * * * *

(b) * * *

(6) Effective August 1, 2011, performing compliance and risk-based surveys and oversight (in accordance with the provisions in the State approving agency contract) without regard to whether the Secretary or the State approving agency approved the courses offered at the educational

institution or the courses were deemed approved; and

* * * * *

(d)(1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3673(a);

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3672, 3673, 3674, 3689; and

(3) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3673(b).

■ 9. Amend § 21.4200 by adding paragraphs (mm) through (oo) following the parenthetical authority citation at the end of the section to read as follows:

§ 21.4200 Definitions.

* * * * *

(mm) *National test for admission.* (1) A *national test for admission* is a test used for admission to an institution of higher learning or graduate school (such as the Scholastic Aptitude Test (SAT), Law School Admission Test (LSAT), Graduate Record Exam (GRE), and Graduate Management Admission Test (GMAT)). A list of national tests approved by VA can be found at: <https://inquiry.vba.va.gov/weampub/buildSearchNE.do>.

(2) This paragraph (mm) issued under the authority of 38 U.S.C. 3452(b), 3315A, 3501(a)(5).

(nn) *National test for credit.* (1) A *national test for credit* is a test that provides an opportunity for course credit at an institution of higher learning (such as the Advanced Placement (AP) exam and College-Level Examination Program (CLEP)). A list of national tests approved by VA can be found at: <https://inquiry.vba.va.gov/weampub/buildSearchNE.do>.

(2) This paragraph (nn) issued under the authority of 38 U.S.C. 3452(b), 3315A, 3501(a)(5).

(oo) *We, us, our.* When we use the terms *we*, *us*, or *our*, we mean the United States Department of Veterans Affairs.

■ 10. Amend § 21.4206 by:

■ a. Revising the introductory text;

■ b. Removing the parenthetical authority citation at the end of paragraph (a);

■ c. Revising paragraph (b) and removing the parenthetical authority citation at the end of the paragraph;

■ d. Removing the parenthetical authority citation at the end of paragraphs (c) and (d);

■ e. Revising paragraph (e) and removing the parenthetical authority citation at the end of the paragraph; and

■ f. Adding paragraph (f).

The revisions and addition read as follows:

§ 21.4206 Reporting fee.

VA will pay annually to each educational institution furnishing education or to each joint apprenticeship training committee acting as a training facility under 10 U.S.C. 510, chapter 1606, or chapter 1607 or 38 U.S.C. 30, 32, 33, 35, or 36 a reporting fee for required reports or certifications. The reporting fee will be paid as soon as feasible after the end of the calendar year.

* * * * *

(b) In computing the reporting fee, VA will not count an eligible individual whose only receipt of educational assistance during a calendar year was tuition assistance Top-Up under 38 U.S.C. chapter 30, a rural relocation payment, or reimbursement for a national test for admission, national test for credit, or a licensing or certification test.

* * * * *

(e) Before VA will pay a reporting fee, an educational institution must certify that—

(1) It has exercised reasonable diligence in determining whether it or any courses approved for VA education benefits offered by it meet all the applicable requirements of 10 U.S.C. 510, chapter 1606, or chapter 1607 or 38 U.S.C. 30, 32, 33, 35, or 36;

(2) It will, without delay, report any failure to meet any requirement to VA; and

(3) The reporting fees received after January 4, 2011, will be used solely for the purpose of making certifications for VA educational assistance under 10 U.S.C. 510, chapter 1606, or chapter 1607 or 38 U.S.C. 30, 32, 33, 35, or 36 or for supporting programs for veterans.

(f)(1) Paragraph (a) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3323(a), 3684(c);

(2) Paragraph (b) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3323(a), 3684(c);

(3) Paragraph (c) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3323(a), 3684(c);

(4) Paragraph (d) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3323(a), 3684(c); and

(5) Paragraph (e) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3323(a), 3684(c).

* * * * *

■ 11. Revise § 21.4235 to read as follows:

§ 21.4235 Programs of education that include flight training.

VA will use the provisions of this section to determine whether an individual may be paid educational assistance for pursuit of flight training. See § 21.4263 for approval of flight courses for VA training.

(a) *Eligibility.* An individual who is otherwise eligible to receive educational assistance under 38 U.S.C. chapters 30, 32, or 33, or a reservist eligible for educational assistance under 10 U.S.C. chapters 1606 or 1607, may receive educational assistance for flight training in an approved program of education provided that the individual meets the requirements of this paragraph (a). Except when enrolled in a ground instructor certification course or when pursuing flight training under paragraph (e) of this section, the individual must—

(1) Possess a valid private pilot certificate or higher pilot certificate such as a commercial pilot certificate;

(2) If enrolled in a course other than an Airline Transport Pilot (ATP) course, hold a second-class medical certificate on the first day of training and, if that course began before October 1, 1998, hold that certificate continuously during training; and

(3) If enrolled in an ATP certification course, hold a first-class medical certificate on the first day of training and, if that course began before October 1, 1998, hold that certificate continuously during training.

(b) *Pursuit of flight courses.* (1) VA will pay educational assistance to an eligible individual for an enrollment in a commercial pilot certification course leading to Federal Aviation Administration certification for a particular category even if the individual has a commercial pilot certificate issued by the Federal Aviation Administration for a different category, since each category represents a different vocational objective.

(2) VA will pay educational assistance to an eligible individual for an enrollment in an instrument rating course only if the individual simultaneously enrolls in a course required for a commercial pilot certificate for the category for which the instrument rating course is pursued or if, at the time of enrollment in the instrument rating course, the individual has a commercial pilot certificate issued by the Federal Aviation Administration for such category. The enrollment in an instrument rating course alone does not establish that the individual is pursuing a vocational objective, as required for VA purposes, since that rating equally may be applied to an individual's private pilot certificate, only evidencing

an intent to pursue a non-vocational objective.

(3) VA will pay educational assistance to an eligible individual for an enrollment in a flight course other than an instrument rating course or a ground instructor course, including courses leading to an aircraft type rating, only if the individual has a commercial pilot certificate issued by the Federal Aviation Administration for the category to which the particular course applies.

(4) VA will pay educational assistance to an eligible individual for an enrollment in a ground instructor certificate course, even though the individual does not have any other flight certificate issued by the Federal Aviation Administration, since the Federal Aviation Administration does not require a flight certificate as a prerequisite to ground instructor certification and ground instructor is a recognized vocational objective.

(5) VA will not pay an eligible individual for simultaneous enrollment in more than one flight course, except as provided in paragraph (b)(2) of this section.

(c) *Some individuals are already qualified for a flight course objective.* (1) The provisions of §§ 21.5230(a)(4), 21.7110(b)(4), and 21.7610(b)(4), prohibiting payment of educational assistance for enrollment in a course for whose objective the individual is already qualified, apply to enrollments in flight courses.

(2) A former military pilot with the equivalent of a commercial pilot certificate and an instrument rating may obtain a commercial pilot certificate and instrument rating from the Federal Aviation Administration without a flight exam within 12 months of release from active duty. Therefore, VA will consider such a veteran to be already qualified for the objectives of a commercial pilot certification course and an instrument rating course if begun within 12 months of the individual's release from active duty.

(d) *Some flight courses are refresher training.* The provisions of §§ 21.5230(c), 21.7020(b)(26), 21.7122(b), 21.7520(b)(20), and 21.7610(b)(4) that provide limitations on payment for refresher training that is needed to update an individual's knowledge and skill in order to cope with technological advances while he or she was on active duty service apply to flight training.

(1) An individual who held a Federal Aviation Administration certificate before or during active duty service may have surrendered that certificate or the Federal Aviation Administration may

have canceled it. The individual may receive the equivalent of the number of months of educational assistance necessary to complete the course that will qualify him or her for the same grade certificate.

(2) A reservist is not eligible for refresher training unless he or she has had prior active duty.

(e) *Flight training at an institution of higher learning.* (1) An individual who is eligible for educational assistance under 10 U.S.C. chapter 1606 or 1607 or 38 U.S.C. chapter 30, 32, 33, or 35 is exempt from the provisions of paragraphs (a)(2) through (c) of this section when his or her courses include flight training that is part of a program of education that leads to a standard college degree.

(2) An individual described in paragraph (e)(1) of this section may pursue courses that may result in the individual eventually receiving recreational pilot certification or private pilot certification, provided that the courses also lead to a standard college degree.

(f) *Authority.* (1) Paragraph (a) of this section issued under the authority of 10 U.S.C. 16136(c); 38 U.S.C. 3034(d), 3241(b);

(2) Paragraph (b) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3002(3)(A), 3034(a), 3202(2)(A), 3241(a), 3241(b), 3452(b), 3680A(a)(3);

(3) Paragraph (c) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3034(a), 3241(a), 3241(b), 3471(4);

(4) Paragraph (d) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3002(3)(A), 3034(a)(3), 3202(2)(A), 3241(a), 3241(b)); and

(5) Paragraph (e) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3002(3)(A), 3034(a)(3), 3202(2)(A), 3241(a), 3241(b).

■ 12. Amend § 21.4253 by:

■ a. Removing the parenthetical authority citation at the end of paragraph (a); b. Revising paragraph (a) introductory text;

■ c. Removing the parenthetical authority citation at the end of paragraphs (d)(1)(iv), (d)(3), (5), and (8), (d)(10)(ii), and (e)(1); and

■ c. Adding paragraph (g).

The revision and addition read as follows:

§ 21.4253 Accredited courses.

(a) *General.* All standard college degree courses offered at proprietary for-profit institutions and non-college degree courses offered at proprietary for-profit institutions and public or

proprietary not-for-profit institutions may be approved as accredited courses if they meet one of the following criteria:

* * * * *

(g) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3675(a);

(2) Paragraphs (b) through (d)(1) of this section issued under the authority of 38 U.S.C. 3675(a), 3676(b);

(3) Paragraphs (d)(2) and (3) of this section issued under the authority of 38 U.S.C. 3675(b);

(4) Paragraphs (d)(4) and (5) of this section issued under the authority of 38 U.S.C. 3474, 3675);

(5) Paragraphs (d)(6) through (8) of this section issued under the authority of 38 U.S.C. 3675(b), 3676(c)(1), (2), (3);

(6) Paragraph (d)(9) of this section issued under the authority of 38 U.S.C. 3675(b)(3), 3676(c), (f); and

(7) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3675.

* * * * *

■ 13. Amend § 21.4259 by:

■ a. Revising paragraphs (a) and (b);

■ b. Removing the parenthetical authority citation at the end of paragraph (e);

■ c. Adding paragraph (f); and

■ d. Removing the parenthetical authority citation under parenthetical “(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900-0051)”.

The revision and addition read as follows:

§ 21.4259 Suspension or disapproval.

(a) The appropriate State approving agency or the Secretary (whichever entity approved the program), after approving a program of education or licensing or certification test—

(1) May suspend the approval of a program of education for new enrollments or for a licensing or certification test for a period not to exceed 60 days to allow the institution to correct any deficiencies if the evidence of record establishes that the program of education or licensing or certification test fails to meet any of the requirements for approval.

(2) Will immediately disapprove the program of education or licensing or certification test if any of the requirements for approval are not being met and the deficiency cannot be corrected within a period of 60 days.

(b)(1) Upon suspension or disapproval, the State approving agency or the Secretary, whichever suspended or disapproved the program of education, will notify the educational

institution by certified or registered letter with a return receipt secured. It is incumbent upon the State approving agency or the Secretary to determine the conduct of the program of education and to take immediate appropriate action in each case in which it is found that the conduct of the program of education in any manner fails to comply with the requirements for approval.

(2)(i) Each State approving agency will immediately notify VA of each program of education or licensing and certification test that it has suspended or disapproved.

(ii) The Secretary will immediately notify the appropriate State approving agency of each program of education or licensing and certification test that it has suspended or disapproved.

* * * * *

(f) Paragraphs (a) through (e) of this section issued under the authority of 38 U.S.C. 3679(d).

■ 14. Amend § 21.4263 by revising paragraph (a) and removing the parenthetical authority citation at the end of the paragraph to read as follows:

§ 21.4263 Approval of flight training courses.

(a)(1) A flight program may be approved if—

(i)(A) For 38 U.S.C. chapters 32 and 35 and 10 U.S.C. chapters 1606 and 1607, the flight courses that constitute the program of education meet Federal Aviation Administration standards for such courses and the Federal Aviation Administration and the State approving agency approve them; or

(B) For 38 U.S.C. chapters 30 and 33, effective August 1, 2011, the flight program is deemed approved (A flight program will be deemed approved if it

is approved by the Federal Aviation Administration and is offered by a certified pilot school that possesses a valid Federal Aviation Administration pilot school certificate or provisional pilot school certificate under 14 CFR part 141. Flight programs offered at flight schools listed in paragraphs (b)(2) and (3) of this section will not be approved for VA training under 38 U.S.C. chapters 30 and 33); and

(ii)(A) The flight training offered by a flight school is generally accepted as necessary for the attainment of a recognized vocational objective in the field of aviation; or

(B) The flight training is offered by an institution of higher learning for credit towards a standard college degree program.

(2) A State approving agency may approve a flight course only if a flight school or an institution of higher learning offers the course. A State

approving agency may not approve a flight course if an individual instructor offers it.

(3) This paragraph (a) issued under the authority of 10 U.S.C. 16136(c), 16166(c), 38 U.S.C. 3032(e), 3241(b), 3672, 3676, 3680A.

* * * * *

■ 15. Amend § 21.4268 by:

- a. Revising paragraph (a) and removing the parenthetical authority citation at the end of the paragraph;
- b. Removing the parenthetical authority citation at the end of paragraphs (b) through (e);
- c. Adding paragraph (g); and
- d. Removing the parenthetical authority citation below the parenthetical “(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900–0051)”; and

The revision and addition read as follows:

§ 21.4268 Approval of licensing and certification tests.

(a) *Authority to approve licensing and certification tests*—(1) *Tests deemed approved.* Effective August 1, 2011, a licensure test offered by a Federal, State, or local government is deemed approved in accordance with § 21.4150(f).

(2) *VA approval.* The Secretary of Veterans Affairs delegates to the Under Secretary for Benefits, and to personnel the Under Secretary for Benefits may designate within the Education Service of the Veterans Benefits Administration, the authority to approve licensing and certification tests and the organizations and entities offering the tests as provided in § 21.4250(c)(2)(vi).

(3) *State approving agency approval.* Except for the licensing and certification tests and organizations or entities offering these tests that are approved under paragraphs (a)(1) and (2) of this section, the Secretary of Veterans Affairs delegates to each State approving agency the authority to approve licensing and certification tests and the organizations and entities offering these tests located within the State approving agency’s jurisdiction as provided in § 21.4250(a).

* * * * *

(g) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 512(a), 3689(a)(2);

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3689;

(3) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3689(c);

(4) Paragraph (d) of this section issued under the authority of 38 U.S.C. 3689(c);

(5) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3689(d);

(6) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3689.

Subpart G—Post-Vietnam Era Veterans’ Educational Assistance Under 38 U.S.C. Chapter 32

■ 16. The authority citation for subpart G continues to read as follows:

Authority: 38 U.S.C. 501(a), chs. 32, 36, and as noted in specific sections.

■ 17. Amend § 21.5022 by:

- a. Removing the parenthetical authority citation at the end of paragraph (a)(1);
- b. In paragraph (a)(1)(ix), removing “or”;
- c. In paragraph (a)(1)(x), removing the period and adding “; or” in its place;
- d. Adding paragraph (a)(1)(xi);
- e. Removing the parenthetical authority citation at the end of paragraphs (a)(2) and (b); and
- f. Adding paragraph (c).

The additions read as follows:

§ 21.5022 Eligibility under more than one program.

(a) * * *

(1) * * *

(xi) Effective August 1, 2011, 10 U.S.C. 510 (National Call to Service).

* * * * *

(c) *Authority.* (1) Paragraph (a)(1) of this section issued under the authority of 38 U.S.C. 3322(a), 3681(b), 3695;

(2) Paragraph (a)(2) of this section issued under the authority of 38 U.S.C. 3033(a), 3322(a); and

(3) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3231, 3323(a).

Subpart K—All Volunteer Force Educational Assistance Program (Montgomery GI Bill—Active Duty)

■ 18. The authority citation for subpart K continues to read as follows:

Authority: 38 U.S.C. 501(a), chs. 30, 36, and as noted in specific sections.

■ 19. Amend § 21.7143 by:

- a. In paragraph (a)(1)(ix), removing “or”;
- b. In paragraph (a)(1)(x), removing the period and adding “; and” in its place;
- c. Adding paragraph (a)(1)(xi);
- d. Adding reserved paragraph (a)(2);
- e. Removing the parenthetical authority citation at the end of paragraphs (b) and (c); and
- f. Adding paragraph (d).

The additions read as follows:

§ 21.7143 Nonduplication of educational assistance.

(a) * * *

(1) * * *

(xi) Effective August 1, 2011, 10 U.S.C. 510 (National Call to Service).

(2) [Reserved]

* * * * *

(d) *Authority.* (1) Paragraphs (a) and (b) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3033(a), 3681(b); and

(2) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3034, 3681.

Subpart L—Educational Assistance for Members of the Selected Reserve

■ 20. The authority citation for subpart L continues to read as follows:

Authority: 10 U.S.C. ch. 1606; 38 U.S.C. 501(a), 512, ch. 36, and as noted in specific sections.

■ 21. Amend § 21.7642 by:

- a. Removing the parenthetical authority citation at the end of paragraph (a);
- b. In paragraph (a)(9), removing “or”;
- c. In paragraph (a)(10), removing the period and adding “; and” in its place;
- d. Adding paragraph (a)(11);
- e. Removing the parenthetical authority citation at the end of paragraphs (c) through (e); and
- e. Adding paragraph (f).

The additions read as follows:

§ 21.7642 Nonduplication of educational assistance.

(a) * * *

(11) Effective August 1, 2011, 10 U.S.C. 510 (National Call to Service).

* * * * *

(f) *Authority.* (1) Paragraph (a) of this section issued under the authority of 10 U.S.C. 16136(b); 38 U.S.C. 3033(a), 3241(a), 3322(a), 3681;

(2) Paragraphs (b) and (c) of this section issued under the authority of 10 U.S.C. 16134; Pub. L. 98–525;

(3) Paragraph (d) of this section issued under the authority of 10 U.S.C. 16136(b), 38 U.S.C. 3681; Public Law 98–525; and

(4) Paragraph (e) of this section issued under the authority of Sec. 4492(a), Public Law 102–484, 106 Stat. 2765–2766.

Subpart P—Post-9/11 GI Bill

■ 22. The authority citation for subpart P continues to read as follows:

Authority: 38 U.S.C. 501(a), 512, chs. 33, 36 and as noted in specific sections.

■ 23. Amend § 21.9505 by:

- a. Revising the section heading;
- b. In the introductory text, removing “apply.” and adding in its place “apply to provisions effective before August 1, 2011, unless otherwise noted.”;

- c. Revising the definition for “Active duty” and removing the parenthetical authority citation at the end of the definition;
- d. Adding in alphabetical order the definition for “Educational institution”;
- e. Revising the definition for “Entry level and skill training” and removing the parenthetical authority citation at the end of the definition;
- f. Adding in alphabetical order the definition for “Fugitive felon”;
- g. Adding a parenthetical with the OMB control number for the approval of the information collection immediately following the parenthetical authority citation at the end of the section.

The revisions and additions read as follows:

§ 21.9505 Definitions—for provisions effective before August 1, 2011.

* * * * *

Active duty means—

(1) Full-time duty:

(i) In the regular components of the Armed Forces; or

(ii) Under a call or order to active duty under 10 U.S.C. 688, 12301(a), 12301(d), 12301(g), 12302, or 12304.

(2) In the case of a member of the Army National Guard of the United States or the Air National Guard of the United States, in addition to service described in paragraph (1)(ii) of this definition, full-time service—

(i) In the National Guard of a State for the purpose of organizing, administering, recruiting, instructing, or training the National Guard; or

(ii) In the National Guard under 32 U.S.C. 502(f) when authorized by the President or the Secretary of Defense for the purpose of responding to a national emergency declared by the President and supported by Federal funds.

(3) Active duty does not include—

(i) Any period during which the individual—

(A) Was assigned full-time by the Armed Forces to a civilian institution to pursue a program of education that was substantially the same as programs of education offered to civilians; or

(B) Served as a cadet or midshipman at one of the service academies; or

(C) Served under the provisions of 10 U.S.C. 12103(d) pursuant to an enlistment in the Army National Guard, Air National Guard, Army Reserve, Naval Reserve, Air Force Reserve, Marine Corps Reserve, or Coast Guard Reserve.

(ii) A period of service—

(A) Required by an officer pursuant to an agreement under 10 U.S.C. 2107(b); or

(B)(1) Required by an officer pursuant to an agreement under 10 U.S.C. 4348, 6959, or 9348; or

(2) Effective for individuals entering into agreements after January 3, 2011, required by an officer pursuant to an agreement under 14 U.S.C. 1925.

(C) That was terminated because the individual is considered a minor by the Armed Forces, was erroneously enlisted, or received a defective enlistment agreement; or

(D) Counted for purposes of repayment of an education loan under 10 U.S.C. chapter 109.

(iii) A period of service after July 31, 2011, used to establish eligibility under 38 U.S.C. chapter 30 or 32, or 10 U.S.C. chapter 1606 or 1607.

(3) This definition issued under the authority of 38 U.S.C. 101(21)(A), 3301(1), 3311(d), 3322(b), (c); Public Law 111–377, 124 Stat. 4107–4108.

* * * * *

Educational institution has the same meaning as the term *institution of higher learning* as defined in § 21.4200(h) for training pursued prior to August 1, 2011.

(1) This definition issued under the authority of 38 U.S.C. 3323(a).

(2) [Reserved]

* * * * *

Entry level and skill training means—

(1) Basic Combat Training, Advanced Individual Training, and, effective January 4, 2011, One Station Unit Training for members of the Army;

(2) Recruit Training (Boot Camp) and Skill Training (“A” School) for members of the Navy;

(3) Basic Military Training and Technical Training for members of the Air Force;

(4) Recruit Training and Marine Corps Training (School of Infantry Training) for members of the Marine Corps; and

(5) Basic Training and, for individuals entering service on or after January 4, 2011, Skill Training (or so-called “A” School) for members of the Coast Guard.

(6) This definition issued under the authority of 38 U.S.C. 3301(2).

* * * * *

Fugitive felon means an individual identified as such by Federal, State, or local law enforcement officials and who is a fugitive by reason of—

(1) Fleeing to avoid prosecution for an offense, or an attempt to commit an offense, which is a felony under the laws of the place from which the person flees;

(2) Fleeing to avoid custody or confinement after conviction for an offense, or an attempt to commit an offense, which is a felony under the laws of the place from which the person flees; or

(3) Violating a condition of probation or parole imposed for commission of a felony under Federal or State law.

(4) This definition issued under the authority of 38 U.S.C. 3323(c), 5313B.

* * * * *

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900–0154.)

■ 24. Add § 21.9506 to read as follows:

§ 21.9506 Definitions—for provisions effective after July 31, 2011.

(a) For the purposes of this subpart (governing the administration and payment of educational assistance under 38 U.S.C. chapter 33), effective after July 31, 2011, unless otherwise noted, the following definitions apply. (See also additional definitions in §§ 21.1029 and 21.4200.)

Academic year means the period of time beginning August 1st of each calendar year and ending July 31st of the subsequent calendar year.

Active duty means—

(i) Full-time duty:

(B) In the regular components of the Armed Forces; or

(C) Under a call or order to active duty under 10 U.S.C. 688, 12301(a), 12301(d), 12301(g), 12302, or 12304.

(ii) In the case of a member of the Army National Guard of the United States or the Air National Guard of the United States, in addition to service described in paragraph (i)(B) of this definition, full time service—

(A) In the National Guard of a State for the purpose of organizing, administering, recruiting, instructing, or training the National Guard; or

(B) In the National Guard under 32 U.S.C. 502(f) when authorized by the President or the Secretary of Defense for the purpose of responding to a national emergency declared by the President and supported by Federal funds.

(iii) Active duty does not include—

(A) Any period during which the individual—

(1) Was assigned full-time by the Armed Forces to a civilian institution to pursue a program of education that was substantially the same as programs of education offered to civilians; or

(2) Served as a cadet or midshipman at one of the service academies; or

(3) Served under the provisions of 10 U.S.C. 12103(d) pursuant to an enlistment in the Army National Guard, Air National Guard, Army Reserve, Naval Reserve, Air Force Reserve, Marine Corps Reserve, or Coast Guard Reserve.

(B) A period of service—

(1) Required by an officer pursuant to an agreement under 10 U.S.C. 2107(b); or

(2)(i) Required by an officer pursuant to an agreement under 10 U.S.C. 4348, 6959, or 9348; or

(ii) Effective for individuals entering into agreements after January 3, 2011, required by an officer pursuant to an agreement under 14 U.S.C. 1925.

(3) That was terminated because the individual is considered a minor by the Armed Forces, was erroneously enlisted, or received a defective enlistment agreement; or

(4) Counted for purposes of repayment of an education loan under 10 U.S.C. chapter 109.

Advance payment means an amount of educational assistance payable under § 21.9641(c) for the month or fraction of the month in which the individual's quarter, semester, or term will begin plus the amount for the following month.

Course means a unit of instruction required for an approved program of education that provides an individual with the knowledge and skills necessary to meet the requirements of the selected educational, professional, or vocational objective.

Distance learning means the pursuit of a program of education via distance education as defined in 20 U.S.C. 1003(7).

Educational assistance means all monetary benefits (including but not limited to tuition, fees, and monthly housing allowances) payable under 38 U.S.C. chapter 33 to, or on behalf of, individuals who meet the eligibility requirements for pursuit of an approved program of education under 38 U.S.C. chapter 33

Educational institution has the same meaning as the term institution of higher learning as defined in § 21.4200(h).

Enrollment period means a term, quarter, or semester during which the educational institution offers instruction.

Entry level and skill training means—

- (i) For members of the Army—
 - (A) Basic Combat Training,
 - (B) Advanced Individual Training,and
 - (C) Effective January 4, 2011, One Station Unit Training.
 - (ii) For members of the Navy, Recruit Training (Boot Camp) and Skill Training (“A” School).
 - (iii) For members of the Air Force, Basic Military Training and Technical Training.
 - (iv) For members of the Marine Corps, Recruit Training and Marine Corps Training (School of Infantry Training).
 - (v) For members of the Coast Guard—
 - (A) Basic Training; and
 - (B) For individuals entering service on or after January 4, 2011, Skill Training (or so-called “A” School).
- Fees* mean any mandatory charges (other than tuition, room, and board)

that are applied by the educational institution for pursuit of an approved program of education. Fees include, but are not limited to, health premiums, freshman fees, graduation fees, and lab fees. Fees do not include those charged for a study abroad course(s) unless the course(s) is a mandatory requirement for completion of the approved program of education.

Fugitive felon means an individual identified as such by Federal, State, or local law enforcement officials and who is a fugitive by reason of—

(i) Fleeing to avoid prosecution for an offense, or an attempt to commit an offense, which is a felony under the laws of the place from which the person flees;

(ii) Fleeing to avoid custody or confinement after conviction for an offense, or an attempt to commit an offense, which is a felony under the laws of the place from which the person flees; or

(iii) Violating a condition of probation or parole imposed for commission of a felony under Federal or State law.

Institution of higher learning (IHL) means a college, university, or similar institution, including a technical or business school, offering postsecondary level academic instruction that leads to an associate or higher degree if the school is empowered by the appropriate State education authority under State law to grant an associate or higher degree. When there is no State law to authorize the granting of such a degree, the school may be recognized as an institution of higher learning if it is accredited for degree programs by a recognized accrediting agency. Such term shall also include a hospital offering educational programs at the postsecondary level without regard to whether the hospital grants a postsecondary degree. Such term shall also include an educational institution that offers courses leading to a standard college degree or its equivalent, and is not located in a State but is recognized as an educational institution by the Secretary of Education (or comparable official) of the country or other jurisdiction in which the institution is located.

Lump sum payment means an amount of educational assistance paid for the entire term, quarter, or semester.

Mitigating circumstances means circumstances beyond the individual's control that prevent him or her from continuously pursuing a program of education. The following circumstances are representative of those that VA considers to be mitigating. This list is not all-inclusive.

(i) An illness or mental illness of the individual;

(ii) An illness or death in the individual's family;

(iii) An unavoidable change in the individual's conditions of employment;

(iv) An unavoidable geographical transfer resulting from the individual's employment;

(v) Immediate family or financial obligations beyond the control of the individual that require him or her to suspend pursuit of the program of education to obtain employment;

(vi) Discontinuance of the course by the educational institution;

(vii) Unanticipated active duty for training; or

(viii) Unanticipated difficulties in caring for the individual's child or children.

Net cost means the amount of in-State tuition and fees the individual enrolled in a program of education is responsible for paying after the application of any—

(i) Waiver of, or reduction in, tuition and fees; and

(ii) Scholarship, or other Federal, State, institutional, or employer-based aid or assistance (other than loans and any funds provided under section 401(b) of the Higher Education Act of 1965) that is provided directly to the institution specifically designated for the sole purpose of reducing the individual's tuition and fee charges.

Non-public institution means a proprietary institution as defined in § 21.4200(z).

Program of education means a curriculum or combination of courses pursued at an educational institution that is accepted as necessary to meet the requirements for a predetermined and identified educational, professional, or vocational objective. Such term also means any curriculum or combination of courses pursued at an educational institution that is accepted as necessary to meet the requirements for more than one predetermined and identified educational, professional, or vocational objective if all the objectives pursued are generally recognized as being reasonably related to a single career field. The curriculum or combination of courses pursued must be listed in the educational institution's catalog and included in the approval notice provided by the State approving agency to VA in accordance with § 21.4258(b)(iv).

Pursuit means to work, during a certified enrollment period, towards the objective of a program of education. This work must be in accordance with approved institutional policy and applicable criteria of title 38 of the U.S.

Code, and must be necessary to reach the program's objective.

Rate of pursuit means the measurement obtained by dividing the number of course hours (or the equivalent hours as determined in § 21.9750) that an individual is pursuing, including hours applied to refresher, remedial, and deficiency courses, by the number of hours considered to be full-time training at the educational institution. The resulting percentage (rounded to the nearest hundredth) will be the individual's rate of pursuit not to exceed 100 percent. For the purpose of this subpart, VA will consider any rate of pursuit higher than 50 percent to be more than one-half time training. *Transferor* means an individual who is entitled to educational assistance under the Post-9/11 GI Bill based on his or her own active duty service and who is approved by the military department to transfer all or a portion of his or her entitlement to one or more dependents.

(b)(1) The *Academic year* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a);

(2) The *Active Duty* definition in this section issued under the authority of 38 U.S.C. 101(21)(A), 3301(1), 3311(d), 3322(b), (c); Public Law 111-377, 124 Stat. 4107-4108;

(3) The *Advance payment* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(d);

(4) The *Course* definition in this section issued under the authority of 38 U.S.C. 3323(c);

(5) The *Distance learning* definition in this section issued under the authority of 20 U.S.C. 1003(7); 38 U.S.C. 3323(c);

(6) The *Educational assistance* definition in this section issued under the authority of 38 U.S.C. 3313;

(7) The *Educational institution* definition in this section issued under the authority of 38 U.S.C. 3323(a);

(8) The *Enrollment period* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(g);

(9) The *Entry level and skill training* definition in this section issued under the authority of 38 U.S.C. 3301(2);

(10) The *Fees* definition in this section issued under the authority of 38 U.S.C. 501(a), 3323(c);

(11) The *Fugitive felon* definition in this section issued under the authority of 38 U.S.C. 3323(c), 5313B;

(12) The *Institution of higher learning (IHL)* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3313(b), 3323(a), 3452(f);

(13) The *Lump sum payment* definition in this section issued under the authority of 38 U.S.C. 3323(c);

(14) The *Mitigating circumstances* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a)(1);

(15) The *Net cost* definition in this section issued under the authority of 38 U.S.C. 3313, 3323(c);

(16) The *Non-public institution* definition in this section issued under the authority of 38 U.S.C. 3323(c);

(17) The *Program of education* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3301, 3323(a), 3452(b);

(18) The *Pursuit* definition in this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(g);

(19) The *Rate of pursuit* definition in this section issued under the authority of 38 U.S.C. 3323, 3680;

(20) The *Transferor* definition in this section issued under the authority of 38 U.S.C. 3319.

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900-0154.)

■ 25. Revise § 21.9520 to read as follows:

§ 21.9520 Basic eligibility.

An individual may establish eligibility for educational assistance under 38 U.S.C. chapter 33, if he or she—

(a) Serves on active duty after September 10, 2001, for a minimum of 90 aggregate days, excluding entry level and skill training (to determine when entry level and skill training may be included in the total creditable length of service, *see* § 21.9640(a) or § 21.9641(a), whichever is applicable) and, after completion of such service—

(1) Continues on active duty;

(2) Is discharged from service with an honorable discharge;

(3) Is released from service characterized as honorable and placed on the retired list, temporary disability retired list, or transferred to the Fleet Reserve or the Fleet Marine Corps Reserve;

(4) Is released from service characterized as honorable for further service in a reserve component; or

(5)(i) Before January 4, 2011, is discharged or released from service for:

(A) A medical condition that preexisted such service and is not determined to be service-connected;

(B) Hardship, as determined by the Secretary of the military department concerned; or

(C) A physical or mental condition that interfered with the individual's

performance of duty but was not characterized as a disability and did not result from the individual's own misconduct;

(ii) On or after January 4, 2011, is discharged or released from service with an honorable discharge for:

(A) A medical condition that preexisted such service and is not determined to be service-connected;

(B) Hardship, as determined by the Secretary of the military department concerned; or

(C) A physical or mental condition that interfered with the individual's performance of duty but was not characterized as a disability and did not result from the individual's own misconduct;

(b) Serves on active duty after September 10, 2001, for a minimum of 30 continuous days and, after completion of such service, is discharged from active duty under other than dishonorable conditions due to a service-connected disability; or

(c)(1) After meeting the minimum service requirements in paragraph (a) or (b) of this section—

(i) An individual makes an irrevocable election to receive benefits under 38 U.S.C. chapter 33 by relinquishing eligibility under either 38 U.S.C. chapter 30, or 10 U.S.C. chapter 106a, 1606, or 1607, if eligible for such benefits;

(ii) A member of the Armed Forces who is eligible for educational assistance under 38 U.S.C. chapter 30 and who is making contributions towards educational assistance under 38 U.S.C. chapter 30 in accordance with 38 U.S.C. 3011(b) or 3012(c) makes an irrevocable election to receive benefits under 38 U.S.C. chapter 33; or

(iii) A member of the Armed Forces who made an election not to receive educational assistance under 38 U.S.C. chapter 30 in accordance with 38 U.S.C. 3011(c)(1) or 3012(d)(1) makes an irrevocable election to receive benefits under 38 U.S.C. chapter 33.

(2) An individual may make an irrevocable election to receive benefits under this chapter by properly completing VA Form 22-1990, submitting a transfer-of-entitlement designation under this chapter to the Department of Defense, or submitting a written statement that includes the following—

(i) Identification information (including name, social security number, and address);

(ii) If applicable, an election to receive benefits under 38 U.S.C. chapter 33 in lieu of benefits under one of the applicable chapters listed in paragraph (c)(1)(i) of this section (e.g., "I elect to

receive benefits under the Post-9/11-GI Bill in lieu of benefits under the Montgomery GI Bill—Active Duty (chapter 30) program.”);

(iii) The date the individual wants the election to be effective (e.g., “I want this election to take effect on August 1, 2009.”). An election request for an effective date prior to August 1, 2009, will automatically be effective August 1, 2009; and

(iv) An acknowledgement that the election is irrevocable (e.g., “I understand that my election is irrevocable and may not be changed.”); or

(d) Is the child of a person who, after September 10, 2001, died in the line of duty while serving on active duty as a member of the Armed Forces. For purposes of this paragraph (d), the term “child” means an individual who meets the requirements of § 3.57 of this chapter, except as to age and marital status. With regard to age and marital status, the term includes individuals who are—

(1) Married; or

(2) Over the age of 23.

(e) Paragraphs (a) through (d) of this section issued under the authority of 38 U.S.C. 3311; Public Law 110–252, 111–32, Stat. 1859, 2375–2376.

(The Office of Management and Budget has approved the information collection provision in this section under control numbers 2900–0154 and 2900–0098.)

§ 21.9525 [Amended]

■ 26. Amend § 21.9525 by removing “under § 21.9640(b)(1)(ii) or (b)(2)(ii)” wherever it appears and adding in its place “under § 21.9640(b)(1)(ii) or (b)(2)(ii) or § 21.9641(c)”.

■ 27. Amend § 21.9530 by:

■ a. In paragraph (a), removing “through (e)” and adding in its place “through (f)”;

■ b. Removing the parenthetical authority citation at the end of paragraphs (c) through (e);

■ c. Adding paragraphs (f) and (g); and

■ d. Adding at the end of the section a parenthetical with the OMB control number for the approval of the information collection.

The additions read as follows:

§ 21.9530 Eligibility time limit.

* * * * *

(f) *Time limit for child eligible under § 21.9520(d) (Marine Gunnery Sergeant John David Fry Scholarship).* (1) In the case of a child who first becomes entitled to educational assistance under § 21.9520(d) before January 1, 2013, the period during which the child may use his or her entitlement expires the day the child turns 33; or

(2) In the case of a child who first becomes entitled to educational assistance under § 21.9520(d) on or after January 1, 2013, the period during which the child may use his or her entitlement never expires.

(g) *Authority.* (1) Paragraphs (a) through (c) of this section issued under the authority of 38 U.S.C. 3311(c), 3321;

(2) Paragraph (d) of this section issued under the authority of 38 U.S.C. 3319;

(3) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3319; and

(4) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3321(b).

(The Office of Management and Budget has approved the information collection provision in this section under control number 2900–0098.)

■ 28. Revise § 21.9550 to read as follows:

§ 21.9550 Entitlement.

(a) Subject to the provisions of § 21.4020 and this section, an eligible individual is entitled to a maximum of 36 months of educational assistance (or its equivalent in part-time educational assistance) under 38 U.S.C. chapter 33.

(b)(1) An individual who, as of August 1, 2009, has used entitlement under 38 U.S.C. chapter 30, but retains unused entitlement under that chapter, makes an irrevocable election to receive educational assistance under the provisions of 38 U.S.C. chapter 33 instead of educational assistance under the provisions of chapter 30, will be limited to one month (or partial month) of entitlement under chapter 33 for each month (or partial month) of unused entitlement under chapter 30 (including any months of chapter 30 entitlement previously transferred to a dependent that the individual has revoked).

(2) An individual who has not used any entitlement under 38 U.S.C. chapter 30 or has not revoked any months of chapter 30 entitlement by transferring to a dependent and who makes an irrevocable election to receive educational assistance under the provisions of 38 U.S.C. chapter 33 instead of educational assistance under the provisions of chapter 30 will be entitled to 36 months of educational assistance under chapter 33.

(c) Except as provided in §§ 21.9560(d), 21.9561(g), 21.9570(m), 21.9571(m), 21.9635(o), and 21.9636(o), no individual is entitled to more than 36 months of full-time educational assistance under 38 U.S.C. chapter 33.

(Authority: 38 U.S.C. 3034(a), 3312(a), 3323(a), 3695; Pub. L. 110–252, 122 Stat. 2377)

■ 29. Amend § 21.9560 by revising the section heading and adding introductory text to read as follows:

§ 21.9560 Entitlement charges—for provisions effective before August 1, 2011.

For training that occurs before August 1, 2011—

* * * * *

■ 30. Add § 21.9561 to read as follows:

§ 21.9561 Entitlement charges—for provisions effective after July 31, 2011.

For training that begins after July 31, 2011—

(a) *Training pursued at an IHL.* The entitlement charge for an individual pursuing training at an IHL will be one of the following:

(1) During any period for which VA pays net costs or a Yellow Ribbon Program payment to the institution of higher learning on the individual's behalf, the individual will be charged a percentage of a day equal to the individual's rate of pursuit for each day of the certified enrollment period;

(2) During any period for which VA does not pay net costs or a Yellow Ribbon Program payment to the institution of higher learning on the individual's behalf but pays a monthly housing allowance or an increase (“kicker”) to the individual, the individual will be charged a percentage of a day equal to the individual's rate of pursuit for each day of the certified enrollment period for each day the individual received a monthly housing allowance or an increase (“kicker”); and

(3) During any period for which VA does not pay net costs or Yellow Ribbon Program payment to the institution of higher learning on the individual's behalf or a monthly housing allowance or an increase (“kicker”) to the individual but makes a lump sum payment to the individual for books, supplies, equipment, and other educational costs, VA will make an entitlement charge of 1 day for every \$41.67 paid, with any remaining amount rounded to the nearest amount evenly divisible by \$41.67.

(b) *Training pursued at a non-college degree institution.* The entitlement charge for an individual pursuing a certificate or other non-college degree at a non-college degree institution will be one of the following:

(1) During any period for which VA pays tuition and fees to the non-college degree institution on the individual's behalf, the individual will be charged entitlement equal to the number of months, and fraction thereof measured in days, determined by dividing the total amount paid by the amount equal to 1/12th of the amount applicable in

the academic year in which payment is made under § 21.9641(b)(3)(ii) or (iii).

(2) During any period for which VA does not pay net costs to the non-college degree institution on the individual's behalf but pays a monthly housing allowance or an increase ("kicker") to the individual, the individual will be charged a percentage of a day equal to the individual's rate of pursuit for each day of the certified enrollment period for each day the individual received a monthly housing allowance or an increase ("kicker").

(3) During any period for which VA does not pay net costs to the non-college degree institution on the individual's behalf or a monthly housing allowance or an increase ("kicker") to the individual but makes a lump sum payment to the individual for books, supplies, equipment, and other educational costs, VA will make an entitlement charge of 1 day for every \$41.67 paid, with any remaining amount rounded to the nearest amount evenly divisible by \$41.67.

(c) *Apprenticeship or other on-the-job training.* For each month an individual is paid educational assistance while pursuing an approved apprenticeship or other on-the-job training program, VA will make a charge against entitlement of—

(1) During the first 6-month period of the program, 1 month for each month of training pursued.

(2) During the second 6-month period of the program, .80 of a month for each month of training pursued.

(3) During the third 6-month period of the program, .60 of a month for each month of training pursued.

(4) During the fourth 6-month period of the program, .40 of a month for each month of training pursued.

(5) After the first 24 months of the program, .20 of a month for each month of training pursued.

(d) *Flight training.* An individual pursuing a non-college degree program consisting of flight training will be charged entitlement equal to the number of months, and fraction thereof measured in days, determined by dividing the total amount paid by 1/12th of the amount applicable in the academic year in which payment is made under § 21.9641(b)(5)(ii) or (iii).

(e) *Correspondence training.* An individual pursuing a program of education by correspondence will be charged entitlement equal to the number of months, and fraction thereof measured in days, determined by dividing the total amount paid by 1/12th of the amount applicable in the academic year in which payment is made under § 21.9641(b)(6)(ii) or (iii).

(f) *Licensing or certification tests and national tests.* When an individual receives educational assistance for taking an approved licensing or certification test, national test for admission, or national test for credit, VA will make a charge against entitlement for each payment made to him or her. The charge will be determined by—

(1) Dividing the total amount of the payment by—

(i) For the academic year beginning August 1, 2011, \$1460; or

(ii) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h) (but for a licensing or certification test the amount will not be greater than \$2,000); and

(2)(i) For tests taken prior to August 1, 2018, rounding the result of paragraph (f)(1) of this section to the nearest whole month. The charge must be at least one month.

(ii) For test taken on or after August 1, 2018, multiplying the result of paragraph (f)(1) of this section by 30, rounding to the nearest whole day. The charge must be at least one day.

(g) *No entitlement charge.* VA will not make a charge against an individual's entitlement—

(1) For tutorial assistance as provided under § 21.9685; or

(2) For the rural relocation benefit as provided under § 21.9660; or

(3) For receipt of a work-study allowance as provided under § 21.4145.

(4) For pursuit of a course or courses when the individual—

(i) Had to discontinue the course or courses as a result of being—

(A) Ordered to active duty service under 10 U.S.C. 688, 12301(a), 12301(d), 12301(g), 12302, or 12304; or

(B) While on active duty service, ordered to a new duty location or assignment or to perform an increased amount of work; and

(ii) Did not receive credit or lost training time for any portion of the period of enrollment in the course or courses for which the eligible individual was pursuing to complete his or her approved educational, professional, or vocational objective as a result of having to discontinue pursuit.

(h) *Interruption to conserve entitlement.* An individual may not interrupt a certified period of enrollment for the purpose of conserving entitlement. An educational institution may not certify a period of enrollment for a fractional part of the normal term, quarter, or semester if the individual is enrolled for the entire term, quarter, or semester. VA will make

a charge against entitlement for the entire period of certified enrollment, if the individual is otherwise eligible for educational assistance, except when educational assistance is interrupted for any of the following conditions:

(1) Enrollment is terminated;

(2) The individual cancels his or her enrollment for the entire certified period of enrollment; or

(3) The individual requests interruption or cancellation for any break when the school was closed during a certified period of enrollment, and VA continued payments under an established policy based upon an Executive Order of the President or an emergency situation regardless of whether or not the individual received a payment for educational assistance provided under this chapter for any part of the certified enrollment period.

(i) *Overpayment cases.* VA will make a charge against entitlement for an overpayment only if the overpayment is discharged in bankruptcy, is waived and not recovered, or is compromised.

(1) If the overpayment is discharged in bankruptcy or is waived and not recovered, the charge against entitlement will be the appropriate rate for the elapsed period covered by the overpayment (exclusive of interest, administrative costs of collection, court costs and marshal fees).

(2) If the overpayment is compromised and the compromise offer is less than the amount of interest, administrative costs of collection, court costs and marshal fees, the charge against entitlement will be at the appropriate rate for the elapsed period covered by the overpayment (exclusive of interest, administrative costs of collection, court costs and marshal fees).

(3) If the overpayment is compromised and the compromise offer is equal to or greater than the amount of interest, administrative costs of collection, court costs and marshal fees, the charge against entitlement will be determined by—

(i) Subtracting from the sum paid in the compromise offer the amount attributable to interest, administrative costs of collection, court costs and marshal fees;

(ii) Subtracting the remaining amount of the overpayment balance as determined in paragraph (i)(3)(i) of this section from the amount of the original overpayment (exclusive of interest, administrative costs of collection, course costs and marshal fees);

(iii) Dividing the result obtained in paragraph (i)(3)(ii) of this section from the amount of the original overpayment (exclusive of interest, administrative

costs of collection, court costs and marshal fees); and

(iv) Multiplying the percentage obtained in paragraph (i)(3)(iii) of this section by the amount of entitlement otherwise chargeable for the period of the original overpayment.

(j) *Authority.* (1) Paragraphs (a) through (f) of this section issued under the authority of 38 U.S.C. 3315, 3315A; (2) Paragraph (g)(1) of this section issued under the authority of 38 U.S.C. 3314;

(3) Paragraph (g)(2) of this section issued under the authority of 38 U.S.C. 3318;

(4) Paragraph (g)(3) of this section issued under the authority of 38 U.S.C. 3485;

(5) Paragraph (g)(4) of this section issued under the authority of 38 U.S.C. 3312(c);

(6) Paragraph (h) of this section issued under the authority of 38 U.S.C. 3323(c); and

(7) Paragraph (i) of this section issued under the authority of 38 U.S.C. 3034(a), 38 U.S.C. 3323(a), 3685.

■ 31. Amend § 21.9570 by:

■ a. Revising the section heading;

■ b. In the introductory text, removing “An individual” and adding in its place “For training that occurs before August 1, 2011, an individual”;

■ c. Adding a parenthetical with the OMB control number for the approval of the information collection at the end of the section.

The revision and addition read as follows:

§ 21.9570 Transfer of entitlement—for provisions effective before August 1, 2011.

* * * * *

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900-0154.)

■ 32. Add § 21.9571 to read as follows:

§ 21.9571 Transfer of Entitlement—for provisions effective after July 31, 2011.

For training that occurs after July 31, 2011, an individual entitled to educational assistance under 38 U.S.C. chapter 33 based on his or her own service as a member of the Uniformed Services, and who is approved by a service department to transfer entitlement, may transfer up to a total of 36 months of his or her entitlement to a dependent (or among dependents). A transferor may not transfer an amount of entitlement that is greater than the entitlement he or she has available at the time of transfer.

(a) *Application of sections in subpart P to individuals in receipt of transferred entitlement.* In addition to the rules in

this section, the following sections apply to a dependent using transferred entitlement in the same manner as they apply to the individual from whom entitlement was transferred.

(1) *Definitions.* Section 21.9506—Definitions—for provisions effective after July 31, 2011.

(2) *Claims and applications.* Section 21.9510—Claims, VA’s duty to assist, and time limits.

(3) *Eligibility.* (i) Section 21.9530—Eligibility time limit, paragraphs (d) and (e) of this section only; and

(ii) Section 21.9535—Extended period of eligibility, except that extensions to dependents are subject to the transferor’s right to revoke or modify transfer at any time and that VA may only extend a child’s ending date to the date the child attains age 26.

(4) *Entitlement.* (i) Section 21.9550—Entitlement;

(ii) Section 21.9561—Entitlement charges—for provisions effective after July 31, 2011.

(5) *Counseling.* (i) Section 21.9580—Counseling;

(ii) Section 21.9585—Travel expenses.

(6) *Approved programs of education and courses.* (i) Section 21.9591—Approved programs of education and courses—for provisions effective after July 31, 2011;

(ii) Section 21.9601—Overcharges—for provisions effective after July 31, 2011.

(7) *Payments—Educational assistance.* (i) Section 21.9620—Educational assistance;

(ii) Section 21.9626—Beginning dates—for provisions effective after July 31, 2011, except for paragraphs (e), (g), (h), (k), or (l) of this section;

(iii) Section 21.9630—Suspension or discontinuance of payments;

(iv) Section 21.9636—Discontinuance dates—for provisions effective after July 31, 2011, except for paragraphs (o) and (v) of this section;

(v) Section 21.9660—Rural relocation benefit;

(vi) Section 21.9667—Reimbursement for licensing or certification tests—for provisions effective after July 31, 2011;

(vii) Section 21.9668—Reimbursement for national tests;

(viii) Section 21.9670—Work-study allowance;

(ix) Section 21.9676—Conditions that result in reduced rates or no payment—for provisions effective after July 31, 2011;

(x) Section 21.9681—Certifications and release of payments—for provisions effective after July 31, 2011;

(xi) Section 21.9685—Tutorial assistance;

(xii) Section 21.9691—Nonduplication of educational

assistance—for provisions effective after July 31, 2011;

(xiii) Section 21.9695—Overpayments, except that the dependent and transferor are jointly and severally liable for any amount of overpayment of educational assistance to the dependent; and

(xiv) Section 21.9700—Yellow Ribbon Program.

(8) *Pursuit of courses.* (i) Section 21.9710—Pursuit;

(ii) Section 21.9715—Advance payment certification;

(iii) Section 21.9721—Certification of enrollment—for provisions effective after July 31, 2011;

(iv) Section 21.9725—Progress and conduct;

(v) Section 21.9735—Other required reports;

(vi) Section 21.9740—False, late, or missing reports; and

(vii) Section 21.9745—Reporting fee.

(9) *Course assessment.* Section 21.9750—Course measurement.

(10) *Administrative.* Section 21.9770—Administrative.

(b) *Eligible dependents.* (1) An individual transferring entitlement under this section may transfer entitlement to:

(i) The individual’s spouse;

(ii) One or more of the individual’s children; or

(iii) A combination of the individuals referred to in paragraphs (b)(1)(i) and (ii) of this section.

(2) A spouse must meet the definition of spouse in § 3.50(a) of this chapter at the time of transfer.

(3) A child must meet the definition of child in § 3.57 of this chapter at the time of transfer. The transferor must make the required designation shown in paragraph(d)(1) of this section before the child attains the age of 23.

(4) A stepchild, who meets VA’s definition of child in § 3.57 of this chapter at the time of transfer and who is temporarily not living with the transferor, remains a member of the transferor’s household if the actions and intentions of the stepchild and transferor establish that normal family ties have been maintained during the temporary absence.

(c) *Timeframe during which an individual may transfer entitlement.* An individual approved by his or her department to transfer entitlement may do so at any time while serving as a member of the uniformed services, subject to the transferor’s 15-year period of eligibility as provided in § 21.9530.

(d) *Designating dependents; designating the amount to transfer; and period of transfer.* (1) An individual transferring entitlement under this section must:

(i) Designate the dependent or dependents to whom such entitlement is being transferred;

(ii) Designate the number of months of entitlement to be transferred to each dependent; and

(iii) Specify the beginning date and ending date of the period for which the transfer is effective for each dependent. The designated beginning date may not be earlier than the date the individual requests approval from his or her service department.

(2) VA will accept the transferor's designations as shown on any document signed by the transferor that shows the information required in paragraphs (d)(1)(i) through (iii) of this section.

(e) *Maximum months of entitlement transferable.* (1) The maximum amount of entitlement a transferor may transfer is the lesser of:

(i) Thirty-six months of his or her entitlement; or

(ii) The maximum amount authorized by the Secretary of the department concerned; or

(iii) The amount of entitlement he or she has available at the time of transfer.

(2) The transferor may transfer up to the maximum amount of transferable entitlement:

(i) To one dependent; or

(ii) Divided among his or her designated dependents in any manner he or she chooses.

(f) *Revocation of transferred entitlement.* (1) A transferor may revoke any unused portion of transferred entitlement (transferred entitlement is "used" in the amount of the entire enrollment period on the first day of the enrollment period; therefore, a transferor cannot revoke the entitlement used for an enrollment period after the enrollment period has begun) at any time by submitting a written notice to both the Secretary of Veterans Affairs and the Secretary of the department concerned that initially approved the transfer of entitlement. VA will accept a copy of the written notice addressed to the Secretary of the department concerned as sufficient written notification to VA.

(2) The revocation will be effective the later of—

(i) The date VA receives the notice of revocation; or

(ii) The date the department concerned receives the notice of revocation.

(g) *Modifying a transfer of entitlement.* (1) A transferor may modify the designations he or she made under paragraph (d) of this section at any time, except that a modification of a beginning date under paragraph (d)(1)(iii) of this section must be

effective on or after the date the modification is submitted. Any modification made will apply only with respect to unused transferred entitlement (transferred entitlement is "used" in the amount of the entire enrollment period on the first day of the enrollment period; therefore, a transferor cannot revoke the entitlement used for an enrollment period after the enrollment period has begun). The transferor must submit a written notice to both the Secretary of Veterans Affairs and the Secretary of the department concerned that initially approved the transfer of entitlement. VA will accept a copy of the written notice addressed to the department as sufficient written notification to VA.

(2) The modification will be effective the later of—

(i) The date VA receives the notice of modification; or

(ii) The date the department concerned receives the notice of modification.

(h) *Prohibition on treatment of transferred entitlement as marital property.* Entitlement transferred under this section may not be treated as marital property, or the asset of a marital estate, subject to division in a divorce or other civil proceeding.

(i) *Entitlement charge to transferor.* VA will reduce the transferor's entitlement at the rate of 1 month of entitlement for each month of transferred entitlement used by a dependent or dependents.

(j) *Secondary school diploma (or equivalency certificate).* Children who have reached age 18 and spouses may use transferred entitlement to pursue and complete the requirements of a secondary school diploma (or equivalency certificate).

(k) *Rate of payment of educational assistance.* VA will apply the rules in § 21.9641 (and §§ 21.9650 and 21.9655 when applicable) to determine the educational assistance rate that would apply to the transferor. VA will pay the dependent and/or the dependent's institution of higher learning (or school, educational institution, or institution as defined in § 21.4200(a) if the dependent is using transferred entitlement to pursue and complete the requirements of a secondary school diploma or equivalency certificate) the amounts of educational assistance payable under 38 U.S.C. chapter 33 in the same manner and at the same rate as if the transferor were enrolled in the dependent's program of education, except that VA will—

(1) Disregard the fact that either the transferor or the dependent child is (or

both are) on active duty, and pay the veteran rate to a dependent child;

(2) Pay the veteran rate to a surviving spouse; and

(3) Proportionally adjust the payment amounts, other than the book stipend, a dependent would otherwise receive under § 21.9641 if the dependent's months of entitlement will exhaust during the certified enrollment period, by—

(i) Determining the amount of payment for the net cost of tuition and fees the dependent would otherwise be eligible to receive for the entire enrollment period, then dividing this amount by the number of days in the dependent's quarter, semester, or term, as applicable, to determine the dependent's daily rate, then determining the actual amount of payment for the net cost of tuition and fees to be paid by multiplying the dependent's daily rate by his or her remaining months and days of entitlement to educational assistance as provided under § 21.9571; and

(ii) Discontinuing the dependent's monthly housing allowance effective as of the date the dependent's months and days of entitlement exhausts.

(l) *Transferor fails to complete required service contract that afforded participation in the transferability program.* (1) Dependents are not eligible for transferred entitlement if the transferor fails to complete the amount of service he or she agreed to serve in the uniformed services in order to participate in the transferability program, unless—

(i) The transferor did not complete the service due to:

(A) His or her death;

(B) A medical condition that preexisted such service on active duty and that the Secretary of the department concerned determines is not service-connected;

(C) A hardship, as determined by the Secretary of the department concerned; or

(D) A physical or mental condition that was not characterized as a disability and did not result from the individual's own willful misconduct but interfered with the individual's performance of duty, as determined by the Secretary of the department concerned; or

(ii) The transferor is considered to have completed his or her service agreement as a result of being discharged for—

(A) A disability; or

(B) A reduction in force.

(2) VA will treat all payments of educational assistance to dependents as overpayments if the transferor does not complete the required service unless the

transferor does not complete the required service due to one of the reasons stated in paragraph (l)(1)(i) of this section or the transferor was not discharged for one of the reasons stated in paragraph (l)(1)(ii) of this section.

(m) *Dependent is eligible for educational assistance under this section and is eligible for educational assistance under 38 U.S.C. chapter 33 based on his or her own service.* Dependents who are eligible for payment of educational assistance through transferred entitlement and are eligible for payment under 38 U.S.C. chapter 33 based on their own active service are not subject to the 48-month limit on training provided for in § 21.4020 when combining transferred entitlement with their own entitlement earned under 38 U.S.C. chapter 33. If the dependent is awarded educational assistance under another program listed in § 21.4020 (other than 38 U.S.C. chapter 33), the 48-month limit on training will apply.

(n) *Authority.* (1) Paragraph (a)(1) through (a)(7)(xiii) of this section issued under the authority of 38 U.S.C. 3319;

(2) Paragraph (a)(7)(xiv) of this section issued under the authority of 38 U.S.C. 3317;

(3) Paragraph (a)(8) through (10) of this section issued under the authority of 38 U.S.C. 3319;

(4) Paragraphs (b) through (k) of this section issued under the authority of 38 U.S.C. 3319;

(5) Paragraph (l) of this section issued under the authority of 38 U.S.C. 3034(a), 3311(c)(4), 3319; and

(6) Paragraph (m) of this section issued under the authority of 38 U.S.C. 3034(a), 3319, 3322, 3323(a), 3695).

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900-0154.)

■ 33. Amend § 21.9590 by revising the section heading and adding introductory text to read as follows:

§ 21.9590 Approved programs of education and courses—for provisions effective before August 1, 2011.

For training that occurs prior to August 1, 2011—

* * * * *

■ 34. Add § 21.9591 to read as follows:

§ 21.9591 Approved programs of education and courses—for provisions effective after July 31, 2011.

For training that begins on or after August 1, 2011—

(a) *Basis for educational assistance payments.* Payments of educational assistance are based on pursuit of a program of education. In order to

receive educational assistance under 38 U.S.C. chapter 33, an eligible individual must—

(1) Be pursuing an approved *program* of education;

(2) Be pursuing refresher, remedial, or deficiency courses as these courses are defined in § 21.7020(b);

(3) Be pursuing other preparatory or special education or training courses necessary to enable the individual to pursue an approved program of education;

(4) Have taken an approved licensing or certification test, national test for admission, or national test for credit for which he or she is requesting reimbursement; or

(5) Be an individual who has taken a course for which the individual received tuition assistance provided under a program administered by the Secretary of a military department under 10 U.S.C. 2007(a) or (c), for which the individual is requesting educational assistance for the amount of tuition and fees not covered by military tuition assistance.

(b) *Approval of the selected program of education.* Subject to paragraph (a) of this section, VA will approve a program of education under 38 U.S.C. chapter 33 selected by the individual if:

(1) The program meets the definition of a program of education in § 21.9506;

(2) Except for a program consisting of a licensing or certification test, a national test for admission, or a national test for credit, the program has an educational, vocational, or professional objective as described in § 21.7020(b)(13) or (22);

(3) The courses, subjects, licensing or certification tests, national tests for admission, or national tests for credit in the program are approved for VA training; and

(4) Except for a program consisting of a licensing or certification test designed to help the individual maintain employment in a vocation or profession, or for a program consisting of a national test for admission or a national test for credit, the individual is not already qualified for the objective of the program.

(c) *Change of program.* In determining whether an individual may change his or her selected program of education, VA will apply the provisions of § 21.4234.

(d) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3313, 3315, 3315A, 3323(a), 3689; and

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3471, 3689.

■ 35. Amend § 21.9600 by revising the section heading and adding introductory text to read as follows:

§ 21.9600 Overcharges—for provisions effective before August 1, 2011.

The provisions of this section apply to enrollment periods that begin before August 1, 2011.

* * * * *

■ 36. Add § 21.9601 to read as follows:

§ 21.9601 Overcharges—for provisions effective after July 31, 2011.

The provisions of this section apply to enrollment periods that begin after July 31, 2011.

(a) *Overcharges by educational institutions may result in the disapproval of enrollments.* VA may disapprove an educational institution for further enrollments if the educational institution charges an individual, or receives from an individual or from VA on behalf of an individual, an amount for tuition and fees that exceeds the tuition and fees that the educational institution requires from similarly circumstanced individuals enrolled in the same course.

(b) *Overcharges by organizations or entities offering licensing or certification tests, national test for admission, or national tests for credit may result in disapproval of tests.* VA may disapprove an organization or entity offering a licensing or certification test, national test for admission, or national test for credit, when the organization or entity offering the test charges an individual, or receives from an individual, an amount for fees that exceeds the fees that the organization or entity requires from similarly circumstanced individuals taking the same test.

(c) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3690(a); and

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3689(d), 3690(a).

■ 37. Revise § 21.9620 to read as follows:

§ 21.9620 Educational assistance.

VA will pay educational assistance for an eligible individual's pursuit of an approved program of education. The eligible individual and/or the individual's educational institution will receive payment amounts in accordance with the formulas listed in §§ 21.9640 and 21.9641.

(Authority: 38 U.S.C. 3313, 3314, 3315, 3316, 3317)

■ 38. Amend § 21.9625 by:

■ a. Revising the section heading;

■ b. In the introductory text, removing “VA will determine” and adding in its

place “For a claim submitted during the period beginning August 1, 2009, and ending July 31, 2011, VA will determine”; and.

■ c. Adding paragraph (m).

The revision and addition read as follows:

§ 21.9625 Beginning dates—for provisions effective before August 1, 2011.

* * * * *

(m) *Fugitive felons.* An award of educational assistance to an otherwise eligible veteran, person, or dependent of a veteran will begin effective the date the individual ceases to be a fugitive felon, as shown by evidence, which may include evidence that a warrant for an offense involving flight is resolved by—

- (1) Arrest;
- (2) Surrendering to the issuing authority;
- (3) Dismissal; or
- (4) Court documents (dated after the warrant for the arrest of the felon) showing the individual is no longer a fugitive.

(5) This paragraph (m) issued under the authority of 38 U.S.C. 3323(c), 5313B.

■ 39. Add § 21.9626 to read as follows:

§ 21.9626 Beginning dates—for provisions effective after July 31, 2011.

For a claim submitted after July 31, 2011, VA will determine the beginning date of an award or increased award of educational assistance under this section. In no case will the beginning date be earlier than August 1, 2009, or for training pursued at non-degree institutions before October 1, 2011. When more than one paragraph in this section applies, VA will award educational assistance using the latest of the applicable beginning dates.

(a) *Entrance or reentrance including change of program or educational institution.* When an eligible individual enters or reenters into training (including a reentrance following a change of program or educational institution), the beginning date of his or her award of educational assistance will be determined as follows:

(1) *For other than a licensing or certification test, a national test for admission, or a national test for credit.*

(i) If the award is an award for the first period of enrollment for which the eligible individual began pursuing his or her program of education, the beginning date will be the latest of—

(A) The date the educational institution certifies under paragraph (b) or (c) of this section;

(B) One year before the date of claim as determined by § 21.1029(b);

(C) The effective date of the approval of the program of education;

(D) One year before the date VA receives approval notice for the program of education.

(ii) If the award is an award for a second or subsequent period of enrollment for which the eligible individual is pursuing a program of education, the effective date of the award will be the latest of—

(A) The date the educational institution certifies under paragraph (b) or (c) of this section;

(B) The effective date of the approval of the program of education; or

(C) One year before the date VA receives the approval notice for the program of education.

(2) *For a licensing or certification test.* VA will award educational assistance for the cost of a licensing or certification test only when the eligible individual takes such test on or after August 1, 2009—

(i) While the test is approved under 38 U.S.C. chapter 36;

(ii) While the individual is eligible for educational assistance under this subpart; and

(iii) When the claim for reimbursement for the cost of the test is submitted within 1 year of the date the test is taken.

(3) *For a national test for admission or a national test for credit.* VA will award educational assistance for the cost of a national test for admission or a national test for credit only when the eligible individual takes such test after July 31, 2011—

(i) While the test is approved under 38 U.S.C. chapter 36;

(ii) While the individual is eligible for educational assistance under this chapter; and

(iii) When claim for reimbursement for the cost of the test is submitted within 1 year of the date the test is taken.

(b) *Certification for program of education offered at an IHL.* (1) When the individual enrolls in a course offered by independent study or distance learning, the beginning date of the award or increased award of educational assistance will be the date the eligible individual begins pursuit of the course according to the regularly established practices of the educational institution.

(2) When the individual enrolls in a resident course, the beginning date of the award or increased award of educational assistance will be the first scheduled date of classes for the term, quarter, or semester in which the eligible individual is enrolled, except as provided in paragraphs (b)(3) through (5) of this section.

(3) When the individual enrolls in a resident course whose first scheduled class begins on or after the eighth calendar day when, according to the school's academic calendar, classes are scheduled to begin for the term, quarter, or semester, the beginning date of the award or increased award of educational assistance allowance will be the actual date of the first class scheduled for that particular course.

(4) When the individual enrolls in a resident course, the beginning date of the award will be the date of reporting provided that—

(i) The published standards of the school require the eligible individual to register before reporting; and

(ii) The published standards of the school require the eligible individual to report no more than 14 days before the first scheduled date of classes for the term, quarter, or semester for which the eligible individual has registered.

(5) When the eligible individual enrolls in a resident course and the first day of classes is more than 14 days after the date of registration, the beginning date of the award or increased award of educational assistance will be the first day of classes.

(c) *Certification for program of education offered by a non-college degree educational institution.* (1) Except as provided in paragraphs (c)(2) and (3) of this section, when an eligible individual enrolls at a non-college degree educational institution, the beginning date of the award of educational assistance will be the later of—

(i) The date determined in paragraph (b) of this section; or

(ii) October 1, 2011.

(2) When an eligible individual enrolls at a non-degree educational institution for a program of education that is offered by correspondence, the beginning date of the award of educational assistance will be the later of—

(i) The date the first lesson was sent;

(ii) The date of affirmation (as defined in § 21.7020(b)(36)); or

(iii) October 1, 2011.

(3) When an individual enrolls in a program of apprenticeship or other on-the-job training, the beginning date of the award of educational assistance will be the later of—

(i) The first date of employment in the training position; or

(ii) October 1, 2011.

(d) *Liberalizing laws and VA issues.* When a liberalizing law or VA issue affects the beginning date of an eligible individual's award of educational assistance, the beginning date will be adjusted in accordance with the facts

found, but not earlier than the effective date of the act or administrative issue.

(e) *Correction of military records.* As determined in § 21.9530, the eligibility of a veteran may arise because the nature of the veteran's discharge or release is changed by appropriate military authority. In these cases, the beginning date of the veteran's educational assistance will be in accordance with facts found, but not earlier than the date the nature of the discharge or release was changed.

(f) *Individuals in a penal institution.* If an eligible individual is not receiving or is receiving a reduced rate of educational assistance under § 21.9675 (based on incarceration in a Federal, State, local, or other penal institution or correctional facility due to a felony conviction), the rate will be increased or assistance will begin effective the earlier of the following:

(1) The date the tuition and fees are no longer being paid under a Federal (other than one administered by VA), State, or local program; or

(2) The date the individual is released from the penal institution or correctional facility.

(g) *Increase ("kicker") based on critical skills or specialty.* If an eligible individual is entitled to an increase ("kicker") in the monthly rate of educational assistance under 38 U.S.C. 3316, the effective date of that increase ("kicker") will be the later of—

(1) The beginning date of an eligible individual's award as determined by paragraphs (a) through (f) of this section; or

(2) The first date on which the eligible individual is entitled to the increase ("kicker") as determined by the Secretary of the military department concerned.

(h) *Increase in percentage of maximum amount payable based on length of active duty service requirements.* If an eligible individual is entitled to an increase in the percentage of the maximum amount of educational assistance payable as a result of meeting additional length of active duty service requirements, the effective date of that increase will be the later of—

(1) The beginning date of the eligible individual's award as determined by paragraphs (a) through (f) of this section; or

(2) The first day of the term, quarter, or semester following the term, quarter, or semester in which the eligible individual becomes entitled to an increase in the percentage of the maximum amount payable.

(i) *Spouse eligible for transferred entitlement.* If a spouse is eligible for transferred entitlement under § 21.9571,

the beginning date of the award of educational assistance will be no earlier than the latest of the following dates—

(1) The date the Secretary of the military department concerned approves the transferor to transfer entitlement;

(2) The date the transferor completes 6 years of service in the Armed Forces;

(3) The date the transferor specified in his or her designation of transfer; or

(4) The date the spouse first meets the definition of spouse in § 3.50(a) of this chapter.

(j) *Child eligible for transferred entitlement.* If a child is eligible for transferred entitlement under § 21.9571, the beginning date of the award of educational assistance will be no earlier than the latest of the following dates—

(1) The date the Secretary of the service department concerned approves the transferor to transfer entitlement;

(2) The date the transferor completes 10 years of service in the Armed Forces;

(3) The date the transferor specified in his or her designation of transfer;

(4) The date the child first meets the definition of child in § 3.57 of this chapter; or

(5) Either—

(i) The date the child completes the requirements of a secondary school diploma (or equivalency certificate); or

(ii) The date the child attains age 18.

(k) *Change in active duty status.* If an individual is released or discharged from active duty during a certified period of enrollment, VA will begin paying the monthly housing allowance:

(1) If released or discharged before August 1, 2018, beginning the 1st day of the month following the date the individual was discharged; or

(2) If released or discharged on or after August 1, 2018, beginning the day following the date the individual was discharged.

(l) *Election to receive benefits under 38 U.S.C. chapter 33.* (1) If an individual makes an election to receive benefits under 38 U.S.C. chapter 33 in lieu of benefits under 10 U.S.C. chapter 106a, 1606, or 1607, or 38 U.S.C. chapter 30 in accordance with § 21.9520(c), VA will begin paying benefits under 38 U.S.C. chapter 33 effective the later of the following—

(i) August 1, 2009;

(ii) The date the individual became eligible for educational assistance under 38 U.S.C. chapter 33;

(iii) One year before the date the valid election request was received; or

(iv) The effective date of the election as requested by the claimant.

(2) If an individual is in receipt of benefits under 38 U.S.C. chapter 31 during a term, quarter, or semester, and

requests to begin receiving benefits under 38 U.S.C. chapter 33 during that term, quarter, or semester, VA will begin paying—

(i) The monthly housing allowance under 38 U.S.C. chapter 33 effective the 1st of the month following the date of the request.

(ii) Net cost of tuition and fees, and the books and supplies stipend, the first day of the following term, quarter, or semester.

(m) *Fugitive felons.* An award of educational assistance to an otherwise eligible veteran, person, or dependent of a veteran will begin effective the date the individual ceases to be a fugitive felon, as shown by evidence, which may include evidence that a warrant for an offense involving flight is resolved by—

(1) Arrest;

(2) Surrendering to the issuing authority;

(3) Dismissal; or

(4) Court documents (dated after the warrant for the arrest of the felon) showing the individual is no longer a fugitive.

(n) *National Guard members' retroactive beginning dates for claims submitted through September 30, 2012.* For any claim received up until September 30, 2012, for retroactive benefits based on service in the National Guard, the beginning date of the award will be the later of either:

(1) the date the National Guard member satisfied the eligibility requirements in § 21.9520 of this title; or

(2) August 1, 2009.

(o) *Child eligible for the Marine Gunnery Sergeant John David Fry Scholarship.* If a child is eligible for entitlement under § 21.9520(d), the beginning date of the award of educational assistance will be no earlier than the earlier of the following dates—

(1) The date the child completes the requirements of a secondary school diploma (or equivalency certificate); or

(2) The date the child attains age 18.

(p) *Authority.* (1) The introductory text of this section issued under the authority of 38 U.S.C. 3313, 3316, 3323(a), 5110, 5111, 5113;

(2) Paragraphs (a) through (a)(1)(ii)(C) of this section issued under the authority of 38 U.S.C. 3034(a), 3313, 3316, 3323(a), 3672, 5103;

(3) Paragraphs (a)(2) and (a)(3) of this section issued under the authority of 38 U.S.C. 3034(a), 3315A, 3323(a), 3452(b);

(4) Paragraphs (b) and (c) of this section issued under the authority of 38 U.S.C. 3313, 3316, 3323;

(5) Paragraph (d) of this section issued under the authority of 38 U.S.C. 3323(c), 5113;

(6) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3323(c);

(7) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3482(g);

(8) Paragraph (g) of this section issued under the authority of 10 U.S.C. 16131(i); 38 U.S.C. 3015(d), 3316(a);

(9) Paragraph (h) of this section issued under the authority of 38 U.S.C. 3311, 3313;

(10) Paragraphs (i) and (j) of this section issued under the authority of 38 U.S.C. 3319;

(11) Paragraph (m) of this section issued under the authority of 38 U.S.C. 3323(c), 5313B; and

(12) Paragraph (o) of this section issued under the authority of Pub. L. 111–32, 123 Stat. 1859.

(The Office of Management and Budget has approved the information collection provision in paragraph (a) of this section under control number 2900–0706 and the information collection provisions in paragraphs (b) and (c) of this section under control numbers 2900–0154, 2900–0178, 2900–0162, 2900–0353, and 2900–0576.)

■ 40. Amend § 21.9635 by:

- a. Revising the section heading;
- b. In the introductory text, removing “The effective date” and adding in its place “During the period beginning August 1, 2009, and ending July 31, 2011, the effective date”;
- c. Revising paragraph (c) and removing the parenthetical authority citation at the end of the paragraph;
- d. Revising paragraph (d) and removing the parenthetical authority citation at the end of the paragraph;
- e. Revising paragraph (w) and removing the parenthetical authority citation at the end of the paragraph;
- f. Removing the parenthetical authority citation at the end of paragraph (bb);
- g. Redesignating paragraph (bb) as paragraph (cc);
- h. Adding new paragraph (bb); and
- g. Revising newly-redesignated paragraph (cc).

The revisions and addition read as follows:

§ 21.9635 Discontinuance dates—for provisions effective before August 1, 2011.

* * * * *

(c) *Withdrawal or unsatisfactory completion of all courses.* If the eligible individual, for reasons other than being called or ordered to active duty service, withdraws from all courses or receives all nonpunitive grades after the first day of the term, VA will terminate educational assistance as follows—

(1) If the eligible individual withdraws from all courses after the school’s drop/add period, and there are no mitigating circumstances, VA will terminate educational assistance

effective the first day of the term from which the eligible individual withdrew.

(2) If the eligible individual withdraws from all courses with mitigating circumstances; withdraws during the school’s drop/add period or within the first 30 days of the enrollment period, whichever is earlier; or withdraws from all courses for which a punitive grade is or will be assigned, VA will terminate educational assistance for—

(i) Residence training; effective the last date of attendance; and

(ii) Independent study or distance learning; effective on the official date of change in status under the practices of the educational institution.

(3) When an eligible individual withdraws from an approved correspondence course offered by an educational institution, VA will terminate educational assistance effective the date the last lesson was serviced.

(4) This paragraph (c) issued under the authority of 38 U.S.C. 3323, 3680(a).

(d) *Reduction in the rate of pursuit of a program of education.* If the eligible individual reduces the rate of pursuit by withdrawing from one or more courses in a program of education but continues training in one or more courses, VA will apply the provisions of this paragraph (d).

(1) If the reduction in the rate of pursuit occurs other than on the first date of the term, VA will reduce the eligible individual’s educational assistance effective the end of the month during which the reduction occurred when—

(i) The withdrawal from one or more courses occurs during the school’s drop/add period or within the first 30 days of the enrollment period, whichever is earlier; or

(ii) A nonpunitive grade is assigned for the course from which the eligible individual withdraws and the withdrawal occurs with mitigating circumstances; or

(iii) A punitive grade is assigned for the course from which the eligible individual withdraws.

(2) VA will reduce educational assistance effective the first date of the enrollment in which the reduction occurs when—

(i) The reduction occurs on the first date of the term; or

(ii) A nonpunitive grade is assigned for the course from which the eligible individual withdraws, and—

(A) The eligible individual does not withdraw because he or she is called to active duty service, or in the case of an individual serving on active duty, he or she is not ordered to a new duty

location or assignment, or is not ordered to perform an increased amount of work, and

(B) The withdrawal occurs without mitigating circumstances.

(3) This paragraph (d) issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a).

* * * * *

(w) *Receipt of educational assistance allowance under another educational assistance program.* (1) An individual in receipt of educational assistance under chapter 33 who is also eligible for educational assistance under 10 U.S.C. chapter 106a, 1606, or 1607; 38 U.S.C. chapter 30, 31, 32, or 35; the Hostage Relief Act of 1980; or, effective August 1, 2011, 10 U.S.C. 510, may choose to receive educational assistance under another program.

(2) This paragraph (w) issued under the authority of 38 U.S.C. 3322(a).

* * * * *

(bb) *Fugitive felons.* (1) VA will not award educational assistance to an otherwise eligible Veteran or dependent of an otherwise eligible Veteran for any period during which the Veteran is a fugitive felon. The date of discontinuance of an award of educational assistance to a Veteran who is a fugitive felon or dependent of a Veteran who is a fugitive felon is the date of the warrant establishing that the individual is a fugitive felon or the date otherwise shown by evidence to be the date the individual became a fugitive felon.

(2) This paragraph (bb) issued under the authority of 38 U.S.C. 3323(c), 5313B.

(cc) *Other reasons for discontinuance.*

(1) If an eligible individual’s educational assistance must be discontinued for any reason other than those stated in paragraphs (a) through (bb) of this section, VA will determine the ending date of educational assistance based on the facts found.

(2) This paragraph (cc) issued under the authority of 38 U.S.C. 3323(c), 5112(a), 5113.

■ 41. Add § 21.9636 to read as follows:

§ 21.9636 Discontinuance dates—for provisions effective after July 31, 2011.

The effective date of a reduction or discontinuance of educational assistance that occurs after July 31, 2011, will be as stated in this section. If more than one type of reduction or discontinuance is involved, VA will reduce or discontinue educational assistance using the earliest of the applicable dates.

(a) *Death of eligible individual.* (1) If the eligible individual receives a lump

sum payment for the books and supplies stipend under § 21.9641(d) and dies before the end of the period covered by the lump sum payment, the discontinuance date of educational assistance for the purpose of that lump sum payment will be the last date of the period covered by the lump sum payment.

(2) If the educational institution receives a lump sum payment for tuition and fees under § 21.9641(b) on behalf of an eligible individual and the individual dies before the end of the period covered by the lump sum payment, the discontinuance date for the purpose of that lump sum payment will be the last date of the period covered by the lump sum payment. The educational institution will be required to return to VA any portion of the tuition and fees paid by VA that would normally be refunded to a similarly circumstanced individual according to the regularly established practices of the educational institution.

(3) If the eligible individual receives an advance payment of the monthly housing allowance pursuant to § 21.9681(b)(2) and dies before the period covered by the advance payment ends, the discontinuance date of educational assistance shall be the last date of the period covered by the advance payment.

(4) For all other payments, *e.g.*, monthly housing allowance under § 21.9641(c), if the eligible individual dies while pursuing a program of education, the discontinuance date of educational assistance will be the date of death.

(b) *First instance of withdrawal of course.* In the first instance of a withdrawal from a course or courses for which the eligible individual received educational assistance, VA will consider mitigating circumstances to exist with respect to the withdrawal of a course or courses totaling no more than six semester hours or the equivalent. In determining whether a withdrawal is the first instance of withdrawal, VA will not consider a course or courses dropped during an educational institution's drop-add period in accordance with § 21.4200(l). If mitigating circumstances are considered to exist in accordance with this paragraph (b), VA will terminate or reduce educational assistance effective—

(1) For withdrawals occurring before March 17, 2025 the end of the month during which the withdrawal occurred;

(2) For withdrawals occurring on or after March 17, 2025, the last date of attendance.

(c) *Withdrawal or unsatisfactory completion of all courses.* If the eligible individual, for reasons other than being called or ordered to active duty service, withdraws from all courses or receives all nonpunitive grades after the first day of the term, VA will terminate educational assistance as follows—

(1) If the eligible individual withdraws from all courses after the school's drop/add period, and there are no mitigating circumstances, VA will terminate educational assistance effective the first day of the term from which the eligible individual withdrew.

(2) If the eligible individual withdraws from all courses with mitigating circumstances; withdraws during the school's drop/add period or within the first 30 days of the enrollment period, whichever is earlier; or withdraws from all courses for which a punitive grade is or will be assigned, VA will terminate educational assistance for—

(i) Residence training: effective the last date of attendance; and

(ii) Independent study or distance learning: effective on the official date of change in status under the practices of the educational institution.

(3) When an eligible individual withdraws from an approved correspondence course offered by an educational institution, VA will terminate educational assistance effective the date the last lesson was serviced.

(d) *Reduction in the rate of pursuit of a program of education.* If the eligible individual reduces the rate of pursuit by withdrawing from one or more courses in a program of education but continues training in one or more courses, VA will apply the provisions of this paragraph (d).

(1) If the reduction in the rate of pursuit occurs other than on the first date of the term, VA will reduce the eligible individual's educational assistance effective either the end of the month during which the reduction occurred (in the case of reductions occurring before March 17, 2025), or the last date of attendance (in the case of for reductions occurring on or after March 17, 2025), when—

(i) The withdrawal from one or more courses occurs during the school's drop/add period or within the first 30 days of the enrollment period, whichever is earlier; or

(ii) A nonpunitive grade is assigned for the course from which the eligible individual withdraws and the withdrawal occurs with mitigating circumstances; or

(iii) A punitive grade is assigned for the course from which the eligible individual withdraws.

(2) VA will reduce educational assistance effective the first date of the enrollment in which the reduction occurs when—

(i) The reduction occurs on the first date of the term; or

(ii) A nonpunitive grade is assigned for the course from which the eligible individual withdraws, and—

(A) The eligible individual does not withdraw because he or she is called to active duty service, or in the case of an individual serving on active duty, he or she is not ordered to a new duty location or assignment, or is not ordered to perform an increased amount of work, and

(B) The withdrawal occurs without mitigating circumstances.

(e) *End of course or period of enrollment.* If an eligible individual's course or period of enrollment ends, the effective date of reduction or discontinuance of the individual's award of educational assistance will be the ending date of the course or period of enrollment as certified by the educational institution.

(f) *Nonpunitive grade.* (1) If an eligible individual does not officially withdraw from a particular course and the individual receives a nonpunitive grade for that course, VA will reduce the individual's educational assistance effective the first date of enrollment for the term in which the grade applies unless mitigating circumstances are found.

(2) If an eligible individual does not officially withdraw from a particular course and the individual receives a nonpunitive grade for that course, VA will reduce the individual's educational assistance effective the end of the month during which the student last attended when mitigating circumstances are found.

(3) If an eligible individual receives an incomplete grade for a course or courses, VA will delay creating an overpayment for such course or courses to allow the individual an opportunity to complete the course or courses. However, if the incomplete grade is not replaced with a punitive grade, VA will reduce the individual's educational assistance in accordance with paragraph (f)(1) or (2) of this section effective the earliest of—

(i) The last date permitted by the educational institution to complete the course;

(ii) The date the educational institution permanently assigns a nonpunitive grade; or (iii) One year from

the date the incomplete grade was assigned.

(g) *Discontinued by VA.* If VA discontinues payment to an eligible individual following procedures stated in § 21.4210(d) and (g), the discontinuance date of payment of educational assistance will be—

(1) The date the Director of the VA Regional Processing Office of jurisdiction first suspended payments provided in § 21.4210, if the discontinuance was preceded by suspension; or

(2) The end of the month during which VA made the decision to discontinue payments under § 21.9630 or § 21.4210(d) and (g), if the Director of the VA Regional Processing Office of jurisdiction did not suspend payments before the discontinuance.

(h) *Disapproved by State approving agency.* If a State approving agency disapproves a program of education in which an eligible individual is enrolled, the discontinuance date of payment of educational assistance will be—

(1) For a program of education at an IHL or a non-college degree institution, the end of the course or period of enrollment, as certified by the educational institution, in which the disapproval is effective; or

(2) For an apprenticeship or other on-the-job training program, the end of the program or the end of the academic year, whichever is earlier, in which the disapproval is effective or in which VA receives notice of the disapproval, whichever is later, provided the Director of the VA Regional Processing Office of jurisdiction did not suspend payments before the disapproval.

(i) *Disapproval by VA.* If VA disapproves a program of education in which an eligible individual is enrolled, the discontinuance date of payment of educational assistance will be—

(1) For a program of education at an IHL or a non-college degree institution, the end of the course or period of enrollment, as certified by the educational institution, in which the disapproval is effective; or

(2) For an apprenticeship or other on-the-job training program, the end of the program or the end of the academic year in which the disapproval occurred, whichever is earlier, provided that the Director of the VA Regional Processing Office of jurisdiction did not suspend payments before the disapproval.

(j) *Unsatisfactory progress.* If an eligible individual's progress is unsatisfactory, his or her educational assistance will be discontinued effective the earlier of the following:

(1) The end of the month during which the educational institution

discontinues the eligible individual's enrollment; or

(2) The end of the month during which the eligible individual's progress becomes unsatisfactory according to the educational institution's regularly established standards of progress, conduct, or attendance.

(k) *False or misleading statements.* Payments may not be based on false or misleading statements, claims, or reports. If educational assistance is paid as the result of an individual submitting false or misleading statements, claims, or reports, VA will apply the provisions of §§ 21.4006 and 21.4007 in the same manner as they apply to veterans under 38 U.S.C. chapter 30.

(l) *Conflicting interests (not waived).* If a conflict of interest exists between an officer or employee of VA and an educational institution, or an officer or employee of a State approving agency and an educational institution, as provided in § 21.4005, and VA does not grant a waiver, the discontinuance date of educational assistance will be 30 days after the date of the letter notifying the eligible individual of the conflicting interests.

(m) *Incarceration in prison or other penal institution due to conviction of a felony.* (1) The provisions of this paragraph (m)(1) apply to an eligible individual whose educational assistance must be discontinued or who becomes restricted to payment of educational assistance at a reduced rate under § 21.9676(c) (based on incarceration in a Federal, State, local, or other penal institution or correctional facility due to a felony conviction).

(2) The discontinuance of any monthly payments will be the end of the month during which the eligible individual is incarcerated in a Federal, State, local, or other penal institution or correctional facility or the end date of the enrollment period as certified by the educational institution, whichever is earlier.

(n) *Change in active duty status.* (1) The discontinuance date for an eligible individual who reduces or terminates training as a result of being called or ordered to serve on active duty under section 688, 12301(a), 12301(d), 12301(g), 12302, or 12304 of title 10 of the U.S. Code, or in the case of an individual serving on active duty, being ordered to a new duty location or assignment or to perform an increased amount of work is—

(i) For tuition and fees, the last date of the certified enrollment period;

(ii) For monthly housing allowance, see paragraph (n)(2) of this section; and

(iii) For the "book stipend," the last date of the period covered by the book stipend payment.

(2) If an individual enters active duty during a certified period of enrollment, regardless of whether there is a reduction or termination of training, the discontinuance date for the monthly housing allowance will be—

(A) For entry occurring before August 1, 2018, the end of the month during which the individual entered active; and

(B) For entry occurring on or after August 1, 2018, the date of entry onto active duty.

(o) *Exhaustion of entitlement.* (1) If an individual enrolled in an educational institution that regularly operates on the quarter or semester basis exhausts his or her entitlement under 38 U.S.C. chapter 33, the discontinuance date will be the last day of the quarter or semester in which the entitlement is exhausted.

(2) The ending date for an individual enrolled in a course that is not scheduled on a quarter or semester basis, who exhausts his or her entitlement under 38 U.S.C. chapter 33 after he or she has completed more than half of the course, will be the earlier of the following—

(i) The last day of the course; or

(ii) 12 weeks from the day the entitlement is exhausted.

(3) If an individual enrolled in a course that is not scheduled on a quarter or semester basis exhausts his or her entitlement under 38 U.S.C. chapter 33 before the individual has completed more than half of the course, the effective ending date will be the date the entitlement was exhausted.

(p) *End of period of eligibility.* If an eligible individual is enrolled in an educational institution on the date of expiration of his or her period of eligibility as determined under § 21.9530, the effective ending date will be the day preceding the end of the period of eligibility.

(q) *Required verifications not received after certification of enrollment.* (1) If VA does not receive the required verification of attendance in a timely manner for an eligible individual enrolled in a course or courses at an educational institution in a program of education not leading to a standard college degree, VA will terminate payments effective the last date of the last period for which verification of the eligible individual's attendance was received. If VA later receives the verification, VA will make any adjustment on the basis of the facts found.

(2) If VA does not receive verification of enrollment within 60 days of the first

day of the term, quarter, semester, or course for which the advance payment was made, VA will determine the actual facts and make an adjustment, if required. If the eligible individual failed to enroll, VA will terminate the award of educational assistance effective the beginning date of the enrollment period.

(r) *Administrative or payee error.* (1) When an administrative error or error in judgment by VA, the Department of Defense, or the Department of Homeland Security with respect to the Coast Guard when it is not operating as a service in the Navy, is the sole cause of an erroneous award, the award will be reduced or terminated effective the date of last payment.

(2) When a payee receives an erroneous award of educational assistance as the result of providing false information or withholding information necessary to determine eligibility to the award, the effective date of the reduction or discontinuance will be the effective date of the award, or the day before the act, whichever is later. The date of the reduction or discontinuance will not be before the last date on which the individual was entitled to payment of educational assistance.

(s) *Forfeiture for fraud.* If an eligible individual must forfeit his or her educational assistance due to fraud, the ending date of payment of educational assistance will be the later of—

(1) The effective date of the award; or
(2) The day before the date of the fraudulent act.

(t) *Forfeiture for treasonable acts or subversive activities.* If an eligible individual must forfeit his or her educational assistance due to treasonable acts or subversive activities, the ending date of payment of educational assistance will be the later of—

(1) The effective date of the award; or
(2) The day before the date the individual committed the treasonable act or subversive activities for which the individual was convicted.

(u) *Change in law or VA issue or interpretation.* If there is a change in the applicable law or VA issue, or in VA's application of the law or issue, VA will use the provisions of § 3.114(b) of this chapter to determine the ending date of the eligible individual's educational assistance.

(v) *Reduction following the loss of increase ("kicker") for Selected Reserve service.* If an eligible individual is entitled to an increase ("kicker") in the monthly rate of educational assistance due to service in the Selected Reserve and loses that entitlement, the effective date for the reduction in the monthly

rate payable is the date that the Secretary of the military department concerned determines that the eligible individual is no longer eligible to the increase ("kicker").

(w) *Receipt of educational assistance allowance under another educational assistance program.* An individual in receipt of educational assistance under chapter 33 who is also eligible for educational assistance under 10 U.S.C. chapter 106a, 1606, or 1607; 10 U.S.C. 510; 38 U.S.C. chapter 30, 31, 32, or 35; or the Hostage Relief Act of 1980 may choose to receive educational assistance under another program.

(1) VA will terminate educational assistance under 38 U.S.C. chapter 33 effective the first day of the enrollment period during which the individual requested to receive educational assistance under 10 U.S.C. chapter 106a, 1606, or 1607; 10 U.S.C. 510; 38 U.S.C. chapter 30, 32, or 35; or the Hostage Relief Act of 1980.

(2) For individuals in receipt of benefits under this chapter during a term, quarter, or semester who are requesting to receive benefits under 38 U.S.C. chapter 31, VA will terminate educational assistance under this chapter effective the first day of the subsequent enrollment period.

(3) An eligible individual may only request a change in receipt of benefits from 38 U.S.C. chapter 33 to 38 U.S.C. chapter 31 once per term, quarter, or semester.

(x) *Independent study course loses accreditation.* If the eligible individual is enrolled in a course offered in whole or in part by independent study, and the course loses its accreditation (or the institution of higher learning offering the course loses its accreditation), the date of reduction or discontinuance will be the end of the course or period of enrollment, as certified by the educational institution in which the withdrawal of accreditation occurred.

(y) *Dependent exhausts transferred entitlement.* The ending date of an award of educational assistance to a dependent who exhausts the entitlement transferred to him or her is the date he or she exhausts the entitlement.

(z) *Transferor revokes transfer of entitlement.* If the transferor revokes a transfer of unused entitlement, the date of discontinuance for the dependent's entitlement is the effective date of the revocation of transfer as determined under § 21.9571.

(aa) *Transferor fails to complete additional active duty service requirement.* VA will discontinue each award of educational assistance given to

a dependent, effective the first date of each such award when—

(1) The transferor fails to complete the additional active duty service requirement that afforded him or her the opportunity to transfer entitlement of educational assistance; and

(2) The military department discharges the transferor for a reason other than one of the reasons stated in § 21.9571(l).

(bb) *Fugitive felons.* VA will not award educational assistance to an otherwise eligible Veteran or dependent of an otherwise eligible Veteran for any period during which the Veteran is a fugitive felon. The date of discontinuance of an award of educational assistance to a Veteran who is a fugitive felon or dependent of a Veteran who is a fugitive felon is the date of the warrant establishing that the individual is a fugitive felon or the date otherwise shown by evidence to be the date the individual became a fugitive felon.

(cc) *Other reasons for discontinuance.* If an eligible individual's educational assistance must be discontinued for any reason other than those stated in paragraphs (a) through (bb) of this section, VA will determine the ending date of educational assistance based on the facts found.

(dd) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(d), 3680(e);

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a)(1);

(3) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3323, 3680(a);

(4) Paragraphs (d) and (e) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a);

(5) Paragraph (f) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680;

(6) Paragraph (g) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3690;

(7) Paragraph (h) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3672(a), 3690;

(8) Paragraph (i) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3671(b), 3672(b)(1), 3690;

(9) Paragraph (j) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3474;

(10) Paragraph (k) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3690;

(11) Paragraph (l) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3683;

(12) Paragraph (m) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3482(g);

(13) Paragraph (n) of this section issued under the authority of 38 U.S.C. 3313(j);

(14) Paragraph (o) of this section issued under the authority of 38 U.S.C. 3031(f), 3312, 3321;

(15) Paragraph (p) of this section issued under the authority of 38 U.S.C. 3321;

(16) Paragraph (q) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680;

(17) Paragraph (r) of this section issued under the authority of 38 U.S.C. 3323(c), 5112(b), 5113;

(18) Paragraph (s) of this section issued under the authority of 38 U.S.C. 3323(c), 5112, 6103;

(19) Paragraph (t) of this section issued under the authority of 38 U.S.C. 3323(c), 6104, 6105;

(20) Paragraph (u) of this section issued under the authority of 38 U.S.C. 3323(c), 5112, 5113;

(21) Paragraph (v) of this section issued under the authority of 10 U.S.C. 16131; 38 U.S.C. 3316(a);

(22) Paragraph (w) of this section issued under the authority of 38 U.S.C. 3322(a);

(23) Paragraph (x) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3676, 3680A(a);

(24) Paragraphs (y) through (aa) of this section issued under the authority of 38 U.S.C. 3319;

(25) Paragraph (bb) of this section issued under the authority of 38 U.S.C. 3323(c), 5313B; and

(26) Paragraph (cc) of this section issued under the authority of 38 U.S.C. 3323(c), 5112(a), 5113.

(The Office of Management and Budget has approved the information collection provision in § 21.9636, paragraph (w) under control number 2900–0154.)

■ 42. Amend § 21.9640 by:

■ a. Revising the section heading and introductory text;

■ b. Revising paragraph (a) and removing the parenthetical authority citation at the end of the paragraph;

■ c. Revising paragraph (d) and removing the parenthetical authority citation at the end of the paragraph.

■ d. Removing the parenthetical citation at the end of paragraph (e); and

■ e. Adding paragraph (f).

The revision and addition read as follows:

§ 21.9640 Rates of payment of educational assistance—for provisions effective before August 1, 2011.

For training that occurs before August 1, 2011, unless otherwise noted, VA will determine the amount of educational assistance payable under 38 U.S.C. chapter 33 as provided in this section.

(a) *Percentage of maximum amounts payable.* (1) Except as provided in paragraphs (a)(2) and (d) of this section, VA will apply the applicable percentage of the maximum amounts payable under this section for pursuit of an approved program of education, in accordance with table 1 to paragraph (a).

TABLE 1 TO PARAGRAPH (a)

Aggregate length of creditable active duty service after 09/10/01	Number of days	Percentage of maximum amounts payable
At least 36 months ¹	If aggregate service (<i>including</i> entry training) is 1095 days or more days.	100
At least 30 continuous days		100
(Must be discharged due to service-connected disability)		
At least 30 months, but less than 36 months ¹	If aggregate service (<i>including</i> entry training) is from 910 to 1094 days.	90
At least 24 months, but less than 30 months ^{1 3}	If aggregate service (<i>including</i> entry training) is from 730 to 909 days.	³ 80
At least 18 months, but less than 24 months ^{2 3}	If aggregate service (<i>excluding</i> entry training) is from 545 to 729 days.	³ 70
At least 12 months, but less than 18 months ²	If aggregate service (<i>excluding</i> entry training) is from 365 to 544 days.	60
At least 6 months, but less than 12 months ²	If aggregate service (<i>excluding</i> entry training) is from 180 to 364 days.	50
At least 90 days, but less than 6 months ²	If aggregate service (<i>excluding</i> entry training) is from 90 to 179 days.	40

¹ Includes entry level and skill training.

² Excludes entry level and skill training.

³ The 70/80% rule: If the aggregate service including training is at least 24 months but less than 30 months (730–909 days) BUT the aggregate service excluding training is at least 18 but less than 24 months (545 to 729 days), the individual will be deemed eligible at the 70% benefit level. This limitation is explicitly mandated by 38 U.S.C. 3311(e).

(2) *Amounts payable for individuals eligible for the Marine Gunnery Sergeant John David Fry Scholarship.* VA will apply 100 percent of the maximum amounts payable for pursuit of an approved program of education by an individual who is eligible for educational assistance under § 21.9520(d).

* * * * *

(d) *Amounts payable for individuals on active duty—(1) Amounts payable for programs of education beginning on or*

after August 1, 2009, and on or before March 4, 2011. Individuals on active duty who are pursuing a program of education during a quarter, semester, or term that starts during the period beginning August 1, 2009, and ending March 4, 2011, may receive a lump sum amount for established charges paid directly to the institution of higher learning for the entire term, quarter, or semester, as applicable. The amount payable will be the lowest of—

(i) The established charges that similarly circumstanced nonveterans enrolled in the individual's program of education would be required to pay;

(ii) That portion of the established charges not covered by military tuition assistance under 10 U.S.C. 2007(a) or (b) for which the individual has stated to VA that he or she wishes to receive payment;

(iii) The lesser amount of paragraph (d)(i) or (ii) of this section, divided by the number of days in the individual's

quarter, semester, or term, as applicable, to determine the individual's daily rate which will then be multiplied by the individual's remaining months and days of entitlement to educational assistance in accordance with §§ 21.4020 and 21.9635(o);

(2) *Amounts payable for a program of education, on more than half-time basis, leading to a degree and beginning after March 4, 2011, but before August 1, 2011.* (i) VA may, on behalf of an individual on active duty who is pursuing a program of education leading to a degree on more than half-time basis at a public IHL, issue a lump sum payment for the term, quarter, or semester directly to the IHL equal to the applicable percentage (as listed in paragraph (a) of this section) of the net cost for in-State tuition and fees.

(ii) VA may, on behalf of an individual on active duty who is pursuing a program of education leading to a degree on more than half-time basis at a non-public or foreign IHL, issue a lump sum payment for the term,

quarter, or semester directly to the IHL equal to the lesser of the applicable percentage (as listed in paragraph (a) of this section) of the net cost for tuition and fees assessed by the institution or—

(A) For the academic year beginning August 1, 2011, \$17,500; or

(B) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h).

(3) *Amounts payable for a program of education, on a half-time basis or less, leading to a degree and beginning after March 4, 2011, but before August 1, 2011.* Amounts payable for the individual will be calculated in accordance with paragraph (d)(1) of this section.

(4) *Amounts payable for a program of education not leading to a degree and beginning after March 4, 2011, but before August 1, 2011.* Amounts payable for the individual will be calculated in accordance with paragraph (d)(1) of this section.

(f) *Authority.* (1) Paragraph (a)(1) of this section issued under the authority of 38 U.S.C. 3311, 3313;

(2) Paragraph (d)(2) of this section issued under the authority of 38 U.S.C. 501(a), 3313(e); and

(3) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3313, 3323(c).

■ 43. Add § 21.9641 to read as follows:

§ 21.9641 Rates of payment of educational assistance—for provisions effective after July 31, 2011.

For training that begins after July 31, 2011, unless otherwise noted, VA will determine the amount of educational assistance payable under 38 U.S.C. chapter 33 as provided in this section.

(a) *Percentage of maximum amounts payable.* (1) Except as provided in paragraph (a)(2) of this section, VA will apply the applicable percentage of the maximum amounts payable under this section for pursuit of an approved program of education, in accordance with table 1 to paragraph (a).

TABLE 1 TO PARAGRAPH (A)

Aggregate length of creditable active duty service after 09/10/01	Number of days	Percentage of maximum amounts payable
At least 36 months ¹	If aggregate service (including entry training) is 1095 days or more days.	100
At least 30 continuous days		100
(Must be discharged due to service-connected disability)		
At least 30 months, but less than 36 months ¹	If aggregate service (including entry training) is from 910 to 1094 days.	90
At least 24 months, but less than 30 months ^{1 3}	If aggregate service (including entry training) is from 730 to 909 days.	³ 80
At least 18 months, but less than 24 months ^{2 3}	If aggregate service (excluding entry training) is from 545 to 729 days.	³ 70
At least 12 months, but less than 18 months ²	If aggregate service (excluding entry training) is from 365 to 544 days.	60
At least 6 months, but less than 12 months ²	If aggregate service (excluding entry training) is from 180 to 364 days.	50
At least 90 days, but less than 6 months ²	If aggregate service (excluding entry training) is from 90 to 179 days.	40

¹ Includes entry level and skill training.

² Excludes entry level and skill training.

³ The 70/80% rule: If the aggregate service including training is at least 24 months but less than 30 months (730–909 days) BUT the aggregate service excluding training is at least 18 but less than 24 months (545 to 729 days), the individual will be deemed eligible at the 70% benefit level. This limitation is explicitly mandated by 38 U.S.C. 3311(e).

(2) *Amounts payable for individuals eligible for the Marine Gunnery Sergeant John David Fry Scholarship.* VA will apply 100 percent of the maximum amounts payable for pursuit of an approved program of education by an individual who is eligible for educational assistance under § 21.9520(d).

(b) *Tuition and fees payable.* (1) *Program of education leading to a degree at public IHLs.* After July 31, 2011, VA may, on behalf of an

individual, who may be either on active duty or not on active duty and pursuing a program of education leading to a degree at a public IHL, issue a lump sum payment for the term, quarter, or semester directly to the IHL equal to the applicable percentage (as listed in paragraph (a) of this section) of the net cost for in-State tuition and fees.

(2) *Program of education leading to a degree at non-public IHLs or foreign IHLs.* (i) After July 31, 2011, VA may, on behalf of an individual, who may be

either on active duty or not on active duty and pursuing a program of education leading to a degree at a non-public or foreign IHL, issue a lump sum payment for the term, quarter, or semester directly to the IHL equal to the applicable percentage (as listed in paragraph (a) of this section) of the lesser of—

(A) The actual net cost for tuition and fees assessed by the institution; or

(B) For the academic year beginning August 1, 2011, \$17,500; or

(C) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h).

(3) *Program of education in pursuit of a certificate or other non-college degree at institutions other than IHLs.* On or after October 1, 2011, VA may, on behalf of an individual pursuing a program of education in pursuit of a certificate or other non-college degree at an institution other than an IHL, issue a lump sum payment for the term, quarter, or semester, directly to the educational institution equal to the applicable percentage (as listed in paragraph (a) of this section) of the lesser of—

(i) The actual net cost for in-State tuition and fees assessed by the institution; or

(ii) For the academic year beginning August 1, 2011, \$17,500; or

(iii) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h).

(4) *Full-time program of apprenticeship or other on-the-job training at institutions other than IHLs.* No tuition and fee amount is payable for this type of training.

(5) *Program of education for flight training (regardless of the institution providing such program of education).* After September 30, 2011, upon receipt of certification for training completed by the individual and serviced by the educational institution, on behalf of an individual pursuing a program of education consisting of flight training, VA may issue a lump sum payment directly to the educational institution equal to the applicable percentage (as listed in paragraph (a) of this section) of the lesser of—

(i) The actual net cost for in-State tuition and fees; or

(ii) For the academic year beginning August 1, 2011, \$10,000; or

(iii) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h).

(6) *Program of education pursued exclusively by correspondence at an IHL or institution other than an IHL.* After September 30, 2011, on behalf of an individual pursuing program of education by correspondence at an IHL or institution other than an IHL, VA may issue a quarterly payment on a pro rata basis for the lessons completed by the individual and serviced by the educational institution during such quarter, directly to the educational institution equal to the applicable percentage (as listed in paragraph (a) of this section) of the lesser of—

(i) The net cost for tuition and fees; or
(ii) For the academic year beginning August 1, 2011, \$8,500; or

(iii) For the academic year beginning on any subsequent August 1, the amount for the previous academic year, as increased under 38 U.S.C. 3015(h).

(7) *No reduction in tuition and fee annual cap.* VA will not make a reduction in the tuition and fee maximum amount payable during the academic year equal to the amount of tuition and fees charged for a course or courses from which the individual withdrew when the individual—

(i) Had to discontinue the course or courses as a result of being ordered to—

(A) Active duty service under 10 U.S.C. 688, 12301(a), 12301(d), 12301(g), 12302, or 12304; or

(B) A new duty location or assignment or to perform an increased amount of work; and

(ii) Did not receive credit or lost training time for any portion of the period of enrollment in the course or courses for which the eligible individual was pursuing to complete his or her approved educational, professional, or vocational objective as a result of having to discontinue pursuit.

(c) *Monthly housing allowance payable.* An individual who is pursuing a program of education leading to a degree at a domestic or foreign IHL, a program of education at a non-college degree institution, or an on-the-job or apprenticeship training can receive a monthly stipend (referred to as the “monthly housing allowance”), subject to the applicable percentage (as listed in paragraph (a) of this section), as follows—

(1) *Residence training at domestic IHLs on more than half-time basis.* An individual, other than one on active duty, who is pursuing a program of education with at least one in-residence course and who has a rate of pursuit of greater than 50 percent at an IHL located in a State, may receive a monthly housing allowance for each month (or prorated amount for a partial month) of training during each term, quarter, or semester, equal to—

(i) During the period beginning August 1, 2011, and ending July 31, 2012, the monthly amount of the basic allowance for housing payable under 37 U.S.C. 403 for a member with dependents in pay grade E-5 using the ZIP code area in which all, or a majority, of the IHL in which the individual is enrolled is located multiplied by the lesser of—

(A) 1.0; or

(B) The individual's rate of pursuit, rounded to the nearest tenth.

(ii) On or after August 1, 2012, the monthly amount of the basic allowance for housing payable under 37 U.S.C. 403 for a member with dependents in pay grade E-5 using the ZIP code or location code, whichever is applicable, in which all, or a majority, of the institution in which the individual is enrolled is located multiplied by the lesser of—

(A) 1.0; or

(B) The individual's rate of pursuit, rounded to the nearest tenth.

(2) *Residence training at foreign IHLs on more than half-time basis.* On or after August 1, 2011, an individual, other than one on active duty, who is pursuing a program of education leading to a degree at a foreign IHL with at least one in-residence course and who has a rate of pursuit of greater than 50 percent, may receive a monthly housing allowance for each month (or prorated amount for a partial month) of training during each term, quarter, or semester, equal to the national average of the monthly amount of the basic allowance for housing payable under 37 U.S.C. 403 for a member with dependents in pay grade E-5, multiplied by the lesser of—

(i) 1.0; or

(ii) The individual's rate of pursuit, rounded to the nearest tenth.

(3) *Residence training at non-college degree institutions on more than half-time basis.* After October 1, 2011, an individual, other than one on active duty, who is pursuing a program of education at a non-college degree institution (other than those listed in paragraph (c)(6) of this section) with at least one in-residence course and who has a rate of pursuit of greater than 50 percent, can receive a monthly housing allowance for each month (or a prorated amount for a partial month) of training pursued. The amount will be calculated in accordance with paragraph (c)(1) of this section.

(4) *Training pursued solely via distance learning on more than half-time basis.* After September 30, 2011, an individual, other than one on active duty, who is pursuing a program of education solely via distance learning at a rate of pursuit of greater than 50 percent, can receive a monthly housing allowance for each month (or prorated amount for a partial month) of training during each term, quarter, or semester, equal to 50 percent of the amount payable under paragraph (c)(2) of this section.

(5) *On-the-job and apprenticeship training on full-time basis.* After September 30, 2011, an individual, other than one on active duty, pursuing a full-time program of apprenticeship or other on-the-job training may receive a monthly housing allowance—

(i) During the first 6-month period of the program, the monthly amount of the basic allowance for housing payable under 37 U.S.C. 403 for a member with dependents in pay grade E-5 residing in the military housing area that encompasses all or a majority portion of the ZIP code area in which the employer is located.

(ii) During the second 6-month period of the program, 80 percent of the amount payable in paragraph (c)(5)(i) of this section.

(iii) During the third 6-month period of the program, 60 percent of the amount payable in paragraph (c)(5)(i) of this section.

(iv) During the fourth 6-month period of the program, 40 percent of the amount payable in paragraph (c)(5)(i) of this section.

(v) During any month after the first 24 months of training, 20 percent of the amount payable in paragraph (c)(5)(i) of this section.

(vi) In any month in which an individual pursuing training fails to complete 120 hours of training, the amount of the monthly housing stipend payable will be the amount determined by multiplying the applicable amount as determined by paragraphs (c)(5)(i) through (v) of this section by the figure determined as follows—

(A) The number of hours worked during the month, rounded to the nearest 8 hours; then

(B) Dividing the result by 120.

(C) Rounding the quotient to the nearest hundred.

(6) *Program of education for vocational flight training at institutions other than IHLs; Program of education pursued exclusively by correspondence; Program of education pursued on a half-time basis or less; Program of education pursued while on active duty.* No monthly housing allowance is payable for these types of training.

(7) *Rate payable during the academic year.* The monthly housing allowance payable during each academic year beginning on August 1 of a calendar year under paragraphs (c)(1) through (5) of this section will be determined using the basic allowance for housing rates payable under 37 U.S.C. 403 in effect as of January 1 of each such calendar year.

(8) *Rate protection.* The monthly housing allowance payable under paragraphs (c)(1) through (5) of this section will not decrease as long as the individual—

(i) Has not had a break in training that exceeds 6 months. An individual called to active duty (during an enrollment period or 6-month grace period) will not see a decrease as long as the individual resumes training at the educational

institution within 6 months from the release from active duty; and

(ii) Previously received the monthly housing allowance based on the same type of training (residence, distance, foreign) at the same educational institution. A change in facility (transferring to a different school or a different branch of the same school) constitutes a change in educational institution.

(9) *Concurrent eligibility for more than one monthly housing stipend rate.* In the event that an individual is concurrently eligible for more than one monthly housing stipend rate, the housing stipend will be paid at the highest rate for which the individual qualifies.

(d) *Books, supplies, and equipment stipend payable.* An individual who is pursuing a program of education at an IHL, non-college degree institution, or an individual pursuing on-the-job or apprenticeship training can receive an amount for books, supplies, equipment, and other educational costs (referred to as the “book stipend”), subject to the applicable percentage (as listed in paragraph (a) of this section), as follows—

(1) *Book stipend for training pursued at an IHL.* (i) The maximum amount payable to an individual pursuing training at an IHL is based on pursuit of twenty-four credit hours (the minimum number of credit hours generally considered to be full-time training at the undergraduate level for an academic year). The lump sum payment for each term, quarter, or semester is equal to \$41.67 (\$1,000 divided by 24 credit hours) multiplied by the number of credit hours (or the equivalent number of credit hours if enrollment is reported in clock hours) taken by the individual in the quarter, semester, or term, up to a cumulative total of twenty-four credit hours for the academic year.

(A) Before October 1, 2011, an eligible individual, other than one on active duty, may receive an amount for each credit hour pursued up to twenty-four credit hours (or the equivalent credit hours if enrollment is reported in clock hours) in a single academic year.

(B) On or after October 1, 2011, an eligible individual, including an individual on active duty, may receive an amount for each credit hour pursued up to twenty-four credit hours (or the equivalent credit hours if enrollment is reported in clock hours) in a single academic year.

(ii) In no event may the amount paid during an academic year exceed \$1,000.

(2) *Book stipend for training pursued at a non-college-degree institution and on-the-job or apprenticeship training.*

After September 30, 2011, an individual pursuing a program of education at a non-college degree institution (other than those listed in paragraph (d)(3) of this section) or full-time on-the-job or apprenticeship training can receive a lump sum payment equal to \$83 for each month (or a prorated amount for a partial month) of training pursued.

(3) *Program of education for vocational flight training at institutions other than IHLs and program of education pursued exclusively by correspondence.* No book stipend is payable for these types of training.

(e) *Publication of educational assistance rates.* VA will publish the maximum amount of tuition and fees payable each academic year in the “Notices” section of the **Federal Register** and on the GI Bill website at <https://www.GIBill.va.gov>.

(f)(1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3311(f);

(2) Paragraph (b)(1) of this section issued under the authority of 38 U.S.C. 3313(c)(1)(A)(i);

(3) Paragraph (b)(2) of this section issued under the authority of 38 U.S.C. 3313(c)(1)(A)(ii);

(4) Paragraph (b)(3) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(A);

(5) Paragraph (b)(4) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(B);

(6) Paragraph (b)(5) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(C);

(7) Paragraph (b)(6) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(D);

(8) Paragraph (b)(7) of this section issued under the authority of 38 U.S.C. 501(a), 3323(c);

(9) Paragraph (c)(1) of this section issued under the authority of 38 U.S.C. 3313(c)(1)(B)(i);

(10) Paragraph (c)(2) of this section issued under the authority of 38 U.S.C. 3313(c)(1)(B)(ii);

(11) Paragraph (c)(3) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(A)(ii);

(12) Paragraph (c)(4) of this section issued under the authority of 38 U.S.C. 3313(c)(1)(B)(iii);

(13) Paragraph (c)(5) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(B)(i);

(14) Paragraph (c)(6) of this section issued under the authority of 38 U.S.C. 3313(e), (f), (g)(3)(C), (g)(3)(D);

(15) Paragraph (c)(7) of this section issued under the authority of 38 U.S.C. 3313(i);

(16) Paragraphs (c)(8) and (c)(9) of this section issued under the authority of 38 U.S.C. 501(a), 3323(c);

(17) Paragraphs (d)(1) and (d)(2) of this section issued under the authority of 38 U.S.C. 3313(g)(3)(A), (B);

(18) Paragraph (d)(3) of this section issued under the authority of 38 U.S.C. 3313(c),(e),(f),(g)); and

(19) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3313, 3323(c).

(The Office of Management and Budget has approved the information collection provisions in paragraphs (a) through (b)(7) of this section under control numbers 2900–0154, 2900–0178, 2900–0162, 2900–0353, and 2900–0576.)

■ 44. Amend § 21.9645 by revising paragraphs (a)(1)(iii), (b)(1)(ii), and (c) to read as follows:

§ 21.9645 Refund of basic contribution to chapter 30.

(a)(1) * * *

(iii) He or she is a member of the Armed Forces who is making contributions as provided in § 21.7042(g) towards educational assistance under 38 U.S.C. chapter 30.

* * * * *

(b) * * *

(1) * * *

(ii) 36 for individuals making contributions towards educational assistance under 38 U.S.C. chapter 30 in accordance with § 21.7042(g).

* * * * *

(c) *Timing of payment.* The amount payable under this section will only be issued to the individual who made the contribution when the individual is in receipt of the monthly housing allowance payable under § 21.9640(b) or § 21.9641(c) at the time his or her entitlement exhausts. No payment will be made if the individual who made the contributions is not in receipt of a monthly housing allowance when entitlement exhausts.

* * * * *

■ 45. Amend § 21.9650 by:

■ a. Revising paragraph (a)(2) and removing the parenthetical authority citation at the end of the paragraph;

■ b. Revising paragraph (b)(2)(ii);

■ c. Revising paragraph (b)(3) and removing the parenthetical authority citation at the end of the paragraph;

■ d. Revising paragraph (c)(2)(ii);

■ e. Revision paragraph (c)(3) and removing the parenthetical authority citation at the end of the paragraph; and

■ f. Adding paragraph (d).

The revisions read as follows:

§ 21.9650 Increase in educational assistance.

* * * * *

(a) * * *

(2) The increase (“kicker”) amount payable under paragraph (a)(1) of this

section will only be paid to the individual as part of the monthly housing allowance if the individual is entitled to receive a monthly housing allowance during the term, quarter, or semester—

(i) For the period beginning August 1, 2009, and ending July 31, 2011, under § 21.9640(b)(1)(ii) or (b)(2)(ii); or

(ii) For the period after July 31, 2011, under § 21.9641(c).

(b) * * *

(2) * * *

(ii)(A) For training pursued during the period beginning August 1, 2009, and ending July 31, 2011, the full-time training amount under paragraph (b)(2)(i) of this section multiplied by the individual’s rate of pursuit.

(B) For training pursued after July 31, 2011, the full-time training amount under paragraph (b)(2)(i) of this section multiplied by the lesser of—

(1) 1.0; or

(2) The individual’s rate of pursuit, rounded to the nearest multiple of 10.

(3) The increase (“kicker”) amount payable under paragraph (b) of this section will be paid to the individual—

(i) As a lump sum for the entire quarter, semester, or term, as applicable, based on the monthly amount to which the individual was entitled at the time of the election of chapter 33, if training is pursued during the period beginning August 1, 2009, and ending July 31, 2011; or

(ii) On a monthly basis, for training pursued after July 31, 2011.

(c) * * *

(2) * * *

(ii)(A) For training pursued during the period beginning August 1, 2009, and ending July 31, 2011, the full-time training amount under paragraph (c)(2)(i) of this section multiplied by the individual’s rate of pursuit.

(B) For training pursued after July 31, 2011, the full-time training amount under paragraph (c)(2)(i) multiplied by the lesser of—

(1) 1.0; or

(2) The individual’s rate of pursuit, rounded to the nearest multiple of 10.

(3) The increase (“kicker”) amount payable under paragraph (c) of this section will be paid to the individual—

(i) As a lump sum for the entire quarter, semester, or term, as applicable, based on the monthly amount to which the individual was entitled at the time of the election of chapter 33, if training is pursued during the period beginning August 1, 2009, and ending July 31, 2011; or

(ii) On a monthly basis, for training pursued after July 31, 2011.

(d) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3015(d)(1), 3313(c), 3316(a);

(2) Paragraph (b) of this section issued under the authority of 38 U.S.C.

3015(d), 3316; Public Law 110–252, 122 Stat. 2378, Public Law 111–377, 124 Stat. 4119; and

(3) Paragraph (c) of this section issued under the authority of 10 U.S.C. 16131(i); Public Law 110–252, Stat. 2378).

§ 21.9655 [Amended]

■ 46. Amend § 21.9655, in paragraph (a)(2), by removing “or (b)(2)(ii)” and adding in its place “, (b)(2)(ii), or § 21.9641(c)”.

■ 47. Amend § 21.9665 by revising the section heading and introductory text to read as follows:

§ 21.9665 Reimbursement for licensing or certification tests—for provisions effective before August 1, 2011.

An eligible individual is entitled to receive reimbursement for taking one approved licensing or certification test during the period beginning August 1, 2009, and ending July 31, 2011. The amount of educational assistance VA will pay as reimbursement for an approved licensing or certification test is the lesser of the following:

* * * * *

■ 48. Add § 21.9667 to read as follows:

§ 21.9667 Reimbursement for licensing or certification tests—for provisions effective after July 31, 2011.

An individual eligible for benefits under the Post-9/11 GI Bill is entitled to receive reimbursement for taking any number of approved licensing or certification tests after July 31, 2011. The amount of reimbursement VA will pay for an approved licensing or certification test taken after July 31, 2011, is the least of the following:

(a) The fee that the licensing or certification organization offering the test charges for taking the test;

(b) \$2,000; or

(c) The amount equal to the number of whole months of remaining entitlement available to the individual at the time of payment for the test multiplied by the rate for one month of payment for licensing and tests, as specified in § 21.9561(f)(1)(ii).

(Authority: 38 U.S.C. 3315)

(The Office of Management and Budget has approved the information collection provision in this section under control number 2900–0695.)

■ 49. Add § 21.9668 to read as follows:

§ 21.9668 Reimbursement for national tests.

An eligible individual is entitled to receive reimbursement for taking a national test for admission or a national

test for credit after July 31, 2011. The amount of reimbursement VA will pay for an approved national test for admission or a national test for credit taken after July 31, 2011, is the lesser of the following:

(a) The fee charged for the test, not including any optional costs not required for the testing process; or

(b) The amount equal to the number of whole months of remaining entitlement available to the individual at the time of payment for the test multiplied by the rate for one month of payment for national tests, as specified in § 21.9561(f)(1)(ii).

(Authority: 38 U.S.C. 3315A)

■ 50. Amend § 21.9675 by:

■ a. Revising the section heading and introductory text;

■ b. Removing the parenthetical authority citation at the end of paragraph (a);

■ c. Revising paragraph (c)(2) and removing the parenthetical citation at the end of the paragraph;

■ d. Removing the parenthetical citation at the end of paragraph (d);

■ e. In paragraph (d)(5), removing “veteran-nonveteran” and adding in its place “supported students versus nonsupported students”; and

■ f. Adding paragraph (e).
The revisions and addition read as follows:

§ 21.9675 Conditions that result in reduced rates or no payment—for provisions effective before August 1, 2011.

During the period beginning August 1, 2009, and ending July 31, 2011, the payment rates as established in §§ 21.9640 and 21.9655 will be reduced in accordance with this section whenever the circumstances described in this section arise.

* * * * *

(c) * * *

(2) The amount of educational assistance payable for pursuit of an approved program of education by an eligible individual, as described in this paragraph (c), will be—

(i)(A) The amount equal to any portion of tuition and fees charged for the course that are not paid by a Federal (other than one administered by VA), State, or local program; plus

(B) The amount equal to any charges to the eligible individual for the cost of necessary books, supplies, and equipment not to exceed \$1,000 each academic year.

(ii) The amounts payable under paragraph (c)(2)(i) of this section will be prorated based on the individual's eligibility percentage as determined in § 21.9640(a).

* * * * *

(e) *Authority.* (1) Paragraph (a) of this section issued under the authority of (a) 38 U.S.C. 3034(a), 3323(a), 3680(a);

(2) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3482(g); and

(3) Paragraph (d) of this section issued under the authority of 38 U.S.C. 501(a), 3034(a), 3323(a).

■ 51. Add § 21.9676 to read as follows:

§ 21.9676 Conditions that result in reduced rates or no payment—for provisions effective after July 31, 2011.

After July 31, 2011, the payment rates as established in §§ 21.9641 and 21.9655 will be reduced in accordance with this section whenever the circumstances described in this section arise.

(a) *Withdrawals and nonpunitive grades.* Except as provided in this paragraph (a), VA will not pay educational assistance for an eligible individual's pursuit of a course from which the eligible individual withdraws or receives a nonpunitive grade that is not used in computing the requirements for graduation. VA may pay educational assistance for a course from which the eligible individual withdraws or receives a nonpunitive grade if—

(1) The individual withdraws because he or she is ordered to active-duty service or, in the case of an individual serving on active duty, he or she is ordered to a new duty location or assignment, or ordered to perform an increased amount of work; or

(2) There are mitigating circumstances; and

(i) The eligible individual submits a description of the mitigating circumstances in writing to VA within one year from the date VA notifies the eligible individual that a description is needed, or at a later date if the eligible individual is able to show good cause why the one-year time limit should be extended to the date on which he or she submitted the description of the mitigating circumstances; and

(ii) The eligible individual submits evidence supporting the existence of mitigating circumstances within one year of the date VA requested the evidence, or at a later date if the eligible individual is able to show good cause why the one-year time limit should be extended to the date on which he or she submitted the evidence supporting the existence of mitigating circumstances.

(b) *No monthly housing allowance for some incarcerated individuals.* An individual who is incarcerated in a Federal, State, local, or other penal institution or correctional facility due to a felony conviction will not receive a monthly housing allowance.

(c) *Reduced educational assistance for some incarcerated individuals.* (1) An individual who is incarcerated in a Federal, State, local, or other penal institution or correctional facility due to a felony conviction will receive—

(i) The net costs for tuition and fees not paid by any other form of financial assistance, not to exceed the amounts specified in § 21.9641(b); and

(ii) The amount of necessary books, supplies, and equipment not paid by any other form of financial assistance, not to exceed \$1,000 each academic year.

(2) The amounts payable under paragraph (c)(1) of this section will be prorated based on the individual's eligibility percentage as determined in § 21.9641(a).

(d) *No educational assistance for certain enrollments.* VA will not pay educational assistance for—

(1) An enrollment in an audited course (see § 21.4252(i));

(2) A new enrollment in a course during a period when the approval has been suspended by a State approving agency or VA;

(3) An enrollment in a course by a nonmatriculated student except as provided in § 21.4252(l);

(4) An enrollment in a course certified to VA by the individual taking the course;

(5) A new enrollment in a course which does not meet the supported students versus nonsupported students ratio requirement as computed under § 21.4201; and

(6) An enrollment in a course offered under contract for which VA approval is prohibited by § 21.4252(m).

(e) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(a);

(2) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3482(g); and

(3) Paragraph (d) of this section issued under the authority of 38 U.S.C. 501(a), 3034(a), 3323(a).

■ 52. Amend § 21.9680 by revising the section heading and adding introductory text to read as follows:

§ 21.9680 Certifications and release of payments—for provisions effective before August 1, 2011.

For training pursued during the period beginning August 1, 2009, and ending July 31, 2011—

* * * * *

■ 53. Add § 21.9681 to read as follows:

§ 21.9681 Certifications and release of payments—for provisions effective after July 31, 2011.

For training pursued after July 31, 2011—

(a) *Payee.* (1) VA will make payment of the appropriate amount of tuition and fees, as determined under § 21.9641, directly to the educational institution as a lump sum payment for the entire quarter, semester, or term, as applicable.

(2) VA will make all other payments to the eligible individual or a duly appointed fiduciary. VA will make direct payment to the eligible individual even if he or she is a minor.

(3) The assignment of educational assistance is prohibited. In administering this provision, VA will apply the provisions of § 21.4146 to 38 U.S.C. chapter 33.

(b) *Payments.* (1) VA will pay educational assistance for an eligible individual's enrollment in an approved program (other than one seeking tuition assistance Top-Up; one seeking reimbursement for taking an approved licensing or certification test; one seeking reimbursement for a national test for admission or a national test for credit; or one who qualifies for an advance payment of the monthly housing allowance) only after the educational institution has certified the individual's enrollment as provided in § 21.9721 and provided its Taxpayer Identifying Number (TIN) and/or Automated Clearing House (ACH) information in accordance with 31 U.S.C 7701(c)(1).

(2) VA will apply the provisions of this section in making advance payments of the monthly housing allowance to eligible individuals.

(i) VA will make payments of the monthly housing allowance in advance when:

(A) The eligible individual has specifically requested such a payment;

(B) The individual is enrolled at a rate of pursuit greater than half-time;

(C) The educational institution at which the eligible individual is accepted or enrolled has agreed to and can satisfactorily carry out the provisions of 38 U.S.C. 3680(d)(4)(B), (d)(4)(C), and (d)(5) pertaining to receipt, delivery, and return of checks, and certifications of delivery and enrollment;

(D) The Director of the VA Regional Processing Office of jurisdiction has not acted under paragraph (b)(2)(iv) of this section to prevent advance payments being made to the eligible individual's educational institution;

(E) There is no evidence in the eligible individual's claim file showing that he or she is not eligible for an advance payment;

(F) The period for which the eligible individual has requested a payment is preceded by a period of nonpayment of 30 days or more.

(G) The educational institution or the eligible individual has submitted the certification required by § 21.9715.

(ii) The amount of the advance payment to an eligible individual is the amount payable for the monthly housing allowance for the month or fraction thereof in which the term or course will begin plus the amount of the monthly housing allowance for the following month.

(iii) VA will mail advance payments to the educational institution for delivery to the eligible individual. The educational institution will not deliver the advance payment check more than 30 days in advance of the first date of the enrollment period for which VA makes the advance payment.

(iv) The Director of the VA Regional Processing Office of jurisdiction may direct that advance payments not be made to individuals attending an educational institution if:

(A) The educational institution demonstrates an inability to comply with the requirements of paragraph (b)(2)(iii) of this section;

(B) The educational institution fails to provide adequately for the safekeeping of the advance payment checks before delivery to the eligible individual or return to VA; or

(C) The Director determines, based on compelling evidence, that the educational institution has demonstrated its inability to discharge its responsibilities under the advance payment program.

(3) VA will make a lump sum payment for the entire quarter, semester, or term:

(i) To the educational institution, on behalf of an eligible individual, for the appropriate amount of tuition and fees;

(ii) To an eligible individual for the appropriate amount for books, supplies, equipment, and other educational costs; and

(iii) To an eligible individual entitled to the \$500 rural relocation benefit.

(4) [Reserved]

(5) VA will pay educational assistance to an eligible individual as reimbursement for taking an approved licensing or certification test only after the eligible individual has submitted to VA a copy of his or her official test results and, if not included in the results, a copy of another official form (such as a receipt or registration form) that together must include:

(i) The name of the test;

(ii) The name and address of the organization or entity issuing the license or certificate;

(iii) The date the eligible individual took the test; and

(iv) The cost of the test.

(6) VA will pay educational assistance to an eligible individual as reimbursement for taking an approved national test for admission or a national test for credit only after the eligible individual has submitted a claim for the test to VA that includes the following information:

(i) The name of the test;

(ii) The name of the organization offering the test;

(iii) The date the eligible individual took the test;

(iv) The cost of the test; and

(v) Such other information as the Secretary may require.

(7) VA may authorize payment of the monthly housing allowance (as increased under §§ 21.9650(a) and 21.9655(a), if applicable) for a temporary school closing in accordance with the provisions of § 21.4138(g) of this chapter.

(c) *Rural relocation benefit.* VA will make the \$500 rural relocation benefit payment after—

(1) The educational institution has certified the individual's enrollment as provided in § 21.9721;

(2) The individual has provided—

(i) *Request for benefit.* An individual must submit a request for the rural relocation benefit in writing;

(ii) *Proof of residence.* (A) An individual must provide proof of his or her place of residence by submitting any of the following documents bearing his or her name and current address:

(1) DD Form 214, Certification of Release or Discharge from Active Duty; or

(2) The most recent Federal income tax return; or

(3) The most recent State income tax return; or

(4) Rental/lease agreement; or

(5) Mortgage document; or

(6) Current real property assessment; or

(7) Voter registration card.

(B) An individual using entitlement granted under § 21.9571 who, because he or she resides with the transferor or, in the case of a child, a parent, who cannot provide any of the documents in paragraph (c)(2)(ii) of this section, may submit as proof of residence any document in paragraphs (c)(2)(ii)(A)(2) through (7) of this section bearing the name and current address of the transferor or, in the case of a child, a parent; and

(C) VA must determine that the individual resided in a county (or similar entity utilized by the Bureau of the Census) with less than seven persons per square mile based on the most recent decennial census prior to relocation.

(iii) *Proof of relocation.* An individual must provide proof that he or she either: (A) physically relocated at least 500 miles, confirmed by means of a commonly available internet search engine for mapping upon entering the individual's resident address provided in paragraph (c)(2)(ii) of this section as the beginning point and the address of the educational institution as the ending point; or

(B) traveled by air to physically attend an institution of higher learning for pursuit of such a program of education because the individual could not travel to the educational institution by land due to the absence of road or other infrastructure. An individual must provide airline receipts for travel with a departure and destination airport within reasonable distance from the home of residence and the educational institution.

(d) *Apportionments prohibited.* VA will not apportion educational assistance.

(e) *Accrued benefits.* Educational assistance remaining due and unpaid on the date of the individual's death is payable under the provisions of § 3.1000 of this chapter.

(f) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3034(a), 3313(g), 3323(a), 3680, 5301;

(2) Paragraph (b)(1) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680(g), 3689; 31 U.S.C. 7701(c);

(3) Paragraph (b)(2) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3689;

(4) Paragraphs (b)(3) through (b)(5) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3689;

(5) Paragraph (b)(6) of this section issued under the authority of 38 U.S.C. 3315A;

(6) Paragraph (b)(7) of this section issued under the authority of 38 U.S.C. 3680(a);

(7) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3318;

(8) Paragraph (d) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3680; and

(9) Paragraph (e) of this section issued under the authority of 38 U.S.C. 5121.

(The Office of Management and Budget has approved the information collection provisions in paragraphs (a) through (b)(1) of this section under control number 2900–0073, the information collection provisions in paragraphs (b)(2) through (5) of this section under control numbers 2900–0695 and 2900–0706, and the information collection provisions in paragraph (b)(6) under control numbers 2900–0695, 2900–0698, and 2900–0706.)

■ 54. Amend § 21.9690 by revising the section heading and adding introductory text to read as follows:

§ 21.9690 Nonduplication of educational assistance—for provisions effective before August 1, 2011.

For training pursued during the period beginning August 1, 2009, and ending July 31, 2011—

* * * * *

■ 55. Add § 21.9691 to read as follows:

§ 21.9691 Nonduplication of educational assistance—for provisions effective after July 31, 2011.

For training pursued after July 31, 2011—

(a) *Nonduplication—Concurrent benefits.* Except for receipt of a Montgomery GI Bill-Active Duty kicker provided under 38 U.S.C. 3015(d) or a Montgomery GI Bill-Selected Reserve kicker provided under 10 U.S.C. 16131(i),

(1) An eligible individual is barred from receiving educational assistance under 38 U.S.C. chapter 33 concurrently with educational assistance provided under—

(i) 10 U.S.C. 510 (National Call to Service);

(ii) 10 U.S.C. chapter 1606 (Montgomery GI Bill—Selected Reserve);

(iii) 10 U.S.C. chapter 1607 (Reserve Educational Assistance Program);

(iv) 10 U.S.C. chapter 106a (Section 901, Educational Assistance Test Program);

(v) 38 U.S.C. chapter 30 (Montgomery GI Bill—Active Duty);

(vi) 38 U.S.C. chapter 31 (Veteran Readiness and Employment Program);

(vii) 38 U.S.C. chapter 32 (Post-Vietnam Era Veterans' Educational Assistance);

(viii) 38 U.S.C. chapter 35 (Survivors' and Dependents' Educational Assistance); or

(ix) Hostage Relief Act of 1980.

(2) An individual who is eligible for educational assistance under more than one program listed in paragraph (a)(1) of this section must specify in writing which benefit he or she wishes to receive. The eligible individual may choose to receive payment under another educational assistance program at any time, but may not change which benefit he or she will receive more than once during a term, quarter, or semester.

(b) *Nonduplication—Federal program.* Payment of educational assistance is prohibited to an otherwise eligible reservist—

(1) For a unit course or courses that are being paid for entirely or partly by the Armed Forces during any period in

which he or she is on active duty service; or

(2) For a unit course or courses that are being paid for entirely or partly by the United States under the Government Employees Training Act.

(c) *Nonduplication—Transferred benefits and Fry Scholarship.* An individual entitled to educational assistance under § 21.9520(d) and because of a transfer of entitlement under § 21.9571—

(1) May not receive educational assistance under both provisions concurrently.

(2) Must specify in writing the provision under which he or she wishes to receive benefits. The individual may request to receive benefits under either provision at any time, but may not change the provision under which he or she will receive benefits more than once during a term, quarter, or semester. Except in cases when an individual exhausts entitlement under a provision during a term, quarter, or semester, the request will be effective the beginning date of the enrollment period following the request.

(d) *Nonduplication—Transferred benefits.* An individual who is entitled to educational assistance based on a transfer of entitlement under § 21.9571 from more than one individual—

(i) May not receive assistance based on transfers from more than one individual concurrently.

(ii) Must specify in writing whose entitlement he or she wishes to use at any one time. The individual may request to use benefits transferred to him or her by any of the transferors at any time, but may not change whose entitlement he or she wishes to use from one individual to another more than once during a term, quarter, or semester. Except in cases when an individual exhausts his or her transferred entitlement during a term, quarter, or semester, the request will be effective the beginning date of the enrollment period following the request.

(e) *Nonduplication—Fry Scholarship and compensation and pension.* The commencement of a program of education based on eligibility for educational assistance under § 21.9520(d) by an eligible individual is a bar to—

(1) Subsequent payments of dependency and indemnity compensation or pension based on the death of a parent to the eligible individual when the eligible individual attains 18 years of age.

(2) Increased rates, or additional amounts, of compensation, dependency and indemnity compensation, or

pension paid on account of the eligible individual.

(f) *Nonduplication—Fry Scholarship.*

(1) An individual who is entitled to educational assistance based on the death of more than one parent under § 21.9520(d) may not receive assistance under § 21.9520(d) for the same enrollment period based on the deaths of both parents.

(2) The individual must specify in writing on which parent's death to base his or her entitlement. The individual may request to base entitlement on either parent's death at any time, but may not change on whose death he or she chooses to base entitlement more than once during a term, quarter, or semester. Except in cases where an individual exhausts entitlement that is based on one parent's death during a term, quarter, or semester, the request will be effective the beginning date of the enrollment period following the request.

(g) *Nonduplication—Entitlement based on individual's active duty service.* (1) An individual who is entitled to educational assistance under § 21.9520(a) or (b) and who is entitled to educational assistance under § 21.9520(d) or § 21.9571 may not receive educational assistance based on his or her own period of service and educational assistance based on someone else's service concurrently.

(2) The individual must specify in writing the provision under which he or she wishes to receive benefits. The individual may request to receive benefits under either provision at any time, but may not change the provision under which he or she will receive benefits more than once during a term, quarter, or semester. Except in cases when an individual exhausts entitlement under one provision during a term, quarter, or semester, the request will be effective the beginning date of the enrollment period following the request.

(h) *Nonduplication—Eligibility based on a single event or period of service—*

(1) *Active duty service.* (i) An individual with qualifying active duty service in the Armed Forces that may be used to establish eligibility for educational assistance under 38 U.S.C. chapter 30, 32, or 33, and 10 U.S.C. chapter 1606 or 1607, must make an irrevocable election in writing specifying under which program to establish eligibility and to which program to credit service.

(ii) An individual may not request that portions of a single period of service be credited to different benefit programs. VA considers a single period of service to be one from which the individual is discharged or released,

including a discharge for immediate reenlistment.

(2) *Assistance based on parent's service.* A child eligible for educational assistance under § 21.9520(d) and 38 U.S.C. chapter 35, based on the parent's death must make an irrevocable election in writing specifying which benefit he or she wishes to receive.

(i) *Authority.* (1) Paragraph (a)(1) of this section issued under the authority of 38 U.S.C. 3034(a), 3322, 3323(a), 3681; section 901, Pub. L. 96–342;

(2) Paragraph (a)(2) of this section issued under the authority of 38 U.S.C. 3034(a), 3322, 3323(a), 3681;

(3) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3681;

(4) Paragraph (c) of this section issued under the authority of 38 U.S.C. 3322(e), 3323(c);

(5) Paragraph (d) of this section issued under the authority of 38 U.S.C. 3322(g), 3323(c);

(6) Paragraph (e) of this section issued under the authority of 38 U.S.C. 3322(f);

(7) Paragraph (f) of this section issued under the authority of 38 U.S.C. 501(a), 3323(c);

(8) Paragraph (g) of this section issued under the authority of 38 U.S.C. 501(a), 3323(c); and

(9) Paragraph (h) of this section issued under the authority of 38 U.S.C. 501(a), 3322(h);

(The Office of Management and Budget has approved the information collection provisions in paragraphs (a) through (e) of this section under control number 2900–0098, and the information collection provisions in paragraphs (f) through (h) of this section under control numbers 2900–0154 and 2900–0098.)

■ 56. Amend § 21.9695 by:

■ a. Removing the parenthetical authority citation at the end of paragraph (a);

■ b. In paragraph (a), removing “institutions of higher learning” and adding in its place “educational institutions”;

■ c. In paragraph (b), removing “institution of higher learning” wherever it appears and adding in its place “educational institution”;

■ d. Revising paragraph (b)(3) and removing the parenthetical authority citation at the end of the paragraph;

■ f. In paragraph (b)(4)(ii)(A), removing “established charges” and adding in its place “tuition and fees”;

■ g. Removing the parenthetical authority citation at the end of paragraph (b)(4)(ii)(C); and

■ h. Adding paragraph (c).

The revision and addition read as follows:

§ 21.9695 Overpayments.

* * * * *

(b) * * * (3)(i) The amount of the overpayment of educational assistance paid to the eligible individual, or paid to the educational institution on behalf of the individual, constitutes a liability of the educational institution if:

(A) VA determines that the overpayment is the result of willful or negligent false certification by the educational institution, or willful or negligent failure to certify excessive absences from a course, discontinuance of a course, or interruption of a course by the eligible individual.

(B) The student never attends classes for which he or she was certified (regardless of the reason for non-attendance);

(C) The student completely withdraws from all courses on or before the first day of the certified period of enrollment;

(D) The student dies during the term (see §§ 21.9635(a)(2) and 21.9636(a)(2));

(E) The educational institution receives a payment for the wrong student;

(F) The educational institution receives a duplicate payment for a student;

(G) The educational institution receives a payment in excess of the amount certified to VA on the enrollment certification; or

(H) The educational institution submits an amended enrollment certification to correctly report a reduced amount of tuition and fee charges, reduced Yellow Ribbon Program contributions, or reduced amounts for both tuition and fees and Yellow Ribbon Program contributions.

(ii) In determining whether an overpayment resulting from the actions listed in paragraph (b)(3)(i) of this section should be recovered from an educational institution, VA will apply the provisions of § 21.4009 (except paragraph (a)(1)) to overpayments of educational assistance under 38 U.S.C. chapter 33.

* * * * *

(c) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3690(b);

(2) Paragraphs (b) through (b)(3)(ii) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3685; and

(3) Paragraphs (b)(3)(iii) through (b)(4) of this section issued under the authority of 38 U.S.C. 3034(a), 3323, 3685, 5302.

■ 57. Amend § 21.9700 by:

■ a. Removing “established charges” wherever it appears and adding in its place “tuition and fees”;

- b. Removing “38 U.S.C. chapter 3313(c)(1)(A)” wherever it appears and adding in its place “paragraphs (b) and (c) of § 21.9640 and paragraphs (b)(1) and (2) of § 21.9641”;
- c. Revising paragraph (b);
- d. In paragraph (d)(6)(i), removing “undergraduate” and adding in its place “certificate, undergraduate”;
- e. In paragraph (f), removing “school” and adding in its place “IHL”;
- f. In paragraph (g), removing “school’s” and adding in its place “IHL’s”; and
- g. Adding at the end of the section a parenthetical with the OMB control number for the approval of the information collection.

The revision and addition read as follows:

§ 21.9700 Yellow Ribbon Program.

* * * * *

(b) *Eligible individuals.* This program is only available to individuals entitled to the 100-percent educational assistance rate (based on service requirements as shown in § 21.9640(a) or § 21.9641(a), whichever is applicable) or to their designated dependents using entitlement transferred under § 21.9570 or § 21.9571, whichever is applicable, or effective August 1, 2018, to individuals using Fry Scholarship entitlement under § 21.9520(d) who are pursuing training at an eligible IHL.

* * * * *

(The Office of Management and Budget has approved the information collection provisions in this section under control numbers 2900–0154 and 2900–0718.)

- 58. Revise § 21.9710 to read as follows:

§ 21.9710 Pursuit.

Except for an eligible individual seeking tuition assistance Top-Up or reimbursement for taking an approved national test for admission, a national test for credit, or a licensing or certification test, the individual’s educational assistance depends upon his or her pursuit of a program of education.

(Authority: 38 U.S.C. 3323(c))

§ 21.9715 [Amended]

- 59. Amend § 21.9715 by:
 - a. Removing “the institution of higher learning” wherever it appears and adding in its place “the educational institution”;
 - b. In the introductory text, removing “§ 21.9640(b)(1)(ii) or (b)(2)(ii)” and adding in its place “§ 21.9640(b)(1)(ii), (b)(2)(ii), or § 21.9641(c), whichever is applicable”;
 - c. In paragraph (b)(1), removing “an institution of higher learning” and

adding in its place “the educational institution”; and

- d. In paragraph (b)(2), removing “§ 21.9730” and adding in its place “§ 21.9735”.

- 60. Amend § 21.9720 by revising the section heading and the introductory text to read as follows:

§ 21.9720 Certification of enrollment—for provisions effective before August 1, 2011.

For training pursued during the period beginning August 1, 2009, and ending July 31, 2011, an IHL must certify an eligible individual’s enrollment before he or she may receive educational assistance, except as stated in § 21.9680.

* * * * *

- 61. Add § 21.9721 to read as follows:

§ 21.9721 Certification of enrollment—for provisions effective after July 31, 2011.

For training pursued after July 31, 2011, an educational institution must certify an eligible individual’s enrollment before he or she may receive educational assistance, except as stated in § 21.9681.

(a) *Educational institutions must certify most enrollments.* VA does not, as a condition of advance payment, require educational institutions to certify the enrollments of eligible individuals who are seeking an advance payment (as described in § 21.9715). VA does not require organizations or entities offering a national test for admission, a national test for credit, or a licensing or certification test to certify that the eligible individual took the test. In all other cases, the educational institution must certify the eligible individual’s enrollment before he or she may receive educational assistance. This certification must be in a form specified by the Secretary and contain such information as specified by the Secretary.

(b) *Length of the enrollment period covered by the enrollment certification.* (1) Educational institutions that offer courses on a term, quarter, or semester basis will report enrollment for the term, quarter, semester, ordinary school year, or ordinary school year plus summer term. If the certification covers two or more terms, the educational institution will report each term, quarter, or semester separately.

(2) Educational institutions organized on a year-round basis that do not offer courses on a term, quarter, or semester basis will report enrollment for the length of the course. The certification will include a report of the dates during which the educational institution closes for any intervals designated in its

approval data as breaks between school years.

(3) When an eligible individual enrolls in a distance learning program leading to a standard college degree, the institution of higher learning’s certification will include—

- (i) The enrollment date; and
- (ii) The ending date for the period being certified. If the educational institution has no prescribed maximum time for completion, the certification must include an ending date based on the educational institution’s estimate for completion.

(c) *Authority.* (1) Paragraph (a) of this section issued under the authority of 38 U.S.C. 3014(b), 3031, 3034(a), 3323(a), 3482(g), 3680, 3687, 3689, 5101(a); and (2) Paragraph (b) of this section issued under the authority of 38 U.S.C. 3034(a), 3323(a), 3684.

(The Office of Management and Budget has approved the information collection provision in this section under control number 2900–0073.)

§ 21.9725 [Amended]

- 62. Amend § 21.9725 by:

- a. Removing “institution of higher learning” wherever it appears and adding in its place “educational institution”; and
- b. In paragraph (b), removing “institution of higher learning’s” and adding in its place “educational institution’s”.

§ 21.9735 [Amended]

- 63. Amend § 21.9735 by removing “individuals and institutions of higher learning” and adding in its place “eligible individuals and educational institutions”.

§ 21.9740 [Amended]

- 64. Amend § 21.9740 by:

- a. Removing “institution of higher learning” wherever it appears and adding in its place “educational institution”; and
- b. Removing “institution of higher learning’s” wherever it appears and adding in its place “educational institution’s”.

- 65. Amend § 21.9750 by:

- a. In paragraph (a), removing “institution of higher learning” and adding in its place “educational institution”;
- b. Revising the heading to paragraph (b);
- c. Removing paragraph (b) introductory text; and
- d. Revising paragraph (b)(1).

The revisions read as follows:

§ 21.9750 Course measurement.

* * * * *

(b) *Measurement of courses reported in clock hours at IHLs.* (1) If the courses pursued at an IHL are measured in clock hours, VA will convert the clock hours to equivalent credit hours by—

- (i) Adding the total number of clock hours pursued during the term, quarter or semester;
- (ii) Dividing the sum of paragraph (b)(1) of this section by the total number of weeks in the term; and

- (iii) Multiplying the result of paragraph (b)(2) of this section rounded to the nearest 100th by—
 - (A) If the educational institution measures courses using both credit and clock hours, the decimal determined by dividing the number of credit hours considered full-time at the educational institution by the number of clock hours considered full-time at the educational institution.
 - (B) If the educational institution only measures courses using clock hours, the

decimal determined by dividing 14 credit hours by the number of clock hours considered full-time at the educational institution.
* * * * *

§ 21.9765 [Amended]
■ 66. Amend § 21.9765 by removing “institution of higher learning” and adding in its place “educational institution”.
[FR Doc. 2024–29907 Filed 1–15–25; 8:45 am]
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15 CFR Part 791

Securing the Information and Communications Technology and Services
Supply Chain: Connected Vehicles; Final Rule

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 791**

[Docket No. 250107–0005]

RIN 0694–AJ56

Securing the Information and Communications Technology and Services Supply Chain: Connected Vehicles**AGENCY:** Bureau of Industry and Security, Department of Commerce.**ACTION:** Final rule.

SUMMARY: This final rule, published by the Department of Commerce's (Department) Bureau of Industry and Security (BIS), sets forth regulations and procedures to address undue or unacceptable risks to national security and U.S. persons posed by classes of transactions involving information and communications technology and services (ICTS) that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of certain foreign adversaries and that are integral to connected vehicles as defined herein.

DATES: This final rule goes into effect on March 17, 2025.

FOR FURTHER INFORMATION CONTACT:

Marc Coldiron, U.S. Department of Commerce, telephone: (202) 482–3678. For media inquiries: Office of Congressional and Public Affairs, Bureau of Industry and Security, U.S. Department of Commerce: *OCPA@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:**I. Background**

In this final rule, BIS prohibits transactions involving Vehicle Connectivity System (VCS) hardware and covered software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the People's Republic of China, including the Hong Kong Special Administrative Region and the Macau Special Administrative Region, (PRC); or the Russian Federation (Russia). It follows an advance notice of proposed rulemaking (ANPRM), 89 FR 15066 (March 1, 2024), and a notice of proposed rulemaking (NPRM), 89 FR 79088 (September 26, 2024). In the ANPRM, BIS sought public comment to inform a rulemaking that would address the undue or unacceptable risks, as identified in Executive Order (E.O.) 13873, "Securing the Information and

Communications Technology and Services Supply Chain," 84 FR 22689 (May 17, 2019), posed by a class of transactions that involve ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary and integral to connected vehicles. The NPRM proposed a rule to address the undue or unacceptable risks identified in the ANPRM and solicited public comment. BIS has considered the comments received during both rounds of public comment, and is making revisions, from the proposed rule, that address significant portions of that feedback.

In E.O. 13873, the President delegated to the Secretary of Commerce (Secretary), to the extent necessary to implement the Order, the authority granted under the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701, *et seq.*), "to deal with any unusual and extraordinary" foreign threat to the United States' national security, foreign policy, or economy, if the President declares a national emergency with respect to such threat. 50 U.S.C. 1701(a). In E.O. 13873, the President declared a national emergency with respect to the "unusual and extraordinary" foreign threat posed to the ICTS supply chain and has, in accordance with the National Emergencies Act (NEA), extended the declaration of this national emergency in each year since E.O. 13873's publication. *See Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 85 FR 29321 (May 14, 2020); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 86 FR 26339 (May 13, 2021); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 87 FR 29645 (May 13, 2022); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 88 FR 30635 (May 11, 2023); *Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain*, 89 FR 40353 (May 9, 2024).

Specifically, the President identified the "unrestricted acquisition or use in the United States of ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or

subject to the jurisdiction or direction of foreign adversaries" as "an unusual and extraordinary" foreign threat to the national security, foreign policy, and economy of the United States that "exists both in the case of individual acquisitions or uses of such technology or services, and when acquisitions or uses of such technologies are considered as a class." *See* E.O. 13873, and 50 U.S.C. 1701(a)–(b).

Once the President declares a national emergency, IEEPA empowers the President to, among other acts, investigate, regulate, prevent, or prohibit, any "acquisition, holding, withholding, use, transfer, withdrawal, transportation, importation or exportation of, or dealing in, or exercising any right, power, or privilege with respect to, or transactions involving, any property in which any foreign country or a national thereof has any interest by any person, or with respect to any property, subject to the jurisdiction of the United States." 50 U.S.C. 1702(a)(1)(B).

To address the identified risks to national security from ICTS transactions, the President in E.O. 13873 imposed a prohibition on transactions that the Secretary, in consultation with relevant agency heads, has determined involve foreign adversary ICTS and pose certain risks to U.S. national security, including U.S. technology and critical infrastructure, or the security and safety of U.S. persons. Specifically, to fall within the scope of the prohibition, the Secretary must determine that a transaction: (1) "involves [ICTS] designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary," defined in E.O. 13873 as "any foreign government or foreign non-government person engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons, which, pursuant to E.O. 13873's implementing regulations at 15 CFR 791.4 are the PRC, Republic of Cuba (Cuba), Islamic Republic of Iran (Iran), Democratic People's Republic of Korea (North Korea), Russia, and Venezuelan politician Nicolás Maduro (Maduro Regime); and (2):

A. "Poses an undue risk of sabotage to or subversion of the design, integrity, manufacturing, production, distribution, installation, operation, or maintenance of information and communications technology or services in the United States;"

B. "Poses an undue risk of catastrophic effects on the security or

resiliency of United States critical infrastructure or the digital economy of the United States;” or

C. “Otherwise poses an unacceptable risk to the national security of the United States or the security and safety of United States persons.”

Factors A through C are collectively referred to as “undue or unacceptable risks.” In addition, section 1(b) of E.O. 13873 grants the Secretary the authority to design or negotiate mitigation measures to allow an otherwise prohibited transaction.

The President also delegated to the Secretary the ability to promulgate regulations that, among other things, establish when transactions involving particular technologies may be categorically prohibited. E.O. 13873 section 2(a)–(b); *see also* 3 U.S.C. 301–02. Specifically, the Secretary may issue regulations establishing criteria, consistent with section 1 of E.O. 13873, by which particular technologies or market participants may be categorically included in or categorically excluded from prohibitions established pursuant to E.O. 13873.

II. Introduction

Today’s vehicles contain a myriad of connected components that provide greater convenience for consumers and increase road safety for both drivers and pedestrians, such as Wi-Fi, Bluetooth, cellular, and satellite connectivity. However, the incorporation of progressively more complex hardware and software systems that facilitate these features has also increased the attack surfaces through which malign actors and foreign adversaries may exploit vulnerabilities to gain access to a vehicle. As BIS outlined in its March 1, 2024, ANPRM and its September 26, 2024, NPRM, certain ICTS integral to connected vehicles present an undue or unacceptable risk to U.S. national security when those systems are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary.

In the *Securing the Information and Communications Technology and Services Supply Chain* interim final rule, 86 FR 4909 (Jan. 19, 2021), the Secretary determined that certain foreign governments or foreign non-government persons—the PRC, Cuba, Iran, North Korea, Russia, and the Maduro Regime—constitute foreign adversaries for purposes of E.O. 13873 and regulations promulgated pursuant to E.O. 13873. *See* 15 CFR 791.4 (to the extent that the list of foreign adversaries identified in 15 CFR 791.4 is updated to

add or remove governments or non-government persons, this final rule intends to reflect the most up-to-date designations of foreign adversaries). Additionally, section 2(b) of E.O. 13873 provides that the Secretary may issue rules that identify particular technologies or countries with respect to transactions involving ICTS that warrant particular scrutiny. For the purposes of this final rule regarding transactions involving ICTS integral to connected vehicles, BIS is focusing its regulatory efforts on ICTS that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. BIS has identified that, for the purposes of addressing the national security risks posed by connected vehicles, these two foreign adversaries pose particular undue and unacceptable risks to U.S. national security because of these adversaries’ legal, political, and regulatory regimes, combined with their current and anticipated growth and involvement in the connected vehicles sector.

As discussed below, the PRC and Russia are able to leverage domestic legislation and regulatory regimes to compel companies subject to their jurisdiction, including carmakers and their suppliers, to cooperate with security and intelligence services. Such control over companies and their products and services means that their equipment is easily exploitable by PRC and Russian authorities. The privileged access that the PRC and Russia may gain to connected vehicles through their components, including software and hardware, could enable those foreign adversaries to (1) exfiltrate sensitive data collected by connected vehicles and (2) allow remote access and manipulation of connected vehicles driven by U.S. persons. Pursuant to E.O. 13873, BIS has determined that certain classes of transactions that can facilitate the exfiltration of data and remote manipulation of connected vehicles by the PRC and Russia pose undue or unacceptable risks to U.S. national security and to the safety and security of U.S. persons. These risks, moreover, present an urgent national security risk to the safety and security of technology used in the United States and to U.S. persons.

The PRC has pre-positioned malware on U.S. information technology and critical infrastructure networks. The PRC has also set objectives for the completion of the People’s Liberation Army’s (PLA) modernization and other military and technology goals by 2027, which—in light of the PLA’s military-civil fusion strategy and the growing

prevalence of PRC dual-use technologies in U.S. commercial supply chains, including in the auto industry—presents additional risks to U.S. national security. Mounting evidence of threats such as these to U.S. critical infrastructure, data security, and broader national security necessitates this urgent action by the U.S. government to address the risk of foreign adversary supply chains in the connected vehicles sector.

a. Overview of the Advance Notice of Proposed Rulemaking (ANPRM)

BIS issued an ANPRM, 89 FR 15066 (Mar. 1, 2024), seeking public comment to inform a rulemaking that would address the undue or unacceptable risks posed by a class of transactions that involve ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary and integral to connected vehicles. In the ANPRM, BIS posed 35 questions to the public for comment and feedback. The questions related to potential definitions used in the rulemaking, the degree of foreign adversary involvement in the connected vehicle supply chain, which systems should be the focus of a potential rulemaking, and what the economic impacts of a potential rulemaking might be, among other questions. BIS identified six systems as the potential focus for a future rule: (1) vehicle operating systems (OS), (2) telematics systems, (3) advanced driver assistance systems (ADAS), (4) automated driving systems (ADS), (5) satellite or cellular telecommunications systems, and (6) battery management systems (BMS). BIS received 57 comment submissions in response to the ANPRM from a variety of parties, including original equipment manufacturers (OEMs), component suppliers, two foreign governments, nonprofit organizations, and individual respondents. Five comments contained Confidential Business Information (CBI), and one comment was retracted at the request of the commenter. The comments generally urged BIS to narrow the scope of a future regulation and to limit the systems to be regulated to only those posing significant national security risks. Commenters also urged BIS to provide industry stakeholders with sufficient lead time to comply. BIS considered each comment in developing the NPRM outlined in the next section.

b. Overview of the Notice of Proposed Rulemaking (NPRM)

BIS then issued an NPRM, 89 FR 79088 (Sept. 26, 2024), that identified a smaller subset of systems in connected

vehicles that pose the most significant undue or unacceptable risk to national security when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Below is a summary of the proposed rule.

Regulated Systems

The proposed rule identified (1) VCS, which is composed of the hardware and software that enable a connected vehicle to communicate off-board above 450 MHz, and (2) ADS, as subject to regulation by BIS. This determination was based, in part, on public comments requesting BIS narrow the scope of the rule, as a regulation that impacted all six of the listed automotive systems would be overbroad. The NPRM listed ADS, operating systems, telematic systems, automated driving assistance systems, satellite and communication systems, and battery management systems as potential automotive systems that could be regulated in the subsequent proposed rule. Public comment as well as BIS's analysis suggested that automotive telematics functions were one of the primary means for a foreign adversary to exploit automotive data and actuation systems. BIS also determined, based on public comment as well as internal analysis, that the term "telematics" generally refers to systems that operate on cellular band protocols. As BIS intended to regulate multiple automotive connectivity systems, not just automotive cellular systems, BIS chose to use the broader term of "VCS" to encompass cellular, Wi-Fi, Bluetooth, and potentially satellite communications. The NPRM proposed to regulate both the hardware and software in VCS and solely the software in ADS.

Prohibited Transactions

The NPRM proposed to (1) prohibit VCS hardware importers from knowingly importing into the United States certain hardware for VCS; (2) prohibit connected vehicle manufacturers from knowingly importing into the United States completed connected vehicles incorporating covered software, which was defined in the NPRM as certain software that supports the function of VCS or ADS; and (3) prohibit connected vehicle manufacturers from knowingly selling within the United States completed connected vehicles that incorporate software that supports the function of VCS or ADS. These prohibitions included in the NPRM applied when such VCS hardware or

covered software was designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The NPRM also proposed to (4) prohibit connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software, even when that hardware or software did not have a nexus to the PRC or Russia.

Declarations of Conformity

The NPRM proposed that VCS hardware importers and connected vehicle manufacturers would submit to BIS, once per calendar year or model year, Declarations of Conformity attesting that they had not engaged in prohibited transactions involving VCS hardware or covered software. The NPRM would have mandated that VCS hardware importers and connected vehicle manufacturers submit a substantial amount of information with their Declarations of Conformity, including a hardware bill of materials (HBOM) or software bill of materials (SBOM), and a list of external endpoints to which the VCS hardware connected. In the final rule, BIS has changed the Declarations of Conformity requirement to clarify the certification, narrow the information required to be submitted, and add recordkeeping requirements.

Authorizations

The NPRM enumerated general authorizations under which a regulated entity would be permitted to engage in an otherwise prohibited transaction without need to notify BIS. Under the NPRM, general authorizations would have been available to small business VCS hardware importers and connected vehicle manufacturers. Specifically, general authorizations applied if (1) the connected vehicle manufacturer or VCS hardware importer produced fewer than 1,000 connected vehicles or VCS hardware units; (2) the completed connected vehicle was used on public roadways for fewer than 30 calendar days in a year; (3) the completed connected vehicle or VCS hardware was used solely for purposes of display, testing, or research; or (4) the completed connected vehicle was imported solely for repair, alteration, or competition off public roads and would have been exported within one year of import. In the final rule, BIS has revised the general authorizations provision so that the above-mentioned general authorizations are not provided in the

rule text itself. Instead, BIS will issue general authorizations through its website and the **Federal Register**.

The NPRM also provided a process for specific authorizations. Following an application to and approval from BIS, a specific authorization granted VCS hardware importers and connected vehicle manufacturers the ability to engage in otherwise prohibited transactions not eligible for a general authorization, subject to certain conditions imposed by BIS.

Exemptions

The NPRM permitted VCS hardware importers to engage in otherwise prohibited transactions involving VCS hardware and exempted them from certain requirements so long as: (1) for VCS hardware not associated with a model year, the import of the VCS hardware had taken place prior to January 1, 2029; or (2) the VCS hardware unit was associated with a vehicle model year prior to 2030 or the VCS hardware was integrated into a connected vehicle (completed or incomplete) with a model year prior to 2030. In the NPRM, connected vehicle manufacturers were permitted to engage in otherwise prohibited transactions involving covered software and exempt from certain requirements so long as the completed connected vehicle that was imported, or sold within the United States, was of a model year prior to 2027. Lastly, connected vehicle manufacturers that are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia were permitted to sell completed connected vehicles with a model year prior to 2027 that incorporated VCS hardware or covered software. The final rule includes new exemptions for parts that are imported for the purpose of warranty or repair of a completed connected vehicle with a model year prior to 2030.

Advisory Opinions, Is-Informed Notices, and Appeals

The NPRM provided an advisory opinion mechanism by which regulated entities could seek guidance from BIS as to whether specific prospective transactions were subject to the proposed rule's prohibitions. The mechanism included in the NPRM applied to actual, as opposed to hypothetical, transactions in which all parties are identified. Additionally, the NPRM permitted BIS to issue certain "Is-Informed" notices to VCS hardware importers and connected vehicle manufacturers to inform them that a specific authorization was required for an activity. The NPRM also included an

appeal process by which any person whose application for a specific authorization was denied, whose specific authorization was suspended or revoked, or who received a written notification of ineligibility for a general authorization could appeal that decision to the Under Secretary for Industry and Security (Under Secretary). In the final rule, BIS has added a 60-day timeline for BIS to respond to advisory opinion requests and clarified procedural requirements of submitting an appeal request.

Recordkeeping and Reporting

The NPRM proposed that regulated entities keep a “full and accurate record” for a period of 10 years after each transaction for which a Declaration of Conformity, general authorization, or specific authorization was required, regardless of whether the transaction was effected pursuant to such an authorization. In the NPRM, VCS hardware importers and connected vehicle manufacturers were required to furnish “complete information” relevant to any transaction involving the import of VCS hardware or covered software, irrespective of any authorization granted by BIS.

Violations

The NPRM additionally outlined the framework by which BIS determined a violation took place, the procedure by which BIS notified an affected party of such a violation (including the party’s right to respond or to settle), the specific penalties BIS was permitted to impose on violators, and the administrative collection of those penalties.

c. Overview of Final Rule

The final rule benefits from the responses received during the public comment periods for the ANPRM and the NPRM and incorporates significant portions of that feedback. For example, BIS considered public feedback to define the scope of connected vehicles, identify ICTS integral to connected vehicles, and better understand the effects of any potential prohibition. As stated in the NPRM, determining the scope of the prohibitions required a balancing of the need to address the undue or unacceptable risk posed by foreign adversary involvement in the connected vehicles supply chain with the impact on the public and industry. For a detailed discussion of how the final rule has changed from the NPRM, refer to Section V: Discussion of the Final Rule and Section VI: Revisions from the Proposed Rule and Response to Comments.

III. Comments on the Notice of Proposed Rulemaking

BIS received 101 comments on the NPRM.¹ Many commenters agreed with BIS’s risk assessment of foreign adversary connected vehicle technology as described in Section IV of the NPRM and supported the decision to address these risks through supply chain regulation. Commenters’ concerns with the NPRM centered on the broad scope of the regulation and the potentially onerous and disruptive nature of the compliance process, particularly the submission of Declarations of Conformity. Some commenters disagreed with the NPRM’s inclusion of the commercial vehicle market, arguing that definitions proposed in the NPRM did not as easily apply to this sector compared to the passenger vehicle market. Commenters also warned that the wide scope of the NPRM across the connected vehicle market may have significant economic impact and that the current implementation timeline could not easily be met by industry.

Commenters requested that BIS implement alternative methods of compliance, such as a self-certification model; provide greater detail on the HBOM and SBOM submission requirements; and describe how BIS intends to protect any submitted data. Commenters also voiced apprehension over any requirement to share proprietary information with customers and the government. For a more thorough discussion of the comment submissions and BIS’s responses, please see Section IV: Risks Associated with Vehicle Connectivity Systems and Automated Driving Systems When Designed, Developed, Manufactured, or Supplied by Persons Owned by, Controlled by, or Subject to the Jurisdiction or Direction of the PRC and Russia.

IV. Risks Associated With Vehicle Connectivity Systems and Automated Driving Systems When Designed, Developed, Manufactured, or Supplied by Persons Owned by, Controlled by, or Subject to the Jurisdiction or Direction of the PRC and Russia

BIS received multiple comments related to the risks stemming from VCS and ADS when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Commenters agreed with the

risks posed by PRC and Russian involvement in the connected vehicle supply chain as laid out in the NPRM, and BIS reiterates those same risks in this section. For instance, one commenter acknowledged that allowing adversarial suppliers into the automotive supply chain poses direct threats to data integrity, consumer safety, and national security. In contrast, another commenter critiqued the proposed rule as overly broad and characterized the threats as hypothetical in nature, underscoring that PRC and Russian companies are incentivized to avoid exploiting vulnerabilities in connected vehicles in order to avoid conflict. BIS recognizes that many of the risks laid out in the NPRM and final rule are forward-looking, and this rulemaking is an attempt to proactively address these risks before PRC and Russian actors are able to leverage them to harm U.S. national security. Moreover, while BIS agrees that action by the PRC or Russia to leverage vulnerabilities in VCS or ADS could feasibly cause undesired conflict, the strategic benefit of exploiting vulnerabilities may outweigh other types of harm it causes and thus is unlikely to preclude such an action altogether from the perspective of the PRC and Russia. Another commenter highlighted that the rule does not apply retroactively to address any of the data already collected by connected vehicle manufacturers that may have already been legitimately transferred to the PRC or other foreign adversaries and may be informing foreign intelligence analysis. BIS recognizes that some connected vehicle and component manufacturers may already transfer vehicle data abroad, a point that is reiterated later in this final rule. However, BIS believes that retroactive application of this rule would not reduce or alleviate any of the harm that has already occurred as a result of foreign intelligence organizations gaining access to that data. Following consideration of the comments received on the NPRM, and further consideration of the risks and vulnerabilities associated with various ICTS components that are critical to the operation of connected vehicles, BIS has decided to retain the proposed rule’s focus on two integral ICTS systems—VCS and ADS—when designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of two foreign adversaries—the PRC and Russia. Below, BIS provides its findings of the undue and unacceptable risks associated with these particular foreign systems, and these particular foreign

¹ This includes four written submissions received after the close of the public comment period, all of which were considered and posted on [regulations.gov](https://www.regulations.gov).

adversaries, following this latest round of public comments.

a. Vulnerabilities Associated With Vehicle Connectivity Systems and Automated Driving Systems

1. Vehicle Connectivity Systems

The term VCS encompasses hardware and software systems—such as the telematics control units (TCU), cellular modems and antennas, and other automotive components—that integrate various radio frequency (RF) communication technologies and enable connected vehicles to access external data sources, facilitate vehicle-to-vehicle communication, and provide enhanced services to users through seamless connectivity options. For example, as the primary automotive VCS component, a TCU acts as the primary interface between the internal network and external communication channels. It collects data from onboard sensors such as Global Positioning Systems (GPS), accelerometers, gyroscopes, BMS, and other Electronic Control Units via wired networks like Controller Area Network (CAN) bus, Local Interconnect Network (LIN), FlexRay, Automotive Ethernet and K-Line, as well as wireless protocols such as Bluetooth and Wi-Fi. Some systems use cameras and microphones to facilitate facial recognition of drivers or to respond to voice commands of drivers. Once gathered, the TCU converts this internal data into radio frequency signals suitable for transmission over the chosen wireless protocol. In other words, as the vast array of sensors on a connected vehicle collect information about a driver's location, speed, voice patterns, battery state of charge, or other vehicle diagnostic and operational information, the TCU converts that data into a format that can be transmitted to systems outside the vehicle and then enables that transmission. Sensing systems, such as radar, audio, video, or Light Detection and Ranging (LiDAR) hardware and software, are not VCS. Based on a number of comments to the proposed rule, BIS recognizes a national security risk posed by LiDAR, but it concludes that focusing this regulation on VCS hardware and software systems, which ultimately enable the external communication of end-point sensors, is an appropriate scope at this time. For a more thorough discussion on the exclusion of PRC or Russian LiDAR from this rule, please see Section VI below.

While the increased degree of vehicle connectivity offers benefits to both consumers and manufacturers, it also

increases risks to consumers and manufacturers due to the number of access points into the internal connected vehicle network. Each access point may present multiple new software vulnerabilities for adversaries to exploit. *See* Cabell Hodge, Konrad Hauk, Shivam Gupta, and Jess Bennett, Vehicle Cybersecurity Threats and Mitigation Approaches, *National Renewable Energy Laboratory*, at 4–5 (Aug. 2019), <https://www.nrel.gov/docs/fy19osti/74247.pdf>. Such compromise of VCS software could occur at various points of the software development lifecycle where software functionality can be accessed and altered, including tool development, source code repositories, open-source dependencies, software updates, and shipment interdiction. For instance, Upstream's 2024 Global Automotive Cybersecurity Report documented a case where security researchers installed malicious software on the VCS by performing a simulated jailbreak attack of an OEM's VCS using a voltage fault injection on the chipmaker's processor. This malicious software unlocked features to manipulate the vehicle, such as acceleration and heated seats. Upstream, *2024 Global Automotive Cybersecurity Report*, at 62 (Feb. 2024), <https://upstream.auto/reports/global-automotive-cybersecurity-report>. The software also provided access to private user data and enabled decryption of encrypted Non-Volatile Memory Express (NVMe) storage, manipulation of the car's identity, and extraction of the vehicle-unique credential used for authenticating and authorizing the OEM's internal service network. *See id.* By compromising software or its dependencies, malign actors may surveil, disrupt, damage, or otherwise exploit the data or systems of those who use the software. *See* National Counterintelligence and Security Center, *Software Supply Chain Attacks*, (Mar. 2021), https://www.dni.gov/files/NCSC/documents/supplychain/Software_Supply_Chain_Attacks.pdf.

The threat of such a cyber operation by malicious actors can grow significantly when firmware or hardware components are intentionally designed with vulnerabilities. Access to the hardware supply chain for VCS provides an avenue for threat actors to manipulate or insert, with malicious intent, hardware, or firmware modules into telematics hardware components such as modems, Systems on Chip (SoC), Printed Circuit Boards (PCB), Central Processing Units, and antennae. Manipulating or modifying hardware and associated firmware in the supply

chain could also allow foreign adversaries to insert a backdoor, granting them control over the VCS. *See* Cybersecurity & Infrastructure Security Agency, *Defending Against Software Supply Chain Attacks*, at 6 (Apr. 2021), https://www.cisa.gov/sites/default/files/publications/defending_against_software_supply_chain_attacks_508.pdf; National Counterintelligence and Security Center, *Software Supply Chain Attacks*, (Apr. 2023), <https://www.dni.gov/files/NCSC/documents/supplychain/Software-Supply-Chain-Attacks.pdf>. For instance, cellular and satellite telecommunications transceivers are pivotal connectivity components in the VCS, utilizing radio frequency (RF) energy to facilitate the transmission and reception of data between a vehicle and the external world. If these transceivers are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, such actors would have the means and capability to introduce vulnerabilities that could be exploited to intercept and/or compromise the information exchanged between the connected vehicle and the external world.

2. Automated Driving Systems

The complexity of ADS software, the large foundation of data sources, and the driving responsibilities inherent to ADS render it a valuable target for exploitation. An ADS encompasses the upper end of the spectrum of autonomy levels that dictate the vehicle's independence, and the extent of driver intervention required. The primary standard setting organization for automotive autonomy is the global mobility standard-setting body SAE International. SAE International sets standards that affect many aspects of automotive production and maintenance, often in concert with the International Standards Organization (ISO). SAE International's *Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles* (SAE J3016) is the current industry norm for evaluating standard levels of vehicle autonomy. SAE J3016 autonomy levels range from Level 0 (no automation) where the driver controls all aspects of driving, to Level 5 (full automation) where the vehicle can operate independently under all conditions without human intervention. Levels 1 and 2 offer driver assistance through systems that control either steering or acceleration and braking, while Levels 3 through 5 (which generally comprise ADS)

progressively increase the system's responsibility for driving tasks. Level 4 requires the ability to complete all driving functions on a sustained basis within defined operational design domains (ODDs), while Level 5 requires the ability to complete all driving functions unconditionally. As the autonomy level increases, the reliability and safety of the ADS become increasingly reliant on the system's operational performance, safety protocols, and cybersecurity measures. See SAE J3016_02104, Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles, *SAE International*, at 31–32 (Apr. 2021), https://www.sae.org/standards/content/j3016_02104/.

An ADS must be able to execute Dynamic Driving Tasks (DDTs) within specific ODDs. DDTs include critical tasks such as steering, braking, acceleration, and Object and Event Detection, Classification and Response (OEDCR). OEDCR enables an ADS to perceive and respond to surrounding objects and events, a responsibility that shifts progressively from the driver to the ADS itself as the degree of vehicle autonomy increases. See *id.* at 17; Edward Griffor, David Wollman, and Christopher Greer, Automated Driving System Safety Measures Part 1: Operating Envelope Specification, *NIST Special Publication 1900–301*, at 2 (2021), <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1900-301.pdf>.

An ADS relies on a large foundation of connected information sources for decisions and outputs which, in turn, could create inherent vulnerabilities. For example, a user of a vehicle, or even an OEM purchaser of ADS likely does not know the sum total of what data the ADS was trained on, or how, specifically, the ADS makes its decisions. It is not possible to find single lines of code that dictate how an ADS responds to specific scenarios in modern ADS systems. Rather, leading ADS are controlled by complex software that can include a neural net that references training data and previous decisions to instantaneously decide on an action in a driving setting. This opacity and lack of understanding of how the system actually reacts is inherently vulnerable to poisoned data injection or specific scenario-based failures. As a result, the complex software systems that drive decisions for an ADS are valuable targets for malicious actors to exploit. Software-based threats to connected vehicles equipped with an ADS include manipulation of sensors to create phantom objects; manipulation of ADS

software to detect, capture, and retain information about specific geographic areas or other sensitive data; or other manipulation of sensor fusion processing software that could lead to faulty and dangerous vehicle decision making, to include unauthorized control over the connected vehicle. See National Counterintelligence and Security Center, *Autonomous Automotive Vehicle Supply Chain Risk*, (2022), <https://www.dni.gov/files/NCSC/documents/supplychain/autonomous-vehicles-placemat-2022-D9A54B50-.pdf>.

A compromised ADS creates opportunities for data exfiltration and unauthorized vehicle manipulation due to the direct access it has to the Internal Vehicle Network (IVN). The IVN controls the communication framework within a connected vehicle, overseeing the electronic control units (ECUs) responsible for engine control, traction control, door locks, climate control, battery management, powertrain, airbags, cameras, and radar functionalities. These ECUs also communicate via overlaid communication networking protocols such as a CAN bus, LIN, and ethernet. See Anastasios Giannaros, et al. Autonomous Vehicles: Sophisticated Attacks, Safety Issues, Challenges, Open Topics, Blockchain and Future Directions, *Journal of Cybersecurity and Privacy* 3.3, at 508–513, (2023). Because ADS interacts with ECUs through the IVN, a compromised ADS has the capability to execute functions that affect nearly all of a connected vehicle's software and hardware components. For example, an update to an ADS could alter outputs the ADS makes to a Body Control Unit, enabling the ADS to erroneously and dangerously open a vehicle's door while in motion. Moreover, because many connected vehicles maintain their own networks and actively scan their operating environment for other proximate networks, an ADS can also potentially be used to impact the IVN of other vehicles or transportation infrastructure networks through vehicle-to-vehicle communication. This could lead to disablement or compromise of other vehicles or of transportation infrastructure, affecting the movement of goods and the physical safety of drivers. See National Counterintelligence and Security Center, *Autonomous Automotive Vehicle Supply Chain Risk* (Apr. 2022), <https://www.dni.gov/files/NCSC/documents/supplychain/autonomous-vehicles-placemat-2022-D9A54B50-.pdf>; Patrick Wagner, Nikolai Puch, and David Emeis, Cybersecurity risk analysis

of an automated driving system, *Fraunhofer Institute AISEC* (Oct. 2023), <https://publica.fraunhofer.de/entities/publication/4d66e81e-3570-4c49-9f8c-8c9967a34ca6/details>.

Given the significant processing power and complex decision-making capability of an ADS, the risks arising from ADS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary extend beyond the IVN itself and include risks to the fidelity and integrity of data that flows to downstream or adjacent transportation infrastructure. Foreign adversaries can corrupt ADS data by exploiting existing vulnerabilities in ADS connectivity environments. See subsection IV.b. As such, direct access to an ADS afforded to a malicious actor or foreign adversary through the design, development, manufacture, or supply of ADS software has the potential to cause severe adverse consequences to U.S. national security and U.S. persons.

b. Threats Associated With the PRC and Russia

Several commenters agreed that PRC laws compel compliance with government requests, thereby making some companies subject to the direction of the PRC government. One commenter provided additional detail about the linkages between prominent Chinese companies, the PRC military, and the global automotive industry. Two commenters noted that current investments by Chinese companies in Mexico may allow effective “backdoor” access to the American auto market. One commenter specifically pointed to the risks posed by Chinese-developed buses with connectivity features as posing a particular threat to U.S. national security. While commercial vehicles such as buses are not in the scope of this final rule, BIS intends to propose a new rule specifically tailored to the commercial vehicle sector in order to address substantial national security risks. Another commenter agreed with the Department's actions, specifically as it related to addressing the large amounts of data collected by connected vehicles already being transmitted to the PRC, regardless of the vehicle's physical location. In response to commenters' agreement with the nature of PRC and Russian legal and regulatory landscapes, BIS is reiterating its legal and risk analyses in this final rule. Moreover, BIS thanks commenters for providing additional information that clarifies the linkages between the PRC state, military, and the broader economy. In light of concerns raised by

commenters regarding PRC companies' investments in Mexico, BIS reiterates that PRC investments in Mexico's auto sector risk creating additional potential nexus points between PRC connected vehicle suppliers and U.S. automakers and consumers. Similarly, BIS agrees with commenters' concerns that the PRC-linked entities already collect large amounts of data, including from vehicles which are currently located in the United States. These concerns directly underscore the importance and necessity of this rulemaking.

The design, development, manufacture, or supply of certain VCS and ADS components by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia poses undue or unacceptable risks to national security and U.S. persons. As discussed further, the PRC and Russia have adopted political, legal, and regulatory regimes that enable their governments to exercise direct and indirect ownership, control, or influence over entities in the connected vehicle supply chain. In addition, unlike other foreign adversaries, the PRC and Russia have certain current and anticipated industrial capabilities and expertise that uniquely position them within the global automotive market to pose an outsized risk, particularly when paired with the vulnerabilities present within certain connected vehicle systems.

1. PRC

The PRC's role in the U.S. connected vehicle supply chain presents undue and unacceptable risks. The PRC has a large and growing automotive sector that has become increasingly integrated into the ICTS supply chains of global automakers, providing the PRC automotive sector with potential increased access to the U.S. automotive market. Further, the PRC's automotive sector has historical and ongoing links to the PRC military and is influenced by pervasive government intervention, including through legal and regulatory structures that increase government oversight of and control over PRC-based companies and their foreign subsidiaries. See Du Xiaoying and Wang Siyi, Dongfeng plays pivotal role in supporting China's military, *China Daily* (Sept. 25, 2015), https://www.chinadaily.com.cn/cndy/2015-09/25/content_21976945.htm; Matthew Funaiolo, et al., China Accelerates Construction of 'Ro-Ro' Vessels, with Potential Military Implications, *Center for Strategic and International Studies* (Oct. 11, 2023), [https://chinapower.csis.org/analysis/china-construct-ro-ro-vessels-military-](https://chinapower.csis.org/analysis/china-construct-ro-ro-vessels-military-implications/)

[implications/](https://chinapower.csis.org/analysis/china-construct-ro-ro-vessels-military-implications/) (describing the involvement of Chinese automakers in the production of "ro-ro" vessels and the dual-use applications of ro-ro vessels, including clear evidence that the PRC military intends to utilize ro-ros to support military operations). Moreover, the PRC possesses advanced cyber espionage capacities that it exercises through both state and non-state cyber actors, exacerbating such risks. See Simon Handler, The 5x5-China's cyber operations, *The Atlantic Council* (Jan. 2023), <https://www.atlanticcouncil.org/content-series/the-5x5-the-5x5-chinas-cyber-operations/>.

First, the size and scale of state control in the PRC auto sector poses outsized risks, increasing the vectors by which the national security threats associated with connected vehicles can enter the United States. The PRC automotive sector has played an important role in its domestic industrial policy since 1986, when the sector was first named a "pillar industry" in the Seventh Five-Year Plan. The Fourteenth Five-Year Plan, the latest strategic framework for the PRC, continues to prioritize the technological innovation and sustainable development of the automobile market, including new energy vehicles and connected vehicle software and hardware systems, as key priorities. See Ben Murphy, Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035, *Center for Security and Emerging Technology*, at 22–23 (May 2021), https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five_Year_Plan_EN.pdf. For many years, the state has pursued policies and practices to further its industrial policy objectives in the automotive sector, including mandatory joint venture requirements, foreign equity restrictions, massive subsidies, and other financial support measures. The PRC automotive sector's growth is also led in part by several prominent state-owned firms, some of which began as military equipment suppliers (e.g., Dongfeng, Sichuan Auto Works, Shanxi Auto Works). See Mattias Holweg, Jianxi Luo, and Nick Oliver, The past, present and future of China's automotive industry: a value chain perspective, *International Journal of Technological Learning, Innovation and Development* 2, at 14 (Feb. 2009), <https://www.pure.ed.ac.uk/ws/portalfiles/portal/7765689/Oliver.pdf>. In recent years, this growth and development has led to a massive surge in domestic vehicle production, with Chinese

vehicle production increasing by 1.5 times over the 15-year span between 2008 and 2023. Indeed, in 2023, the PRC alone was responsible for nearly 33 percent of global passenger vehicle production. See VDA, Global passenger vehicle production in 2023, by country [Graph], (Retrieved July 23, 2024), <https://www.statista.com/statistics/277055/global-market-share-of-regions-on-auto-production/>; OICA & Statista, China's share in global vehicle production from 2008 to 2021 [Graph], (Mar. 17, 2022), <https://www.statista.com/statistics/233942/chinas-share-of-global-production-capacity-of-the-automobile-industry/>.

Amid this significant growth in the PRC's domestic auto industry, Chinese automakers, both state-owned and private firms, have leveraged their significant state-backed support, including subsidies, to fuel a global expansion that has seen Chinese automakers establishing foreign operations in countries like South Africa, the Netherlands, Thailand, Japan, and Brazil, among others, increasing the risks stemming from PRC auto manufacturing in third countries. See Daisuke Wakabayashi and Claire Fu, China E.V. Makers Rush In and Upend a Country's Entire Auto Market, *The New York Times* (Jul. 30, 2024), <https://www.nytimes.com/2024/07/30/business/chinese-electric-vehicles-thailand.html>; Daniel Leussink, BYD's Global expansion push runs into stiff Japan test, *Reuters* (Sept. 4, 2024), <https://www.reuters.com/business/autos-transportation/byds-global-expansion-push-runs-into-stiff-japan-test-2024-09-05/>; China's BYD starts construction on manufacturing complex in Brazil, *Reuters* (Mar. 5, 2024), <https://www.reuters.com/business/autos-transportation/chinas-byd-starts-construction-manufacturing-complex-brazil-2024-03-06/>.

The global expansion of the PRC auto sector's operations in foreign markets and recent foreign investment announcements indicate that Chinese automakers could attempt to enter the U.S. market via exports from third-party countries. Exports from third-party countries of vehicles with Chinese ICTS would expand the scope of the risk that Chinese ICTS poses to U.S. national security. See Paul Wiseman, Prospect of low-priced Chinese EVs reaching US from Mexico poses threat to automakers, *The Associated Press* (June 27, 2024), <https://www.ap.org/news-highlights/spotlights/2024/prospect-of-low-priced-chinese-evs-reaching-us-from-mexico-poses-threat-to-automakers/>; Daina Beth Solomon, Chinese automaker BYD looking for Mexico plant location,

executive says, *Reuters* (Feb. 28, 2024), <https://www.reuters.com/business/autos-transportation/chinese-carmaker-byd-launches-low-cost-dolphin-mini-ev-mexico-2024-02-28/>. Some PRC-based companies have announced plans to establish manufacturing facilities in Mexico, which could enable them to receive favorable trade terms contained in the U.S.-Mexico-Canada Agreement (USMCA). *See id.* Therefore, the PRC's growing presence within the global auto sector, particularly via operations in third-party countries, is expected to expand the number of potential nexus points between PRC connected vehicle suppliers and U.S. automakers and consumers, further undermining U.S. national security.

Second, the military linkage between the PRC government and the automotive sector continues to the current day with the PRC's military-civil fusion strategy, which seeks to, among other goals, exploit investment and innovation within the PRC's private sector to achieve military modernization goals. The military-civil fusion strategy prioritizes specific information and communication technologies and services that are integral to connected vehicle supply chains (e.g., telecommunications, artificial intelligence). *See* Ben Murphy, Translation for Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035, *Center for Security and Emerging Technology*, at 11 and 36 (May 2021), https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five_Year_Plan_EN.pdf. Strategies to achieve these goals include mandating collaboration between PRC-based companies and the military and establishing public and private firms as vectors to facilitate technology transfer, industrial espionage, and intellectual property (IP) theft that would be advantageous for the PRC military. *See* Office of the Dir. of Nat'l Intelligence, *Annual Threat Assessment of the U.S. Intelligence Community*, at 6–10 (Feb. 6, 2023), <https://www.odni.gov/files/ODNI/documents/assessments/ATA-2023-Unclassified-Report.pdf>.

Third, even beyond military-civil fusion, the role of the PRC government

in the auto sector has only grown as government intervention in the market increases. For example, the PRC intervenes in the auto market through direct ownership of prominent industry participants, the purchasing of so-called “golden shares” to gain significant levels of influence within otherwise private firms, embedding Chinese Communist Party (CCP) representatives within corporate boards and management, and the forceful application, or threat, of the PRC's expansive security laws, including its digital era legal structure. *See* Lingling Wei, China's New Way to Control Its Biggest Companies: Golden Shares, *Wall Street Journal* (Mar. 2023), <https://www.wsj.com/articles/xi-jinpings-subtle-strategy-to-control-chinas-biggest-companies-ad001a63>. Laws promulgated in recent years provide the PRC government increased oversight and control over PRC-based companies and their foreign subsidiaries, providing a lever for influence over corporate operations that further exacerbates the threat that the PRC poses to U.S. national security. These laws require PRC-based companies, wherever located, to comply with certain access and information requests upon demand from the PRC and therefore could be used by the PRC to obtain business or other data from PRC-based companies involved in the connected vehicle supply chain. Companies operating under these laws frequently highlight the lack of transparency, consistency, clarity, and predictability of the enforcement of these laws, publicly stating that PRC laws relating to cybersecurity, data storage, or cryptography are not subject to the same degree of judicial accountability as they might be in other jurisdictions. In particular, BIS notes the PRC may utilize a suite of national security laws (e.g., *Counter-Espionage Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, Nov. 1, 2014, amended Apr. 26, 2023, effective July 1, 2023]; *National Security Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, July 1, 2015, effective July 1, 2015]; *National Intelligence Law of the People's Republic of China*

[promulgated by the Standing Committee of the National People's Congress, June 27, 2017, effective June 28, 2017, amended Apr. 27, 2018]; *Anti-Terrorism Law of the People's Republic of China* [promulgated by the Standing Committee of the National People's Congress, Dec. 27, 2015, effective Jan. 1, 2016, amended Apr. 27, 2018]) to compel companies, including those in the connected vehicle supply chain, to support national security efforts—which are more broadly defined in the PRC than in the United States—or military agents upon request. The PRC pursues its broad national security and geopolitical objectives through the creation of backdoors and security vulnerabilities in products sold abroad, and, in many cases, the PRC prohibits companies from disclosing that such a request was made. *See* U.S. Department of Homeland Security, *Data Security Business Advisory: Risks and Considerations for Businesses Using Data Services and Equipment from Firms Linked to the People's Republic of China*, (Dec. 2022), https://www.dhs.gov/sites/default/files/publications/20_1222_data-security-business-advisory.pdf; Ministry of Civil Affairs of the People's Republic of China, *National Security Law of the People's Republic of China*, Arts. 25 and 77, promulgated by the 12th National People's Congress on July 1, 2015, <https://www.mca.gov.cn/zt/n2643/n2647/c1662004999979993333/content.html>. Additionally, PRC authorities have established a regulatory system that effectively allows them to stockpile cyber vulnerabilities. Entities subject to these regulations, including automotive systems manufacturers, are required to report vulnerabilities upon discovery to PRC authorities before patching them. *See* Cyberspace Administration of China, *Provisions on the Management of Security Vulnerabilities of Network Products*, (July 2021), https://www.cac.gov.cn/2021-07/13/c_1627761607640342.htm. This requirement drastically increases the ability of the PRC government and PRC-backed cyber actors to take action against the United States using connected hardware and its associated software by creating an accessible library of known and potentially unpatched vulnerabilities.

Fourth, the PRC has demonstrated a high level of competency in cyber malfeasance. For instance, PRC state-sponsored cyber group Volt Typhoon has proven capable of infiltrating the IT networks of critical U.S. infrastructure using sophisticated tactics, techniques, and procedures such as Living Off the Land Techniques to pre-position themselves across U.S. critical infrastructure and military assets to carry out advanced reconnaissance in IT systems. At a later point, once advanced reconnaissance is conducted, they are then capable of launching cyberattacks to impede U.S. decision making, induce social panic, and interfere with the deployment of U.S. military forces. See Cybersecurity & Infrastructure Security Agency, *PRC State-Sponsored Actors Compromise and Maintain Persistent Access to U.S. Critical Infrastructure*, at 1–5 (Feb. 2024), https://www.cisa.gov/sites/default/files/2024-03/aa24-038a_csa_prc_state_sponsored_actors_compromise_us_critical_infrastructure_3.pdf. A 2022 Annual Report to Congress by the U.S.-China Economic and Security Review Commission found that the PRC's ability and willingness to "weaponize" its own industries, particularly its cybersecurity industry, grants the country an asymmetric advantage over the United States. This argument is supported by public reporting detailing the methods by which known government-affiliated cyber threat groups utilize private firms to carry out their attacks. See U.S.-China Economic and Security Review Commission, *2022 Annual Report to Congress*, at 11 and 14–15 (Nov. 2022), https://www.uscc.gov/sites/default/files/2022-11/2022_Annual_Report_to_Congress.pdf; Christian Shepherd, et al., Leaked files from Chinese firms show vast international hacking efforts, *The Washington Post* (Feb. 22, 2024), <https://www.washingtonpost.com/world/2024/02/21/china-hacking-leak-documents-isoon/>. Additionally, a 2012 report from the United States Senate Permanent Select Committee on Intelligence examining the national security risks posed by the PRC-based companies Huawei and ZTE specifically argued that there are numerous opportunities for PRC-based threat actors to insert malicious hardware or software components into ICTS products throughout the product development stage. See Permanent Select Committee on Intelligence, *Investigative Report on the U.S. National Security Issues Posed by Chinese Telecommunications Companies Huawei and ZTE*, at 3 (Oct. 2012), [https://intelligence.house.gov/sites/intelligence.house.gov/files/documents/huawei-zte%20investigative%20report%20\(final\).pdf](https://intelligence.house.gov/sites/intelligence.house.gov/files/documents/huawei-zte%20investigative%20report%20(final).pdf). This risk is further demonstrated by a study of designed vulnerabilities in products conducted by the Georgetown Security Studies Review, which outlines five years of persistent insertion of malicious code by PRC-based threat actors. See Ryan Neauhard, Flawed by design electronics with pre-installed malware, *Georgetown Security Studies Review*, at 2 (May 23, 2018), <https://georgetownsecuritystudiesreview.org/2018/05/23/flawed-by-design-electronics-with-pre-installed-malware/>. Given the above, the PRC's access to the U.S. connected vehicle supply chain through its growing automotive sector, military-civil fusion and other corporate governance policies and legal institutions, paired with its development of mature cyber espionage capabilities, present a significant risk that the PRC could alter the systems in or obtain and manipulate data about market participants who use connected vehicle ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC.

2. Russia

The Russian state has prioritized the growth of its automotive manufacturing industry, instituted a legal and regulatory framework to compel company data sharing with the state, and maintained a long history of malicious cyber operations against the United States. Under these circumstances, there is an increasing likelihood that Russia emerges as a supplier of connected vehicles technologies for the U.S. market, providing the Russian government a means of exploiting U.S. connected vehicles. Incorporating Russian hardware or software into the U.S. connected vehicle supply chain, therefore, poses undue and unacceptable risks to U.S. persons and critical infrastructure.

First, while Russia has historically been less active in the global automotive sector than the PRC, the Russian government has recently sought to revitalize its domestic auto manufacturing industry following the exodus of foreign automakers after the imposition of significant additional sanctions in 2022 in response to the conflict in Ukraine. In 2024 alone, the Russian auto market is projected to experience a 15 percent increase in passenger vehicle sales, marking a notable uptick since the Russian market crashed in 2022 following the imposition of sanctions, and some

Russian auto manufacturers have continued introducing new models even amid broader economic headwinds. See Russia's 2024 car sales forecast raised to 1.45mln, units, AEB says, *Reuters* (July 3, 2024), <https://www.reuters.com/business/autos-transportation/russias-2024-car-sales-forecast-raised-145-mln-units-aeb-says-2024-07-03>. Russia's domestic auto sector has begun to show signs of resilience, with at least one automaker releasing a new, primarily domestically developed model since the imposition of Western sanctions, even as other domestically sold models are manufactured in the PRC but undergo final assembly in Russia. See Gleb Stolyarov and Alexander Marrow, Focus: Made in Russia? Chinese cars drive a revival of Russia's auto factories, *Reuters* (July 20, 2023), <https://www.reuters.com/business/autos-transportation/made-russia-chinese-cars-drive-revival-russias-auto-factories-2023-07-20/>. In Russia, the revitalization of the domestic economy, particularly the domestic auto sector, has become a key focus of the Russian government since the imposition of sanctions in recent years. The Russian government has released several plans that prioritize the development of its domestic automotive market with a particular focus on research and development of new technology, including autonomous vehicles and V2X ("Vehicle to Everything") vehicle connectivity systems. See Russian Federation, *Order of the Government of the Russian Federation of December 28, 2022 No. 4261-r On Approval of the Strategy for the Development of the Automotive Industry of the Russian Federation until 2035* (Jan. 4, 2023), <https://www.garant.ru/products/ipo/prime/doc/405963861/#1000>; Russian Federation, *Order of the Government of the Russian Federation of August 23, 2021 No. 2290-r On Approval of the Concept for the Development of Electric Vehicle Production and the Transport Strategy of 2030* (2023), <http://static.government.ru/media/files/bW9wGZ2rDs3BkeZHf7ZsaxnlbJzQbJf.pdf>. The development of these interlocking national transportation and automotive industry strategies involves stakeholders from domestic automakers, technology sectors, and the Russian government, illustrating a coordinated effort across the Russian state and its domestic automotive industry. In order to extend the reach of the state into the Russian auto industry, in February 2024, Russia established a state-owned corporation named Rosavto that will act as liaison between government and industry.

Rosavto will develop production plans for vehicles and automotive spare parts, oversee the development of new models and technologies, and manage order distribution, legislative initiatives, and workforce training. See Eugene Gerden, New State Corporation to Oversee Russian Auto Industry, *Wards Auto* (Feb. 2024), <https://www.wardsauto.com/regulatory/new-state-corporation-to-oversee-russian-auto-industry>. Further, Russia has demonstrated resilience against Western sanction and export control regimes while also continuing to grow its electric vehicle market. See Carnegie Endowment, *Why Russia Has Been So Resilient to Western Export Controls*, (Mar. 2024), <https://carnegieendowment.org/research/2024/03/why-russia-has-been-so-resilient-to-western-export-controls?lang=en>. According to market reporting, the Russian electric vehicle market has had a robust performance, with double digit growth in output and sales, largely driven by a surge in the sector's exports. See Russia Automotive Market Report—Analysing EVE Trends and Car Sales Volume Data, *Global Monitor* (retrieved Nov. 2024), <https://www.globalmonitor.us/product/russia-automotive-market>. Projections suggested that with the support of the government, the electric vehicle subsector is poised for further growth. See *id.* Concerted efforts by the Russian government to develop the domestic Russian automotive industry, a growing electric vehicle market, and resilience to western sanction and export control regimes increase the likelihood that Russia-linked connected vehicle technology, such as VCS hardware or covered software, will enter the U.S. connected vehicle supply chain, which, as described below, presents an undue or unacceptable risk to U.S. national security. Given these factors, BIS is taking proactive measures to mitigate any risk posed by Russia's influence over the U.S. connected vehicle supply chain and to prevent Russia from gaining increasing influence over the U.S. connected vehicle supply chain in the future.

Second, like the PRC, the Russian government employs a suite of laws that enable it to compel domestic companies with overseas operations to provide data gleaned through foreign ventures or to surrender similar operational assets to the Russian state. These laws (e.g., Russian Law Federal Security Service No. 40–FZ, “Operational-Investigative Activity” No. 144–FZ, 2014 Amdt. to No. 97–FZ) allow the Russian government direct control over Russian corporations' activities and facilities,

including data or customer information, and mandate that companies assist with counterintelligence actions as requested by the state, including the Federal Security Service of the Russian Federation (FSB). The FSB can, in some cases, mandate that companies allow the FSB to install equipment on their infrastructure or collect data. Firms that are required to facilitate this surveillance or intrusion activity can also be required to actively obfuscate such requests and must provide the state with any information essential to the decryption of any communications captured. Together, these laws enable the Russian state to collect and exploit sensitive data on or about U.S. persons via Russian businesses and, should Russian companies become more prominent in the connected vehicle supply chain, create a pathway through which the Russian government could secure wide-ranging access to the vast amounts of data collected and processed by connected vehicles in the United States. See Internet Governance, *Report of Peter B. Maggs*, (Dec. 2017), <https://www.internetgovernance.org/wp-content/uploads/12-7-Exhibit-AR-Part-6-Maggs-report.pdf>. Public reports have consistently raised concerns about Russian government laws concerning data collection, citing a lack of appropriate safeguards to prevent misuse, including judicial or public oversight. More broadly, reports have repeatedly documented the uneven application of the rule of law, lack of judicial accountability, recurrent violations of judicial proceedings, and challenges with judicial independence. See Justin Sherman, Russia is weaponizing its data laws against foreign organizations, *Brookings* (Sept. 2022), <https://www.brookings.edu/articles/russia-is-weaponizing-its-data-laws-against-foreign-organizations/>; Evgeni Moyakine and A. Tabachnik, Struggling to strike the right balance between interests at stake: The ‘Yarovaya,’ ‘Fake news,’ and ‘Disrespect’ laws as examples of ill-conceived legislation in the age of modern technology, *Computer Law & Security Review*, at 40 (Apr. 2021), <https://www.sciencedirect.com/science/article/pii/S0267364920301175>.

Third, apart from the risks presented by the Russian government access as codified in Russia's legal framework, the country has a longstanding pattern of utilizing cyber operations to gain illicit access to systems that advance the strategic ends of Russian authorities. For example, in December 2020, the company SolarWinds announced it was the target of a two-year-long cyber

operation perpetrated by Russian hackers in the Russian Foreign Intelligence Services (SVR). See U.S. Securities and Exchange Commission, *SEC Charges SolarWinds and Chief Information Security Officer with Fraud, Internal Control Failures*, (Oct. 2023), <https://www.sec.gov/newsroom/press-releases/2023-227>. The perpetrators of the SolarWinds supply chain attack used a software update to deliver malware to the platform's users after Russian intelligence services obtained covert access to the computer systems on which the platform was installed. The attack ultimately impacted more than 18,000 users, including more than 100 companies and nine U.S. Government agencies. This attack credibly demonstrates how Russian actors can infiltrate global enterprise systems via software updates and exemplifies how they could similarly leverage software as a means to exploit connected vehicles in the United States. Additionally, a 2023 Cyber Security Advisory suggests that exploitation of information technology firms and their software will be a persistent tactic leveraged by the Russian government to collect intelligence. See Joint Cyber Security Advisory, *Russian Foreign Intelligence Service (SVR) Exploiting JetBrains TeamCity CVE Globally*, at 3 (Dec. 2023), <https://www.cisa.gov/news-events/cybersecurity-advisories/aa23-347a>. BIS has further identified Kaspersky Lab as an example of the risks imposed by Russia's ability to leverage software companies to allow Russia the ability to collect and weaponize the personal information of Americans. See Bureau of Industry and Security, *Final Determination: Case No. ICTS–2021–002, Kaspersky Lab, Inc.* (June 2024), <https://www.federalregister.gov/documents/2024/06/24/2024-13532/final-determination-case-no-icts-2021-002-kaspersky-lab-inc>.

These political, legal, and regulatory frameworks, combined with the demonstrated capabilities of Russia to exploit ICTS supply chains through malicious cyber activity, exacerbate BIS's concern that the threats posed by Russia could be directed at the U.S. connected vehicle supply chain, including integral systems such as VCS and ADS. The persistent connectivity and software-driven capabilities of VCS and ADS, combined with the vast amounts of data that traverse these systems, make them valuable and likely targets for the Russian government to compromise.

c. Consequences

Taken together, VCS and ADS designed, developed, manufactured, or supplied by persons under the ownership, control, jurisdiction, or direction of the PRC or Russia manifest undue and unacceptable risks to United States national security and to the safety and security of U.S. persons in several ways. If left unaddressed, the interaction of threats and vulnerabilities could result in the exfiltration of sensitive U.S. persons' data to foreign adversaries or the remote or automated manipulation of connected vehicles by the PRC and Russia, among other concerns.

First, the integration of compromised VCS or ADS into a completed vehicle could undermine the reliability of a connected vehicle or its underlying control systems. Compromised components in VCS or ADS could result in increased frequency and severity of connected vehicle malfunctions that could, in turn, detrimentally impact U.S. national security, including the resiliency of U.S. critical infrastructure, or the safety of U.S. persons.

Given the persistent connectivity of VCS and ADS and the essential functions that they serve in the operation of connected vehicles, these systems, if compromised and co-opted by an adversary, could serve as the nodes through which a foreign actor could probe or breach broader ICTS systems within the United States. Remote malicious cyber activities—which rely on network connectivity (e.g., Wi-Fi, Bluetooth, 3/4/5G networks)—have increased significantly in recent years and consistently outnumber malicious cyber activities carried out through physical access to devices since at least 2010, accounting for 95 percent of all malicious cyber activities in 2023. See Upstream, *Upstream's 2024 Global Automotive Cybersecurity Report* (2024), <https://upstream.auto/reports/global-automotive-cybersecurity-report/>. Considering the increasingly sophisticated methodologies employed by foreign adversaries to gain access to critical U.S. cyber infrastructure, compromised VCS and ADS, with their inherent connectivity, would easily present another attack surface for foreign adversaries to exploit. As detailed in the previous analysis of vulnerabilities inherent in VCS, adversaries with access to VCS, such as telematics systems, could inject malicious code into a vehicle's operational systems. Additionally, such malware could be developed in such a way as to exploit vehicle connectivity to

propagate itself across multiple systems as the vehicle travels and connects to those discrete systems. In this way, not only would the ICTS integral to connected vehicles be compromised, but vehicle systems could be exploited to spread malware with the intent of harming all ICTS systems to which a vehicle connects. See Anastasios Giannaros, et al., *Autonomous Vehicles: Sophisticated Attacks, Safety Issues, Challenges, Open Topics, Blockchain and Future Directions*, *Journal of Cybersecurity and Privacy* 3.3, at 505 (2023).

Second, as discussed, both VCS and ADS have significant control over and access to critical vehicle functions, including steering, braking, speed control, ignition, and almost all other mechanical functions of the vehicle. Such extensive control over vehicle operations could enable a foreign adversary to use a compromised VCS or ADS component to hamper vehicle functions or even to manipulate a connected vehicle for malicious purposes. As VCS and ADS control or link to integral vehicle functions, a foreign adversary could even exploit compromised VCS or ADS components to impair or disable a connected vehicle while in transit. Disabled, impaired, or otherwise improperly functioning vehicles could result in grave damage or impediment to critical infrastructure within the United States or could result in physical harm to U.S. persons. A disabled, impaired, or erratically functioning connected vehicle, or potentially multiple connected vehicles all experiencing problems simultaneously, could cause traffic patterns that would effectively block critical transportation arteries. This scenario could also cause collisions, ultimately damaging transportation features (e.g., roadways, bridges, tunnels), energy, telecommunications, and similar infrastructure situated near transportation systems. The potential consequences of widespread connected vehicle impairment could be particularly acute if the targets were fleet vehicles operating in support of infrastructure vital to transportation, energy, water, waste, telecommunications, and other essential services.

The risks to the resiliency of critical U.S. infrastructure posed by connected vehicle components designed, developed, manufactured, or supplied by persons that are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia are further compounded by the potential for VCS and ADS to collect data on infrastructure. Advances in VCS

and ADS necessitate increasingly cutting-edge sensor suites incorporating radar, LiDAR, camera, sonar, and computer vision to gather information on the surrounding environment for both onboard computing and remote cloud computing to process data in informing vehicle operating decisions. See Anastasios Giannaros, et al., *Autonomous Vehicles: Sophisticated Attacks, Safety Issues, Challenges, Open Topics, Blockchain and Future Directions*, *Journal of Cybersecurity and Privacy* 3.3, at 515 (2023); Luis Hernandez, et al., *Applications of Cloud Computing in Intelligent Vehicles*, *Journal of Artificial Intelligence and Machine Learning in Management*, at 12–13 (2022). This vast wealth of data, collected over time by multiple vehicles, likely contains valuable information such as location data about critical U.S. infrastructure. For example, data gathered from GPS or global navigation satellite systems (GNSS) in a connected vehicle could be cross-referenced and collated with a multitude of other data to produce information about the location, function, and operational trends of various transportation, energy, or other critical infrastructure. See Cybersecurity & Infrastructure Security Agency, *Autonomous Ground Vehicle Security Guide: Transportation Sector*, at 1 (2021), <https://www.cisa.gov/sites/default/files/publications/Autonomous%2520Ground%2520Vehicles%2520Security%2520Guide.pdf>; Cybersecurity & Infrastructure Security Agency, *Cybersecurity and Physical Security Convergence*, at 1 (2020), https://www.cisa.gov/sites/default/files/publications/Cybersecurity%2520and%2520Physical%2520Security%2520Convergence_508_01.05.2021.pdf. A foreign adversary could extract such critical infrastructure data using its control over designers, developers, manufacturers, or suppliers of VCS and ADS components subject to the foreign adversary's ownership, control, jurisdiction, or direction, thereby increasing the risk and precision of attacks on such critical infrastructure.

Finally, given the volume of information collected by vehicles to support VCS and ADS operation, exploitation of these systems could enable an adversary to cull a tremendous amount of data on vehicle movement across the United States. This information could potentially include data generated on or from fleet vehicles used by emergency response, law enforcement, or the military. This data, and particularly all metadata and

derived data that can be drawn from the raw data, can provide considerable insight into fleet size, composition, and capabilities, as well as information on organizational response times and response procedures. Such information would prove valuable to an adversary seeking to disrupt U.S. emergency response operations. Any potential risks to U.S. national security arising from disrupting emergency response activities are further compounded by the potential for an adversary to exploit access to VCS and ADS to leverage the persistent connectivity required for malign operations, including exploits to trigger improper engine shutdown, brake activation, or electrical system deactivation. Any of these actions would have serious consequences for U.S. persons' health and safety. VCS and ADS, if corrupted by the producer at the direction of a foreign adversary, could improperly access driver mobile devices to collect, exfiltrate, and exploit personally identifiable information (PII) or even protected health information (PHI). It is also possible that a foreign adversary could use covert access to VCS and ADS to provide false or misleading operational information to a driver, causing degraded and dangerous vehicle operation conditions. Such tactics could be used either indiscriminately to sow panic and cause disruption, or to intentionally target specific drivers. Additionally, and as noted by the Office of the Director of National Intelligence in the 2024 National Counterintelligence Strategy, foreign adversaries, like the PRC and Russia, view this kind of PII and PHI as particularly valuable as it provides them "not only economic and R&D benefits, but also useful [counterintelligence] information, as hostile intelligence services can use vulnerabilities gleaned from such data to target and blackmail individuals." See The Director of Nat'l Intelligence, *2024 National Counterintelligence Strategy* (Aug. 2024), https://www.dni.gov/files/NCSC/documents/features/NCSC_CI_Strategy-pages-20240730.pdf.

Even when such systems are not subject to compromise, companies owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, if occupying certain positions within the supply chain, may potentially legally gain access to their users' personal data. For example, one prominent Chinese auto manufacturer with operations in the United States publicly states in its U.S. privacy policy that the personal data it may collect (e.g., identifiers, customer records information, internet or other electronic

network activity information, geolocation information, professional or employment-related information) is only stored in the United States in principle, but goes on to note that personal data may be transferred to its headquarters in China for processing and storage. While the incorporation in the U.S. supply chain of VCS hardware and covered software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia poses one type of risk, transactions involving VCS hardware and covered software pose a separate risk when the connected vehicle manufacturer is, itself, owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, even when the connected vehicle manufacturer is located in the United States. Connected vehicle manufacturers have privileged and direct access to all systems in the vehicle, including the VCS hardware and covered software. Not only are VCS hardware and covered software built to the connected vehicle manufacturers' specifications but prior to the sale of a completed connected vehicle, connected vehicle manufacturers are able to exercise significant levels of control over that VCS hardware and covered software with little to no external oversight prior to the sale of the completed connected vehicle. Based on the foregoing, BIS assesses that ICTS transactions involving VCS hardware or covered software designed, developed, manufactured, or supplied by persons owned or controlled by, or subject to the jurisdiction or direction of the PRC or Russia—including transactions to supply the VCS hardware or covered software into the United States market as part of the sale of the completed connected vehicle—present undue or unacceptable risks to the national security of the United States within the meaning of E.O. 13873.

V. Discussion of the Final Rule

This final rule prohibits—absent a general or specific authorization otherwise—(1) VCS hardware importers from knowingly importing into the United States certain hardware for VCS (section 791.302, "Prohibited VCS hardware transactions"), (2) connected vehicle manufacturers from knowingly importing into the United States completed connected vehicles incorporating covered software, and (3) connected vehicle manufacturers from knowingly selling within the United States completed connected vehicles that incorporate covered software (section 791.303, "Prohibited covered

software transactions"). These prohibitions apply to transactions when such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The rule also (4) prohibits connected vehicle manufacturers who are persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software (section 791.304, "Related prohibited transactions"), regardless of whether such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia (collectively, "prohibited transactions").

This rule primarily impacts market participants who could be considered VCS hardware importers or connected vehicle manufacturers, such as OEMs and importers of completed connected vehicles, as well as tier one and tier two suppliers of VCS hardware. For these entities, three compliance mechanisms—Declarations of Conformity, general authorizations, and specific authorizations—are available, depending on whether the VCS hardware importer or connected vehicle manufacturer wishes to engage in an otherwise prohibited transaction. Importantly, because VCS hardware importers and connected vehicle manufacturers frequently offer many different types of products, any one of the three mechanisms may not be available for their entire business. Rather, depending on the product, VCS hardware importers and connected vehicle manufacturers could be required to use a combination of these three mechanisms to meet their obligations under the rule.

First, Declarations of Conformity are required to be submitted to BIS by VCS hardware importers and connected vehicle manufacturers prior to importing VCS hardware or importing or selling completed connected vehicles that incorporate covered software, certifying that the VCS hardware or covered software was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia (section 791.305, "Declaration of Conformity"). The Declarations of Conformity require VCS hardware importers and connected vehicle manufacturers to certify to BIS, once a year or whenever material

changes occur, that they are not engaging in prohibited transactions and provide certain information on the import of VCS hardware and/or the import or sale of completed connected vehicles as relevant.

Second, a general authorization could be available for VCS hardware importers and/or connected vehicle manufacturers seeking to engage in an otherwise prohibited transaction, depending on the circumstances (section 791.306, “General authorizations”). General authorizations are available only in a narrow set of circumstances in which the conditions of the otherwise prohibited transaction appropriately mitigate the level of risk associated with the particular type of transaction. In determining whether to issue a general authorization, BIS may consider any information or material BIS deems relevant and appropriate, classified or unclassified, from any Federal department or agency, or from any other source. BIS will publish general authorizations issued pursuant to this subpart on its website (<https://www.bis.gov/OICTS>) and will also publish them in the **Federal Register**. Those availing themselves of a general authorization are required to continuously monitor their use of the VCS hardware or completed connected vehicles covered by the general authorization to ensure the authorization still applies. If a change renders the transaction ineligible for a general authorization, such as a change in the vehicle’s use, the VCS hardware importer or connected vehicle manufacturer is required to apply for a specific authorization and cease engaging in such transaction unless and until a specific authorization is granted.

Lastly, a specific authorization may be permitted for VCS hardware importers and connected vehicle manufacturers who wish to engage in a prohibited transaction, but do not otherwise qualify for a general authorization from BIS (section 791.307, “Specific authorizations”). Such VCS hardware importers and connected vehicle manufacturers are required to pause engaging in these transactions before they may proceed with the prohibited transaction under a specific authorization. A specific authorization will only be available in circumstances where BIS determines, based on the information submitted by the applicant as well as any information or material BIS deems relevant and appropriate, classified or unclassified, from any Federal department or agency, or from any other source, that the otherwise prohibited transaction does not present an undue or unacceptable risk to U.S.

national security. However, as a condition of approving the specific authorization, BIS might impose certain requirements and mitigation measures upon the VCS hardware importers and connected vehicle manufacturers seeking to proceed with the prohibited transaction.

VCS hardware importers and connected vehicle manufacturers can appeal any of the following BIS decisions to the Under Secretary: the determination that a VCS hardware importer or connected vehicle manufacturer is ineligible for a general authorization, the denial of an application for a specific authorization, or the suspension or revocation of a previously granted specific authorization (section 791.309, “Appeals”). Further, the regulation establishes a method for VCS hardware importers and connected vehicle manufacturers to seek guidance on prospective transactions that may be prohibited through a BIS advisory opinion (section 791.310, “Advisory opinions”). BIS may also share guidance on its website for VCS hardware importers or connected vehicle manufacturers that certain activities could constitute a prohibited transaction.

In issuing this rule, BIS recognizes that Section 203(b) of IEEPA—*i.e.*, the “Berman Amendment”—limits the scope of the authority to regulate or prohibit transactions relating to “information” or “informational materials.” In relevant part, the Berman Amendment states that the “authority granted to the President by this section does not include the authority to regulate or prohibit, directly or indirectly . . . the importation from any country, or the exportation to any country, whether commercial or otherwise, regardless of format or medium of transmission, of any information or informational materials, including but not limited to, publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact disks, CD ROMs, artworks, and newswire feeds.” 50 U.S.C. 1702(b)(3). Consistent with the statute’s text and purpose, as demonstrated by legislative history and context as well as judicial interpretations, BIS interprets the phrase “information or informational materials” to be limited to expressive material, consistent with the purpose of 50 U.S.C. 1702(b)(3) to protect materials involving the free exchange of ideas from regulation under IEEPA and with IEEPA’s broader purpose to limit material support to adversaries. A broader interpretation of the term would

enable adversaries and countries of concern to use non-expressive data to undermine our national security.

In the NPRM, BIS explained this regulation is consistent with the Berman Amendment. BIS sought comment on this issue, including whether and how to address the term “information or informational materials” in the final rule. One commenter claimed that the prohibitions included in the rule could extend beyond IEEPA’s intended purpose and result in litigation risk for BIS. Therefore, according to the commenter, BIS should clarify what types of information sharing will be allowed in light of the IEEPA limitations included in the Berman Amendment. One commenter requested clarification on what types of information sharing will be allowed under the rule, including documentation of technology designs. Another commenter asked about “the information/materials—including technology design documentation—that will be permitted or required when the Berman Amendment applies.” In response, BIS notes that this rule does not add any restrictions on the sharing of technology designs, technical documentation, or similar information, nor does it remove any restrictions that may exist under any other regulation (*e.g.*, export controls). Additionally, while this rule requires regulated parties to maintain documentation relevant to their compliance with this rule, it does not prescribe any specific requirements as to what that documentation must consist of. BIS did not receive any comments requesting that specific provisions relating to information or informational materials be added to the rule.

This final rule is consistent with the Berman Amendment. Its purpose is to regulate transactions involving certain hardware and software based on functional capabilities that can be exploited by foreign adversaries, not to restrict the import or export of expressive speech and communicative works and mediums that may be carrying such expressive content. As discussed in Section IV, VCS hardware and covered software process and transmit data such as geolocation information or systems diagnostics reports, which are used to monitor and control the vehicle’s safe operation, and that a foreign adversary could manipulate in ways that could impair or disable the vehicle’s function, leading to dangerous outcomes that pose a harm to U.S. national security. Similarly, the functional data collected by covered software—such as high-definition mapping data of infrastructure and

roadways—would pose serious risks to that critical infrastructure if collected and exploited by a foreign adversary. This final rule “balances IEEPA’s competing purposes” in “restricting material support for hostile regimes while encouraging the robust interchange of information.” *United States v. Amirnazmi*, 645 F.3d 564, 587 (3d Cir. 2011). Thus, BIS has determined that the prohibitions in this rule are consistent with the Berman Amendment. To the extent that any parties believe that a transaction governed by this rule qualifies as “information or informational materials” that is exempt under 50 U.S.C. 1702(b)(3), they can seek clarification using the administrative processes for seeking an advisory opinion.

VI. Revisions From the Proposed Rule and Response to Comments

Each section of the final rule is discussed below, including BIS’s consideration of comments received in response to the NPRM.

a. Definitions

BIS received a variety of comments regarding the definitions listed in the NPRM. In the following sections, BIS summarizes and responds to those comments, outlines the definitions for this final rule, and for some definitions, provides additional interpretation to assist readers in understanding the final definition (see section 791.301, “Definitions”). BIS notes that multiple commenters requested BIS include definitions for terms that are already defined within 15 CFR 791.1, such as U.S. person. In response, BIS emphasizes that definitions contained in 15 CFR 791.1 apply to this subpart, except where the same term is defined differently in this rule.

1. Automated Driving System

In the NPRM, BIS proposed *Automated Driving System (ADS)* to mean hardware and software that, collectively, are capable of performing the entire dynamic driving task for a completed connected vehicle on a sustained basis, regardless of whether it is limited to a specific ODD. After considering commenters’ feedback, BIS has chosen to retain this definition in the final rule.

Many commenters requested clarity on the definition of *ADS*, particularly urging BIS to explicitly reference SAE International’s J3016 standard in the definition. Commenters also recommended that BIS explicitly exclude Levels 1 and 2 of the SAE J3016 standard or plainly state that the

regulation does not capture ADAS in the definition. Similarly, BIS received feedback to incorporate language that excludes hardware and software that are not capable of performing the entire dynamic driving task and to provide examples of these exclusions, such as steering, braking, acceleration, and speed.

BIS declines to include a reference to the current version of SAE J3016 at this time and believes that the current definition adequately covers only those systems that would fall into SAE categorization Level 3 and above. However, this does not preclude BIS from amending this rule in the future to make explicit reference to the current version (April 2021) or any future version of J3016. BIS emphasizes that in enforcing this rule, it will only consider Automated Driving Systems that meet the full definition of this rule to be in scope, and BIS believes that the details regarding the specifics of Levels 3, 4, and 5 systems contained within J3016 are useful guidance for connected vehicle manufacturers to determine if their products fall within scope. Following the effective date of this rule, entities that seek clarification if a specific piece of software is subject to the prohibitions of this rule may submit a request for an advisory opinion from BIS. Further, in response to commenters requesting that BIS explicitly state that ADAS is out of scope, BIS believes this to be unnecessary as the definition aligns with SAE J3016, which differentiates between ADAS and ADS.

Comments contained various positions on the specific exclusion or inclusion of LiDAR and other sensing systems within the prohibitions. Several commenters advised BIS to identify examples of specific components that are outside the scope of the prohibitions, such as radar and camera technology. Others advocated for the inclusion of ADS sensor technology in the prohibitions and explained that BIS should explicitly scope the prohibitions to include cameras, radar, LiDAR, Time of Flight internal sensors, ultrasonic sensors, and microphones. Commenters pointed out that LiDAR is proliferating across critical infrastructure industries and heavily sourced by foreign adversaries, further urging that LiDAR, in particular, should fall in scope of the prohibitions, including LiDAR hardware, software for sensor control, and perception software.

BIS maintains its position from the NPRM that this rulemaking will address only ADS software and not the multiple hardware systems that support or directly enable ADS operation. BIS agrees that proliferation of LiDAR and

other sensing technologies from entities with a foreign adversary nexus throughout multiple critical infrastructure sectors may pose a threat to national security. However, within the limited scope of the automotive sector, and with this initial rulemaking, BIS assesses that a prohibition that focuses specifically on transactions that provide ADS software is appropriate at this time to mitigate the national security risks that they present while limiting the supply chain and economic impact. As stated in the NPRM, BIS is proposing to regulate ADS software rather than the hardware components of ADAS and ADS so as to reduce unnecessary economic impacts and supply disruption. The hardware that enables ADAS and ADS varies widely between different OEMs. ADAS and ADS hardware encompasses a wide variety of different sensors, distributed electronic control units (ECUs), centralized computing units, actuators, and signaling units, among others. These sensors and internal vehicle networking hardware rarely have independent connectivity. A rule that coherently and feasibly addresses these varied supply chains would have disproportionate economic and supply chain impacts relative to the reduction of national security risks. Further, focusing on the ADS software supply chain appropriately mitigates the national security risks that they present while limiting the supply chain and economic impact. Commenters should also refer to the discussion below on covered software for greater detail on BIS’s decision to omit LiDAR from this rule. BIS’s decision not to focus on sensing technologies in this rule does not preclude BIS from addressing them in a subsequent rulemaking.

Commenters recommended providing definitions for terms within the *ADS* definition, such as “operational design domain.” BIS declines to specify a definition for operational design domain as it believes this to be an industry standard term in the autonomous vehicle sector that refers to operating conditions under which an ADS or feature thereof is specifically designed to function. Additionally, BIS hopes to provide industry with additional flexibility to interpret these terms within the contexts of their own technologies, reducing the compliance burden of the rule. However, BIS emphasizes that the related definitions in J3016 are useful guidance for industry and interested entities.

One commenter also advised removing “for a completed connected vehicle” from the definition of *ADS* and adding an “ADS-equipped vehicle” to

the definition to avoid industry confusion because not all connected vehicles will have ADS. BIS maintains that the ADS-related prohibitions of the rule affect only completed connected vehicles that are equipped with ADS by the nature of how the covered software prohibition is crafted, and therefore narrowing the definition of ADS to remove “for a completed connected vehicle” is not necessary.

Commenters noted that the ADS definition includes hardware, while the prohibited transactions do not include ADS hardware. The ADS definition captures the whole of ADS, including hardware, while the regulation prohibits only ADS software and does not prohibit ADS hardware. Commenters advised removing “hardware” from the definition of ADS or providing language that clarifies that the definition of ADS generally describes what an ADS is, but not necessarily what aspects of the system are regulated by this rule. After consideration, BIS declines this suggestion. In the interest of maintaining a harmonized definition that is consistent with other Federal regulations and with industry standards such as NHTSA’s Second Amended Standing General Order 2021–01 and SAE J3016, BIS maintains that inclusion of “hardware” in the definition of ADS is appropriate, even though this does not mean that the hardware of an ADS system is regulated. The structure of the covered software definition and the covered software prohibitions are the only instances of a use of the ADS definition and make clear that ADS hardware is not prohibited when designed, developed, manufactured, or supplied by entities owned by, controlled by, or subject to the jurisdiction or direction of the PRC.

One commenter requested that BIS clarify that ADS software that carries out only a single function, such as parking, be excluded from the definition of ADS. While BIS generally believes that systems that are not capable of executing the entire dynamic driving task (as required by the definition of ADS) are not covered by this regulation, BIS declines to amend the definition in this rule as such a determination would be highly fact specific. BIS emphasizes that persons seeking greater clarity may, upon the effective date of this rule, seek an advisory opinion from BIS regarding a specific transaction involving ADS software.

2. Completed Connected Vehicle

In the NPRM, BIS proposed to define *completed connected vehicle* as follows: “a connected vehicle that requires no further manufacturing operations to

perform its intended function. For the purposes of this subpart, the integration of an ADS into a connected vehicle constitutes a manufacturing operation for a completed connected vehicle.” BIS chose to retain this definition of *completed connected vehicle* in the final rule based on comments, further research, and other changes to the regulation.

Some commenters, particularly from the commercial vehicle sector, argued that the proposed rule did not provide a clear definition of completed vehicle within the context of the commercial market. As discussed in the following section addressing the definition of connected vehicle, BIS recognizes the substantial compliance concerns associated with the complex commercial vehicle sector and has determined that the commercial vehicle sector will not be covered by this rulemaking. Recognizing there are substantial national security concerns in the commercial vehicle market, BIS intends to issue a new proposed rule specifically tailored to this sector.

One commenter urged BIS to substitute a new definition for “ADS-equipped connected vehicle” instead of “completed connected vehicle” in order to avoid implying that all connected vehicles contain ADS software. BIS recognizes that not all connected vehicles are ADS-equipped. However, BIS declines this suggestion because the prohibitions resulting from the regulation pertain to completed connected vehicles, as defined by the regulation, and BIS does not want to engender confusion or suggest that the prohibitions pertain only to products equipped with ADS. Therefore, BIS chooses not to integrate this recommendation into the final rule.

3. Connected Vehicle

In the NPRM, BIS proposed *connected vehicle* to mean a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. Vehicles operated only on a rail line are not included in this definition. BIS modified its definition in the final rule based on comments from the public.

A few commenters requested clarifications or refinements for BIS’s definition of a “connected vehicle.” Some commenters highlighted that

other regulatory bodies, such as National Highway Traffic Safety Administration (NHTSA) and the Environmental Protection Agency (EPA), often implement separate rulemaking efforts for light/passenger vehicles and heavy/commercial vehicles. BIS has opted to exclude commercial vehicles from the final rule. As discussed elsewhere, BIS emphasizes that the national security risks associated with PRC or Russian VCS and ADS in commercial vehicles are grave, and BIS’s decision to exclude commercial vehicles from this rulemaking in no way implies that these risks are lesser than in the passenger vehicle market. Rather, BIS intends to propose a separate regulation tailored to the commercial sector in the coming months.

Specifically, BIS has amended the definition of “connected vehicle,” for the purposes of this rule, to exclude vehicles with a gross vehicle weight rating (GVWR) of over 10,000 pounds, which generally aligns with the weight delineation included in definitions used by other government agencies (including the Federal Motor Carrier Safety Administration) and by industry to delineate between passenger and commercial vehicles.

One commenter also requested that BIS clarify that recreational vehicles (RVs) are not included in the definition of a “connected vehicle.” BIS declines to amend the definition as it believes RVs will largely be excluded from the regulation. First, as amended, RVs weighing over 10,000 pounds will not be captured by this rule and will instead be subject to an intended future rule covering commercial vehicles. Second, as the commenter noted, BIS intends to issue a general authorization pertaining to vehicles used on public roads for fewer than 30 days a year, which could capture additional RVs that weigh under 10,001 pounds, if manufacturers are able to verify their RVs are eligible. Manufacturers availing themselves of any future general authorization need not notify BIS of its use nor apply for the authorization, contrary to the comment’s suggestion. In the future, BIS may consider whether a general authorization that specifically addresses RVs would be appropriate.

One commenter requested that BIS explicitly exclude agricultural equipment, construction equipment, and mining equipment from the definition of “connected vehicle.” BIS does not believe this modification necessary as it believes the existing definition of “connected vehicle,” which mandates that the vehicle must be manufactured “primarily for use on

public streets, roads, and highways,” and under 10,001 pounds, sufficiently excludes these vehicles from the provisions of the rule. Another commenter urged BIS to clarify that the rule does not apply to entities importing VCS hardware intended for integration into vehicles that are not covered by this rule. BIS believes that modifications to the definition of VCS and VCS hardware address this comment.

Commenters urged BIS to amend the definition of “connected vehicle” to clarify that Personal Delivery Devices (PDDs) and bicycles are not captured by the rule. BIS does not believe this modification is necessary as it does not believe PDDs nor bicycles meet the definition of a connected vehicle. PDDs and bicycles primarily operate in shoulders of roads, bike lanes, and sidewalks, which BIS does not believe meets the definition of “manufactured primarily for use on public streets, roads, and highways.” The exclusion of these devices from this regulation is further in line with Federal and State-level interpretations that have also excluded PDDs from the definition of motor vehicle and related policies.

Commenters asked that BIS clarify whether a “connected vehicle” includes a motorcycle. One commenter offered the definition of motorcycle from 40 CFR 205.151: “[A]ny motor vehicle, other than a tractor, that: (i) [h]as two or three wheels; (ii) [h]as a curb mass less than or equal to 680 kg (1499 lb); and (iii) [i]s capable, with an 80 kg (176 lb) driver, of achieving a maximum speed of at least 24 km/h (15 mph) over a level paved surface.” BIS understands and acknowledges that this definition of motorcycle fits into its definition of “connected vehicle” in this rule, meaning that motorcycles are subject to this regulation, and BIS believes that an additional definition is unnecessary to improve ease of administration of this rule. Further, BIS notes that vehicles such as electric scooters and e-bicycles are not “manufactured primarily for use on public streets, roads, and highways,” given that in most jurisdictions such vehicles cannot be ridden legally on public highways and many roads. Therefore, BIS assesses that the definitions provided are scoped appropriately.

One commenter asked BIS to clarify that the regulation does not apply to VCS hardware importers and connected vehicle manufacturers that import covered hardware intended for assembly into vehicles that are not covered by the definition of connected vehicle. In response, BIS confirms that transactions involving covered software and VCS hardware that are not integrated into a

connected vehicle are not subject to this regulation. VCS hardware importers and connected vehicle manufacturers executing covered software and VCS hardware transactions that are intended to be incorporated into a connected vehicle, as defined in the final rule, are subject to this regulation.

BIS has chosen to define “connected vehicle” to mean a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. Vehicles operated only on a rail line are not included in this definition. For the purposes of this subpart, a connected vehicle with a gross vehicle weight rating of more than 4,536 kilograms or 10,000 pounds is not included in this definition.

The primary change from the definition in the proposed rule is the inclusion of a weight constraint. This final rule has been narrowed to address vehicles under 10,001 pounds (which largely apply to the passenger vehicle market). BIS intends to supplement this rulemaking with an additional rule to address vehicles over 10,000 pounds (which largely applies to the commercial vehicle market), given the national security risks.

4. Connected Vehicle Manufacturer

In the NPRM, BIS proposed “connected vehicle manufacturer” to mean a U.S. person (1) manufacturing or assembling completed connected vehicles in the United States; and/or (2) importing completed connected vehicles for sale in the United States. Based on feedback from commenters, BIS has amended its definition of “connected vehicle manufacturer” in the final rule.

Commenters advised BIS to be more specific about who is responsible for reporting to BIS under this regulation. Commenters recommended that BIS clarify that contracting with another party to manufacture or assemble a completed connected vehicle that integrates one’s own ADS or VCS for one’s own business is out of scope of the regulation. BIS declines to do so. Through modifications to the *connected vehicle manufacturer* definition, BIS specifies that a person whose sole manufacturing or assembly operation is integrating ADS into an otherwise completed connected vehicle would

qualify such a person as being a “connected vehicle manufacturer.” BIS also included changes to the definition of *sale* to ensure that these contracting operations are within scope of the regulation. As discussed further below relating to the modifications to the definition of *sale*, BIS has determined that contracting operations could, but may not necessarily, be a sale under the terms of this rule.

Commenters encouraged BIS to consider whether a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, whose sole manufacturing or assembly operation is integrating ADS into an otherwise completed connected vehicle, should be subject to the prohibitions in the rule and need to obtain a specific authorization before importing or selling that completed connected vehicle in the United States. BIS determined that such integration of ADS software into a completed connected vehicle by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia is an extension of the national security risk relating to covered software and intended to be restricted. In response, BIS clarifies that ADS integration into an otherwise completed connected vehicle is subject to this regulation and has updated the definition of connected vehicle manufacturer in the final rule to reflect this.

Commenters also encouraged BIS to make third-party manufacturers or assemblers operating on behalf of a U.S. entity, regardless of the origin of the ADS or VCS, exempt from this regulation. BIS rejects this request and has updated the regulation to clarify that third-party manufacturers who are persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia are subject to this rule. Third-party manufacturers are an integral aspect to a connected vehicle manufacturer’s overall manufacturing operations; therefore, if such third parties were persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, this would continue to perpetuate the national security risks that this rule is seeking to address.

In the final rule, BIS has chosen to define a *connected vehicle manufacturer* to mean a U.S. person who:

(1) Manufactures or assembles completed connected vehicles in the United States for sale in the United States;

(2) Imports connected vehicles for sale in the United States; and/or

(3) Integrates ADS software on a completed connected vehicle for sale in the United States.

A connected vehicle manufacturer may also be a VCS hardware importer, as defined herein, if VCS hardware has already been installed in a connected vehicle when the connected vehicle manufacturer imports it.

This modified definition clarifies BIS's intention to capture entities who purchase otherwise completed (and compliant) connected vehicles from a third party and then integrate their proprietary ADS on the vehicle to enable autonomous driving. For example, a U.S. person who purchases completed connected vehicles from a U.S. connected vehicle manufacturer (even if those vehicles do not contain PRC or Russian VCS hardware or ADS software) and then integrates its own ADS software on the vehicles would be performing a manufacturing operation and would be explicitly captured as a connected vehicle manufacturer under this amended definition. If that U.S. person is an entity owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, it would require a specific authorization to sell those vehicles in the United States, which includes transferring those vehicles for commercial operations. The modified definition also clarifies that the first paragraph of the definition, which relates to persons who manufacture or assemble completed connected vehicles in the United States, applies only if the vehicles are intended for sale in the United States (not for export and sale abroad).

5. Covered Software

In the NPRM, BIS proposed to define *covered software* as “the software-based components, in which there is a foreign interest, executed by the primary processing unit of the respective systems that are part of an item that supports the function of Vehicle Connectivity Systems or Automated Driving Systems at the vehicle level. Covered software does not include firmware, which is characterized as software specifically programmed for a hardware device with a primary purpose of controlling, configuring, and communicating with that hardware device. Covered software also does not include open-source software that can be freely used, modified, and distributed by anyone, with both access to the source code and the ability to contribute to the software's development and improvement unless that open-source software has been modified for proprietary purposes and not redistributed or shared.” Based on

comments, BIS changed its definition of *covered software* to better align with industry practices.

Commenters commonly sought more guidance on the layers of software regulated under the rule. Commenters requested examples regarding how covered software applies to the software stack for VCS and ADS. Common feedback urged BIS to define software-based components that fall in and out of scope of the regulation, such as application, firmware, middleware, and system software. Commenters also encouraged BIS to provide a definition of these layers of software, particularly emphasizing that a definition was needed for firmware. Commenters advocated for the exclusion of embedded software (e.g., middleware and system software) because the application software more directly facilitates external communications, and the embedded software is not divisible or distinguishable from hardware. Commenters also suggested that regulating embedded software would introduce more complex supply chain bottlenecks and prevent many companies from meeting the covered software prohibition within a year's time.

In response to these comments, BIS has added specificity to the *covered software* definition to explicitly include application, middleware, and system software, while continuing to exclude firmware. BIS has also included a description of firmware. BIS declined to generally exclude embedded software from the definition, because doing so would exclude certain software that could pose a national security risk. Rather, BIS has chosen to classify software along “application,” “system,” “middleware,” and “firmware” categories. To determine whether particular embedded software is excluded from the definition, parties should consider whether the embedded software leverages specific code executed by the primary processing unit or units of the system. This requirement may exclude embedded software systems that are executed on ancillary surface modules or processors, depending on the specific architecture of the VCS.

Two commenters recommended that BIS limit covered software to *only* the application layer. BIS rejects this feedback. BIS intends covered software to include application software, operating system software and a library of established functions which are generally referred to as “middleware.” BIS chose to include operating system and middleware function software in the definition of “covered software”

because if either the operating system or middleware functions are compromised, the resulting application would not execute securely. So long as the software in question is application, operating system, or middleware executed by the primary processing unit of the subject system, it would likely be covered software unless otherwise excluded.

One commenter requested that BIS define the term “primary processing unit” in the “covered software” definition. BIS declines to incorporate an explicit definition in the regulatory text because a definition is unnecessary; unlike other specialized terms defined in the final rule, “primary processing unit” is a generally widely understood term. To provide additional interpretive guidance on the term, BIS intends the term “primary processing unit” to encompass the central or graphics computing unit of a system responsible for running both the application(s) and the associated operating system that directly enable VCS or ADS on the vehicle. Commenters supported the exclusion of open-source software from the rule and requested BIS align the definition of open-source software with the definitions from the National Defense Authorization Act (NDAA) of 2019, CISA 2023 Open-Software Security Roadmap, and the Open Source Initiative. Commenters also wanted BIS to clarify if open-source software modified by Russian or Chinese entities falls under scope of the regulation. BIS accepts the recommendation of multiple commenters to align the definition of open-source software with that of the 2019 NDAA. Further, BIS added certain clarifying clauses to the 2019 NDAA definition to address advances in artificial intelligence and the evolution of the use of the term “open-source” in artificial intelligence applications by including “in its entirety” to the definition. However, BIS declines to limit the open-source software exclusion by the geographical location of specific administrators or contributors to open-source projects or libraries. BIS is not well placed to arbitrate the validity of individual open-source contributors and rather relies on the inherent structure and transparency of open-source software to identify potential security compromises by malicious actors. BIS excludes open-source software from covered software and characterizes it as software for which the human-readable source code is available in its entirety for use, study, re-use, modification, enhancement, and redistribution by the users of such software unless that open-source

software has been modified for proprietary purposes and not redistributed or shared.

In addition to BIS being more specific about the definition of *covered software*, commenters requested that BIS explicitly scope out different software components. Some commenters recommended modifying the definition to cover only component software of ADS and VCS. These commenters argued that tying the covered software to the hardware helps narrow the scope and removes the ambiguity of the term “item that supports,” which they argued was ambiguous because it is generally understood as part of a system. To this end, commenters advised BIS to define “covered software” as “software, in which there is a foreign interest, executed by the primary processing unit of the Vehicle Connectivity System or Automated Driving System item that directly enables the Vehicle Connectivity System or Automated Driving System function,” or similarly. Commenters argued that marrying the definitions of VCS and ADS to the definition of covered software provides clarity to connected vehicle developers and other automotive industry actors while retaining BIS’s stated goal of targeting “two integral ICTS systems,” of VCS and ADS, and no other vehicle equipment or technologies. Commenters also said this change removes the language “an item that support the function of VCS,” which is confusing to industry.

In response to these comments, BIS clarified the definitions of “covered software” and “VCS hardware” to include items that “directly enable” the function of those systems as opposed to “supports” those systems. BIS defined the term “item” in conformity with SAE International’s 21434 “Road Vehicles—Cybersecurity Engineering” standard of September 2021, as a term that would be commonly understood by industry. The SAE 21434 standard promotes the delineation of item definitions for different automotive systems and for assessing the cybersecurity of those systems. BIS therefore considered the SAE 21434 terms and practices in drafting its definitions so that connected vehicle manufacturers can consult existing compliance mechanisms to determine the item definition of different systems and assess what is included within the item definition of a VCS. BIS also retained “covered software” and “VCS hardware” as separate terms and separate prohibitions due to other structural and legal considerations.

Commenters also wanted to better understand the granularity of the ADS

software prohibition, seeking clarity as to whether final software is considered “designed” or “developed” by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC when a software module from the PRC is part of the larger ADS suite. If only one software subcomponent of an ADS software suite is designed, developed, manufactured, or supplied by a PRC or Russian entity, then the entire ADS software suite would be considered designed, developed, manufactured, or supplied by a foreign adversary entity. BIS modified the *covered software* definition to make clear that it applies to software components of application, middleware, and system software. BIS acknowledges the burden of determining the provenance of software subcomponents for legacy code bases and therefore added an exclusion for code that was designed, developed, manufactured, or supplied before one year from the effective date of the rule.

One commenter requested clarity about VCS software architecture, specifically regarding whether the regulation’s scope includes upstream communication transfer, downstream communications transfer, and communications processing. This commenter thought that upstream communications were within scope of the proposed rule, while the downstream communication transfer and communication processing were out of scope. Some commenters requested specific opinions about specific automotive in-vehicle network architectures. Because of the variety and diversity of automotive network designs, BIS sought to provide definitions that could be applied across the industry and declines to specifically opine on specific architectures. However, BIS intends to work with industry to answer specific questions during the implementation of the rule and through the issuance of advisory opinions.

Commenters commonly sought clarity on the degree and type of remedy necessary for the software to no longer be deemed covered software and therefore not subject to the prohibitions and compliance requirements in this rule. To this end, commenters recommended that BIS consider integrating accepted international regulatory standards to drive its guidance. For example, commenters suggested that BIS adopt the ISO/SAE 21434 Road Vehicles—Cybersecurity Engineering Threat Analysis and Risk Assessment (TARA) to assess the cybersecurity risks in automotive products. Commenters flagged that this standard provides a methodology for the

software developer to identify critical assets and privacy concerns and allows for the greatest specificity to address the critical asset(s), such as the specific lines of source code or module at issue, rather than broadly including all software packages. BIS appreciates this recommendation and acknowledges that it previously considered such a framework. BIS ultimately declines to consider compliance with SAE 21434 as a standalone security control sufficient for mitigating the national security risks identified in this rule. BIS determined that a combination of security controls could successfully mitigate the national security risk relating to connected vehicles and intends to use a multi-layered approach when issuing a specific authorization. BIS anticipates that requiring security features controls such as conformity with cybersecurity standards, audits conducted by third parties or BIS, enhanced reporting requirements, and controls on corporate governance may be effective ways to manage risk. However, BIS will consider compliance with cybersecurity standards like SAE 21434, R155, and NHTSA Cybersecurity Best Practices when evaluating applications for specific authorizations.

Many commenters requested that BIS exclude legacy code from the definition to minimize supply chain disruption and ensure warranties can be fulfilled. BIS acknowledges comments regarding the mature code bases that have been built, audited, and refined over time and the significant burden that determining the specific developers that contributed to those libraries over time would create. Based on the comments, BIS incorporated a specific exclusion within the *covered software* definition for legacy code. This addition to the covered software definition will exclude all source code that is designed, developed, manufactured, or supplied before a date that is one year from the effective date of the rule. This “legacy” code exclusion will protect products that have already gone to market. Furthermore, excluding legacy code designed, developed, manufactured, or supplied prior to March 17, 2026 will provide regulated entities time to transfer intellectual property rights as well as responsibility for development and maintenance of code to within their organizations in order to come into compliance with the covered software prohibition. BIS believes that this appropriately balances addressing the national security risks posed by software that is actively maintained in the PRC and Russia while lowering

potential burdens and disruptions to the market.

Commenters also warned that the regulation does not clearly articulate if ADS added to a completed connected vehicle falls in scope of the prohibition. Commenters advised limiting the scope of the regulation by adding language at the end of the *covered software* definition to ensure that the addition of ADS software that itself is not designed, developed, manufactured, or supplied by PRC or Russian entities to a connected vehicle is not a manufacturing operation for the purposes of this rule. BIS declines to adopt this recommendation. BIS explicitly included the sentence, “For the purposes of this subpart, the integration of an Automated Driving System into a connected vehicle constitutes a manufacturing operation for a completed connected vehicle,” to make clear that the addition of ADS to a completed connected vehicle falls within scope of this rule as it is a manufacturing operation for a completed connected vehicle. If the addition of covered ADS software to a completed connected vehicle involves software in which there is no foreign interest, then the integrating entity would not be required to submit a Declaration of Conformity. However, if there is a foreign interest in that covered software transaction, then it would require a Declaration of Conformity, or in the case the software is covered by the prohibitions of this rule, a specific authorization. BIS assesses that the addition of covered ADS software to a completed connected vehicle by an aftermarket vendor poses the same national security threat as the addition of covered ADS software at the initial point of manufacture. BIS believes such a modification or integration of ADS software could introduce the same underlying risk that the connected vehicle can be manipulated, to include unauthorized access to vehicle data.

Commenters also inquired if electronic logging devices (ELDs), insurance-related vehicle tracking devices, and after-market safety technologies are in the scope of covered software. BIS recommends that commenters review the technical specifications of these devices against the updated definition of *covered software* to confirm if they are executed by the primary processing unit or units of an item that directly enables the function of VCS or ADS at the vehicle level to determine if said devices fall within the scope of the definition of covered software. BIS believes the definitions for *covered software* and *VCS hardware* should provide clarity;

however, a person may submit a request for an advisory opinion regarding transactions involving specific technologies, along with technical information related to these technologies, so BIS may provide an opinion specific to the technology presented. BIS understands “after-market safety technologies” to be broad and can encompass a range of varying technologies. Such technologies would likely be covered as they relate to ADS software directly; however, uses outside of this scope would likely require BIS to receive additional information within a request for an advisory opinion. While the use of these technologies in the commercial vehicle market is out of scope of this regulation, under certain circumstances these technologies may be subject to this regulation (e.g., if they are used in vehicles weighing less than 10,001 pounds).

Commenters wanted BIS to define “integrated or attached hardware or software” to clarify whether software or hardware attached by a Bluetooth device or USB to a vehicle would be subject to the rule, or if the rule includes only integrated technologies. Per its definitions, this final rule is not limited to integrated technologies.

Commenters advised BIS to reconsider the zero percent threshold for software containing code from prohibited foreign entities, such as a de minimis threshold. BIS chose to not adopt a de minimis threshold approach due to the risk of circumvention that it would create. For example, entities could add additional code to make their percentage of prohibited content appear to fall below the minimum threshold. This suggestion would not adequately mitigate the risks identified. Additionally, seeking to create an implementable de minimis standard of code, wherein code could be analyzed by various metrics such as per bit, per line, per execution command, per library, etc., would be extremely complex, and the associated difficulty of assessing whether content is de minimis or not would be inefficient and ineffective. Furthermore, BIS added a significant exclusion in the “covered software” definition by excluding all code that had been designed, developed, or supplied prior one year from the effective date of this rule. This legacy code exclusion, paired with the infeasibility and ineffectiveness of a de minimis threshold led BIS to reject this suggestion.

A commenter urged BIS to require companies to implement cybersecurity requirements for edge cloud architecture and to establish domestic or allied sourcing requirements for ADS cloud

infrastructure, as well as continuous monitoring of ADS cloud and edge systems. BIS addresses its considerations for cybersecurity requirements in its discussion of Declarations of Conformity, as well as other places in this text. Cloud architecture and infrastructure are out of scope of this current regulation. However, BIS understands the concern and may consider this area for future rulemaking.

Commenters recommend that BIS consider narrowing the *covered software* definition, or the annual reporting requirement, to exclude covered software produced by companies based in trusted or allied nations. Commenters suggest that this change would both streamline connected vehicle manufacturers’ reporting obligations and reduce the burden on BIS in reviewing vast quantities of submitted information and allow BIS to focus its resources and efforts on overseeing the use of software-based components in completed connected vehicles that may present actual or heightened risks to U.S. security. One commenter was particularly concerned that not narrowing the foreign interest scope meant that all technology must be sourced from a U.S. vendor, limiting global supply chains to using only U.S. software. BIS addresses these concerns in its discussion of Declarations of Conformity more in depth. At a high level and as explained in more depth below, BIS will not exclude non-foreign adversary nations from the scope of covered software, because BIS assesses that it is necessary to address the threats posed by interconnected but opaque supply chains writ large, as opposed to finished products imported from non-foreign adversary nations.

Commenters urged BIS to establish a process that would allow an OEM to fully own software purchased from a prohibited supplier so that the purchased software would not be considered prohibited. BIS is willing to discuss such an approach through an advisory opinion request to determine whether such a software purchase may adequately mitigate the identified risk if the transaction is not otherwise excluded by the modified definition of covered software.

In this final rule, BIS has chosen to define *covered software* to mean the software-based components, including application, middleware, and system software, in which there is a foreign interest, executed by the primary processing unit or units of an item that directly enables the function of VCS or ADS at the vehicle level. Covered software does not include firmware,

which is characterized as software specifically programmed for a hardware device with a primary purpose of directly controlling, configuring, and communicating with that hardware device. Covered software also does not include open-source software, which is characterized as software for which the human-readable source code is available in its entirety for use, study, re-use, modification, enhancement, and redistribution by the users of such software, unless that open-source software has been modified for proprietary purposes and not redistributed or shared. Covered software also does not include software subcomponents that were designed, developed, manufactured, or supplied prior to March 17, 2026, as long as those software subcomponents are not maintained, augmented, or otherwise altered by an entity owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary after March 17, 2026.

With this definition of *covered software*, BIS focused on both the functional characteristics of the software that it intends to regulate as well as the common industry terminology used to refer to that software. For example, BIS acknowledges that there is not a bright line between application-level software, middleware (e.g., device drivers, database management functions), and firmware. However, by combining both industry terminology and a functional definition in its definition of *covered software*, BIS seeks to provide two levels of clarity. In making a reasonable, good faith determination of whether a software subcomponent falls within the *covered software* definition, entities should refer to the architecture of the product to assess whether the software component would be generally considered “application” level software based on industry practice using established methodologies like AUTOSAR software component definitions or ISO 26262 guidelines. When there is uncertainty, entities should consider whether the primary processor (e.g., a central processing unit, a graphics processing unit) processes the executables, or whether the software is executed by a peripheral microcontroller. If the primary processor does not execute the software, and the software would not be classified as application software by an industry standard like AUTOSAR, it is unlikely the software would qualify as application software for the purpose of this definition.

BIS has also provided examples to clarify what constitutes application, middleware, and systems software

below. If regulated parties have questions about what constitutes covered software in specific cases, they may request an advisory opinion.

Example 1: A U.S. person licenses automotive software from a vendor who is a foreign person that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The automotive software the U.S. person licenses includes a message processing application that receives a digital message from a peripheral radio device, processes that message, and uses the information within that message to issue a digital control command to a related electronic control unit. This software would be considered application software. Because the licensed software includes application software designed, developed, manufactured, or supplied by an entity owned by, controlled by or subject to the jurisdiction of a foreign adversary, the licensed software would be prohibited, unless it qualifies for a general or specific authorization granted by BIS.

Example 2: A U.S. person licenses automotive software from a vendor who is a foreign person that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The automotive software the U.S. person licenses includes a software device driver intended for use in the operating system for applications to activate and utilize specific VCS hardware. This driver would be considered middleware. Because the licensed software includes middleware designed, developed, manufactured, or supplied by an entity owned by, controlled by or subject to the jurisdiction of a foreign adversary, the licensed software would be prohibited, unless it qualifies for a general or specific authorization granted by BIS.

Example 3: A U.S. person licenses automotive software from a vendor who is a foreign person that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The automotive software the U.S. person licenses includes a software component in the operating system that coordinates communications between distributed applications and between applications and an internal reference database. This software component would be considered middleware. Because the licensed software includes middleware designed, developed, manufactured, or supplied by an entity owned by, controlled by or subject to the jurisdiction of a foreign adversary, the licensed software would be prohibited, unless it qualifies for a

general or specific authorization granted by BIS.

Example 4: A U.S. person licenses automotive system software from a vendor who is a foreign person that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The automotive system software the U.S. person licenses is a proprietary real time operating system that manages system resources as well as task scheduling, prioritization, and synchronization for an automotive system. This software component would be operating system software. Because the licensed software includes operating system software designed, developed, manufactured, or supplied by an entity owned by, controlled by or subject to the jurisdiction of a foreign adversary, the licensed software would be prohibited, unless it qualifies for a general or specific authorization granted by BIS.

Example 5: A U.S. person purchases a V850 CAN controller from a vendor who is a foreign person. The V850 CAN controller includes a software subcomponent that is embedded into the controller’s non-volatile memory and directly enables the transmission and receipt of analog electric signals by interacting with the VCS hardware system’s application software. This software component would be considered firmware. Assuming no other facts, this purchase does not involve covered software and would not be affected by the covered software prohibition (but may be affected by the VCS hardware prohibition, depending on other facts and circumstances of the transaction).

BIS determined that it was necessary to exclude firmware because firmware is often shipped with and designed in coordination with the provision of automotive hardware subcomponents. Therefore, while there are similar national security and cybersecurity risks at the firmware level, BIS determined that a firmware prohibition would be tantamount to a hardware prohibition. Finally, BIS made slight modifications to the open-source software definition from the 2019 National Defense Authorization Act when crafting the “covered software” definition. These minor modifications are to make clear that large language models or neural networks that may bill themselves as “open source” but do not openly share their source code or training data in their entirety do not meet the commonly held definition of open-source software. Furthermore, the clause appended to the end of the definition is redundant but meant to emphasize that if an open-source product is modified outside the

limits of the open-source license and not shared, the resulting product is definitionally not open source. However, modification would not include integration into an existing code base by engaging with an open-source product's application programming interface, permissible customization within the terms of the open-source license, or selection of modular sections of the open-source product while excluding others.

In light of comments the agency received, BIS emphasizes that regulated entities are not absolved of conducting due diligence on open-source software when that open-source software has been modified outside the scope of its license. Additionally, BIS declines to introduce a static list of approved or excluded open-source software libraries and tools into the text of the rule, as these libraries and tools are dynamic by nature. BIS will maintain and update compliance information on its website and will also be available to work with regulated entities through advisory opinions or compliance education and outreach programs.

BIS included the term "item" within its definition of *covered software* because industry standards define "item" as a scoping boundary when analyzing specific automotive systems for cybersecurity and functional safety requirements to ensure that assessments are targeted and comprehensive. For example, ISO 21434's threat analysis and risk assessment methodology for assessing cybersecurity relies on "item definition" boundaries. Entities seeking additional guidance on the term "item" in this context may find it helpful to refer to its use in ISO 21434 and ISO 26262, and its use by automotive cybersecurity and safety professionals when making a reasonable determination whether a component is part of a covered software system item. Comments about this term are further explained in the "item" subsection of this Definitions section. BIS has incorporated specific language to ensure that legacy parts are not subject to the covered software prohibitions of this regulation. This "legacy" code exclusion in covered software protects products that have already gone to market. By incorporating a one-year timeline, BIS allows regulated entities time to transfer intellectual property rights as well as responsibility for development and maintenance of code within their organizations to come into compliance with the covered software prohibition.

6. Declarant

In this final rule, BIS includes a new definition for "declarant" to mean the U.S. person submitting a Declaration of Conformity to BIS. BIS has included "declarant" in the final rule text to provide more clarity in the regulation since the term is used throughout.

7. FCC ID Number

In the NPRM, BIS proposed defining the term "FCC ID Number" to mean the unique alphanumeric code identifying a product subject to certification by the Federal Communications Commission composed of a: (1) grantee code; and (2) product code. Commenters provided no feedback about this particular definition. BIS retains its definition in the final rule.

While commenters did not provide feedback on the definition of "FCC ID Number," they provided input in how the regulation incorporates them. Commenters pointed out that not all VCS hardware items have FCC Numbers. Taking this point into consideration, BIS will only require an FCC ID Number if known by the submitting party. This change is reflected in 791.305 of the regulation text, which discusses Declarations of Conformity.

8. Foreign Interest

In the NPRM, BIS proposed to define "foreign interest" to mean any interest in property of any nature whatsoever, whether direct or indirect, by a non-U.S. person. Many commenters encouraged BIS to narrow its definition of foreign interest or otherwise provide greater clarity. After consideration of these comments, BIS retains this definition of *foreign interest* in the final rule.

Several commenters, for example, requested that BIS clarify this definition to mean a legally cognizable interest in property. BIS declines to limit this definition to a legally cognizable interest because "legally cognizable" may be overly narrow for purposes of this regulation. Moreover, BIS's approach retains consistency with other IEEPA-based programs, which similarly use a broad definition of "foreign interest." Some commenters suggested that requiring a legally cognizable interest would address the scenario in which the only foreign interest in software is the fact that foreign persons worked on the development of the software. In response, BIS notes that a foreign interest must be an interest in property, and the sole fact a foreign individual worked on a software development team would not meet this requirement unless additional factors

(such as ongoing financial or beneficial interests or contractual rights) are present.

Multiple commenters encouraged BIS to carve out allied persons from the definition of *foreign interest*, defined as citizens of, residents of, or corporations incorporated in nations in "Country Group A" of BIS's own Export Administration Regulations. BIS declines to amend the definition of foreign interest to exclude certain allied nations or to grant preferential status for entities in allied nations as this would inadequately mitigate the national security risk this rule seeks to address. The mere fact that a connected vehicle manufacturer is headquartered in, incorporated in, or otherwise organized under the laws of a non-foreign adversary country does not imply that the manufacturer has appropriate practices in place to address the risks identified by this rule. For example, a connected vehicle manufacturer located in a non-foreign adversary country may actually be controlled by a PRC or Russian entity, or the manufacturer sources design and development of its ADS software or VCS hardware from an entity located in or controlled by the PRC or Russia. However, the fact that a transaction has a foreign interest does not mean that the transaction is prohibited. Rather, the presence of a non-PRC and non-Russian foreign interest in a transaction without the requisite foreign adversary nexus would require the connected vehicle manufacturer or VCS hardware importer to submit a declaration of conformity, a requirement that BIS has substantially streamlined in this rule to facilitate compliance and reduce the burden on regulated entities. BIS is separately working to identify if any security standards or best practices exist, or may be developed, that will sufficiently mitigate this national security risk and allow companies, wherever located, to engage in transactions without need to notify BIS through a Declaration of Conformity.

One commenter also urged BIS to ensure that software developed in the PRC or Russia by wholly owned subsidiaries of U.S. companies would not be considered to contain a foreign interest. BIS declines to create an exemption for software developed by wholly owned subsidiaries of U.S. businesses from the definition of foreign interest. As articulated in this rule, entities operating in the PRC or Russia are subject to the jurisdiction and control of the PRC or Russian governments, even if wholly owned by a U.S. or allied entity. These types of entities, despite their ownership, are

subject to the regulations and laws of the PRC or Russia that could obligate them to comply with information or access requests resulting in undue or unacceptable risks, as discussed in Section IV of this rule.

One commenter stated that BIS's broad definition of *foreign interest* would mean that a publicly traded company with some foreign shareholders would be required to submit a Declaration of Conformity even if the company's covered software itself contained no foreign interest. In response to this comment, BIS has introduced an exemption for the submission of Declarations of Conformity for those transactions where the *only* foreign interest in the product arises from a foreign entity's equity ownership in a U.S. person. This exemption is narrowly tailored intentionally to minimize the compliance burden. BIS continues to understand equity ownership to be a form of foreign interest. However, BIS recognizes that attaching a static percentage foreign interest threshold would be particularly challenging for regulated entities and their compliance teams in practice. For example, shareholders change daily, and while there are some reporting requirements for principal shareholders according to Regulation D of the Securities Exchange Act of 1934, setting a percentage threshold based on equity ownership alone would mean there could be no reporting obligations for a transaction one day and foreign interest that required a Declaration of Conformity. To avoid this outcome, BIS clarifies through this exemption that Declarations of Conformity are not required for transactions where the *only* foreign interest arises from foreign equity ownership of one of the U.S.-based parties to a transaction. If the foreign equity ownership is paired with another foreign interest (e.g., degree of control over the U.S. entity or licensing of intellectual property), a Declaration of Conformity would be required. To provide further clarity regarding transactions involving foreign interest as a result of public shareholder ownership, BIS offers the following examples.

Example 6: Company A develops VCS. Company A is incorporated in the United States and is publicly traded on the New York Stock Exchange. No foreign entity owns more than 5% of Company A's common stock. Assuming no other facts, because no foreign entity shareholder of Company A's common stock can materially affect Company A's operations and corporate management, there is not a foreign interest in

Company A's VCS. As such, the sale of completed connected vehicles incorporating Company A's VCS does not require a Declaration of Conformity.

Example 7: Same facts as previous example, except Company A is headquartered in a foreign jurisdiction. The import of completed connected vehicles incorporating Company A's VCS software from a foreign jurisdiction would require a Declaration of Conformity because the import gives rise to a foreign interest independent of equity ownership.

Example 8: Company A develops VCS software, is incorporated in the United States, and is publicly traded on the NASDAQ Stock Exchange. Company A states that one of its shareholders is a foreign person holding 60% of Company A's outstanding shares and is not a person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary. Assuming no other facts, because a foreign entity is a shareholder whose holding is such that the foreign entity can materially affect Company A's operations and corporate management, there is a foreign interest in Company A's VCS software other than equity ownership. As such, the sale of completed connected vehicles incorporating VCS software developed by Company A requires submission of a Declaration of Conformity.

Example 9: Company A is incorporated in the United States and is publicly traded on a U.S. stock exchange. In aggregate, foreign shareholders hold 28 percent of Company A's outstanding shares. These shareholders have an informal agreement to act in concert with respect to voting decisions for Company A. The collective 28 percent would allow such foreign shareholders to block resolutions and important decisions regarding Company A's management. The foreign shareholders have an interest in Company A's VCS software independent of their equity ownership by virtue of their control over the company. As such, the sale of completed connected vehicles incorporating VCS software developed by Company A requires submission of a Declaration of Conformity.

Example 10: Company A, a U.S. person completed connected vehicle manufacturer, purchases ADS software from Company B. Company B is a U.S. person publicly traded company that designs, develops, and manufactures its ADS software solely in the United States. A foreign entity holds 15% of Company B's outstanding public shares. The foreign investor has no board seat and exerts no management or control over Company B. Assuming no other

facts, Company A is exempt from the requirement to file a Declaration of Conformity.

Another commenter requested that BIS clarify that foreign IP claims, which may not be recognized under U.S. law, do not constitute a foreign interest. BIS declines to insert language that would require an extensive inquiry into the legal status of IP claims in multiple jurisdictions in order to determine whether a foreign interest is present. BIS notes that there may be situations, such as where a foreign IP claim is frivolous, in which the foreign IP claim would not constitute a valid interest. The commenter suggests revising the definition of *foreign interest* to add that it does not include "legal claims or other allegations, or rights that might be afforded by law even when all other rights have been assigned to another party, such as employee-inventor remuneration obligations and moral rights in works of authorship." BIS believes that many such claims would fall outside of the scope of *foreign interest*. For example, rights that cannot legally be transferred might not meet the definition of "property." BIS does not believe it necessary to amend the definition to specify this point or to provide an exhaustive list of claims that are not included under the definition of foreign interest. If regulated parties have a question about whether a foreign IP interest constitutes a foreign interest in specific cases, they may request an advisory opinion from BIS.

Multiple commenters also requested that BIS amend the provisions on the import of VCS hardware to clarify that a Declaration of Conformity is required only when the VCS hardware itself contains a foreign interest. Others suggested that BIS remove the foreign interest requirement from the definition of *covered software*. BIS declines to make these changes. As discussed in the NPRM, IEEPA requires a foreign interest in the property that BIS seeks to regulate. BIS has included a foreign interest requirement in the definition of *covered software* because some prohibited covered software transactions are sales that occur within the United States. By requiring a foreign interest in the definition of *covered software*, BIS ensures that this rule only captures those sales covered by IEEPA. By contrast, this rule prohibits imports (not sales within the United States) of VCS hardware. BIS assesses that items crossing into the United States from a foreign jurisdiction will necessarily contain a foreign interest by nature of the transaction, and therefore does not find it necessary to include a foreign interest requirement in the definition.

Additionally, the final rule does not require a Declaration of Conformity to be submitted if the only foreign interest related to covered software resides in open-source or legacy code.

After considering all comments, BIS has retained the definition of *foreign interest*, when used with respect to property, to mean any interest in property, of any nature whatsoever, whether direct or indirect, by a non-U.S. person. Under this definition, a foreign interest can include, but is not limited to, an interest through ownership of the item itself, intellectual property present in the item, a contractual right to use, update, or otherwise impact the property, (e.g., ongoing maintenance commitments, any license agreement related to the use of intellectual property), profit-sharing or fee arrangement linked to the property, as well as any other cognizable interest. This definition is consistent with the definition of “interest” used in the context of OFAC sanctions, which are, in relevant part, also established pursuant to the statutory requirements of IEEPA. See 31 CFR Chapter V, and, e.g., 31 CFR 510.313, 535.312.

With respect to VCS hardware that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, this rule regulates the importation of VCS hardware, making VCS hardware importers responsible for compliance.

With respect to covered software, based on feedback from connected vehicle manufacturers, automotive suppliers, and other stakeholders, BIS continues to understand that typically, ADS and VCS software are designed or developed to a connected vehicle manufacturer’s specification. ADS and VCS software is frequently designed, developed, or supplied by foreign persons, and those persons frequently retain an interest in the underlying software, even after it has been integrated into the connected vehicle. For example, foreign software developers may earn profits from use of their software, retain data access and sharing rights to the software, have obligations to maintain and update the software, or participate in other ongoing contractual arrangements. Such arrangements are among the types of interests that BIS identifies as giving rise to an obligation to submit a Declaration of Conformity or, if the software designer, developer, or supplier is a person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, an obligation to qualify for a

general authorization or seek a specific authorization under this final rule. BIS therefore will regulate covered software by regulating the importation or sale of completed connected vehicles, making connected vehicle manufacturers responsible for compliance.

Finally, in addition to the general regulations related to VCS hardware and covered software described above, with respect to connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, this rule additionally regulates VCS hardware and covered software by regulating the sale of completed connected vehicles that incorporate VCS hardware or covered software. In this circumstance, BIS understands from extensive engagement with connected vehicle manufacturers and automotive suppliers that persons who own, control, or direct the operations of the connected vehicle manufacturer would maintain an interest in the vehicle transactions that the connected vehicle manufacturer carries out. For example, this could include, but is not limited to, profit sharing agreements between a parent company and its U.S. subsidiary; data sharing agreements; intellectual property rights transfers from the U.S. subsidiary to the parent company; cooperation in technological development between the parent and U.S. subsidiary; arrangements by which the parent company directly or indirectly appoints the leadership of the U.S. subsidiary; the ability of the parent company to direct some or all corporate decision making by the U.S. subsidiary; and parent company influence over procurement by the U.S. subsidiary. BIS understands many if not all of these arrangements to be standard for the automotive industry. Additionally, because the PRC and Russian legal regimes discussed in Section IV of this rule could compel a PRC or Russia-based parent company of a connected vehicle manufacturer to provide those governments with information on or access to the operations of the U.S.-based connected vehicle manufacturer, BIS understands that the foreign parent company typically retains a legal right to access the data collected by the U.S. subsidiary, representing a foreign interest in that U.S. subsidiary and its connected vehicle sales.

BIS provides the following examples to assist in interpreting whether a foreign interest is present.

Example 11: Company A is headquartered in a foreign jurisdiction and is the owner of the code, algorithms, and other design elements in a software development kit (SDK)

that is used to develop software used in certain payment systems. Company A provides its SDK to Company B, a U.S. person, who uses it to develop software that is installed in connected vehicles in the United States to provide secure communication and payment with transportation infrastructure. Even though Company A has no legal property interest in the software itself, it has an indirect beneficial interest in the use of such software because updates to the software will need to be made using Company A’s SDK. Thus, the software Company B develops with Company A’s SDK retains a continuing foreign interest.

Example 12: Company A is a wholly owned U.S.-based subsidiary of Company B, a multinational holding corporation incorporated in the British Virgin Islands. Company A imports products for sale in the United States, which generate revenue. Based on Company B’s corporate structure and governance of its subsidiary holding companies including Company A, Company B dictates how Company A’s revenue and profits are allocated across Company B’s holdings. Because Company B, a foreign person, benefits from each of Company A’s domestic transactions and because Company B directs the allocation of revenue generated by those transactions, there is a foreign interest in Company A’s domestic United States transactions.

Example 13: Company A is a U.S. based connected vehicle manufacturer. Company B is a parts manufacturer headquartered in a foreign jurisdiction. Company B manufactures systems on chip (SoC) based on customer specifications that are specifically used in VCS. Company A and Company B have entered into a multi-year agreement whereby, among other conditions, Company B will be the exclusive supplier, with rights of first refusal, for replacements and any maintenance and services repairs of SoCs to Company A for the term of the agreement. Because Company B is a foreign entity and because Company A may use no other parts supplier for its VCS SoCs during the term of the agreement, the SoCs that Company B provides to Company A under the agreement retain a continuing foreign interest once those SoCs enter the United States.

Example 14: Company A is a U.S. based connected vehicle manufacturer. Company B is a U.S. subsidiary of a foreign software company, Company C. Company B sells ADS software licenses on behalf of its foreign parent Company C, who holds the intellectual property rights to the software. Company B

licenses Company C's ADS software to Company A for system integration and further commercialization within the limits of its licensing agreement. Company C, a foreign entity, will have a continued interest in Company A's use of its software after commercialization.

9. Hardware Bill of Materials

In the NPRM, BIS defined *Hardware Bill of Materials (HBOM)* to mean a comprehensive list of parts, assemblies, documents, drawings, and components required to create a physical product, including information identifying the manufacturer, related firmware, technical information, and descriptive information. Public comment provided feedback that led BIS to change the final rule definition of *HBOM*. Commenters provided a variety of opinions on the HBOM requirements of this regulation. Several commenters expressed opposition to the inclusion of HBOMs in Declaration of Conformity submissions on the grounds that they contain highly confidential business information and intellectual property, citing security issues related to storage and transmission. Several commenters noted that the HBOM requirement is overly broad and suggested that they only include "electronic components that execute software." Several commenters recommended that BIS provide a "specific" resource as an example of an HBOM, such as the *HBOM Framework for Supply Chain Risk Management*. Commenters also suggested that BIS remove references to documents and drawings within the HBOM definition to exclude protected intellectual property from compliance submissions. Other commenters requested that BIS provide an HBOM sample model.

After considering the issues raised in these comments, BIS will no longer require the submission of HBOMs as part of Declarations of Conformity. However, BIS will require entities to maintain primary business records related to their certification that due diligence was conducted in analyzing their VCS hardware supply chains, which could include HBOMs. These primary business records must be made available to BIS upon request. BIS has also included a section in the rule dedicated to the submission of CBI, which would cover the submission of HBOMs. BIS will continue to work with industry partners to identify best practices in HBOM development, including templates and advisory documents.

To better align HBOM criteria with industry practices, BIS has modified its definition of *HBOM*. Specifically, BIS

has removed documents, drawings, technical information, and descriptive information from the HBOM definition because these elements do not strictly fall under the scope of a bill of materials. This change also addresses industry concerns about the potential exposure of intellectual property and CBI. Additionally, BIS has replaced the term "comprehensive list" with "formal record" since "record" is a more general term and "comprehensive" is difficult to define precisely.

BIS has chosen to define "Hardware Bill of Materials (HBOM)" as a formal record of the supply chain relationships of parts, assemblies, and components required to create a physical product, including information identifying the manufacturer, and related firmware.

10. Import

In the NPRM, BIS proposed to define the term "import" to mean, with respect to any article, the entry of such article into the United States Customs Territory. It does not include admission of an article from outside the United States into a foreign-trade zone for storage pending further assembly in the foreign-trade zone or shipment to a foreign country. BIS did not receive comment on its definition of "import" or how the term is used in the regulation text. Therefore, BIS retains the NPRM definition of "import" in the final rule. For clarity, BIS has added a sentence clarifying that the same definition applies to related terms such as "importing" and "imported."

While BIS did not receive any comment on the proposed meaning of "import," one commenter requested that BIS clarify that for the purposes of the regulation, "article" means VCS hardware and covered software as defined in this regulation. BIS is confirming for the purposes of this rule that "article" is referring to VCS hardware and covered software.

11. Item

In the NPRM, BIS proposed to define "item" to mean a component or set of components with a specific function at the vehicle level. A system may also be considered an item if it implements a function. BIS received a few comments on how this term is used within its regulation text but based on further research chooses to retain this definition of "item" for the final rule. Some commenters urged BIS to replace the term item with "system," both in the context of VCS hardware and covered software to clarify that the terms refer to overall systems. BIS declines this suggestion and maintains the use of the term item. This term is used both in ISO

26262 and ISO/SAE 21434 to delineate system boundaries. BIS further believes the use of the term item in both covered software and VCS will allow regulated entities to harmonize compliance with this rule with existing cybersecurity and functional security work as dictated by ISO/SAE 21434 and ISO 26262.

12. Knowingly

In the NPRM, BIS proposed to define "knowingly" to mean "having knowledge of a circumstance (the term may be a variant, such as 'know,' 'reason to know,' or 'reason to believe'), to include not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person's willful avoidance of facts." BIS received no comments requesting changes to this definition and retains this definition for the final rule.

BIS did receive some public comments relating to due diligence and Declaration of Conformity requirements, which are relevant to the context in which the definition of "knowingly" would be applied. Commenters suggested that BIS consider implementing a whitelist of vendors that do not require additional due diligence. According to commenters, a whitelist would provide more clarity on the compliance requirement for regulated entities. One commenter also stated that a whitelist would preclude the need for Declarations of Conformity. BIS declines to create a whitelist at this time. Due to the complexity of connected vehicle supply chains and the multitude of factors involved in each unique transaction undertaken by manufacturers, BIS believes the creation of a whitelist would insufficiently address the national security risks present in the connected vehicle supply chain. However, BIS maintains the flexibility to grant general authorizations for certain types of transactions subject to the prohibitions at a future date.

Several commenters also requested clarity on how far into a supply chain importers are required to maintain visibility. BIS encourages entities to reference the definitions of VCS hardware and covered software when determining the depth of supply chain due diligence necessary to certify that the VCS hardware or covered software was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC

or Russia. Based on the definitions provided in this rule, importers would need to conduct due diligence on supply chain components if these components directly enable the function of and are directly connected the VCS systems or are part of an item that directly enable the function of the VCS. Component parts that do not contribute to the communication function of VCS hardware are not considered VCS hardware per the above, and so would not have due diligence requirements.

One commenter suggested that suppliers should be prohibited from importing or selling covered software or VCS hardware linked to the PRC or Russia if they have knowledge that it will be integrated in connected vehicles built for the U.S. market. BIS declines to place the onus of this prohibition on suppliers of VCS hardware and covered software rather than on VCS hardware importers and connected vehicle manufacturers due to the numerous suppliers of the myriad components involved in the VCS hardware and covered software supply chain from which BIS would need to accept specific authorization applications in such circumstances. Instead, through requiring specific authorization applications and Declarations of Conformity from VCS hardware importers and connected vehicle manufacturers, BIS has implemented a more targeted approach, which BIS believes will still create the necessary changes to VCS hardware and covered software supply chains in the interest of national security. However, VCS hardware importers and connected vehicle manufacturers may rely on statements and documentation from suppliers in support of specific authorization applications and Declarations of Conformity so long as all necessary due diligence is documented and made available to BIS (section 791.313, “Reports to be furnished on demand”).

Another commenter asked for clarity that a “regulated entity can wholly and reasonably rely on statements of its tier 1 suppliers that a supplied part or piece of equipment does not contain a restricted component or subcomponent.” As stated above, BIS clarifies that VCS hardware importers and connected vehicle manufacturers may rely on statements and documentation from suppliers in any Declarations of Conformity or specific authorization application. For example, in certifying that regulated entities have conducted due diligence in their covered software and VCS hardware supply chains, entities must also certify that they maintain documentation

specifying their due diligence efforts and that they have made arrangements with suppliers to furnish any necessary documentation upon request by BIS (section 791.312, “Recordkeeping”). In making these certifications to BIS, entities may rely on statements from suppliers that a component is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

13. Model Year

In the NPRM, BIS proposed to define “model year” to mean the year used to designate a discrete vehicle model, irrespective of the calendar year in which the vehicle was actually produced, provided that the production period does not exceed 24 months. While many commenters raised issues with the specific model years selected by BIS as the implementation dates for this regulation, none addressed BIS’s definition of the term. BIS has addressed concerns over implementation dates further below, under “Exemptions.” BIS retains the NPRM definition of “model year” in the final rule.

Several commenters raised the concept of vehicle generations and highlighted that connected vehicle manufacturers do not conduct a major refresh of vehicle technologies every year. Rather, vehicle generation refreshes may only take place every four to six years. As discussed further below, BIS understands that the implementation dates for the rule may fall mid-generation for many connected vehicle manufacturers. In this situation, BIS would consider issuing a time-bound specific authorization in cases where connected vehicle manufacturers are able to demonstrate that they are moving into compliance with the rule for the next vehicle generation refresh. BIS may also contemplate allowing a phased-in implementation of the prohibitions, as advocated for by some commenters, in a specific authorization for manufacturers mid-generation during the implementation period. Please see the specific authorizations section to learn more about how a phased approach can occur under this regulation.

14. Person Owned by, Controlled by, or Subject to the Jurisdiction or Direction of a Foreign Adversary

In the NPRM, BIS proposed to define “person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary” to mean:

(1) Any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary;

(2) Any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States;

(3) Any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or

(4) Any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine, direct, or decide important matters affecting an entity.

BIS has retained this definition in its final rule. However, it has provided further examples on how to apply this definition below.

Example 15: Company A, incorporated in the United States, is a wholly owned subsidiary of Company B. Company B is a state-owned enterprise of the PRC or Russia. Because Company B is a state-owned enterprise, Company A would be considered “owned by” the PRC or Russia.

Example 16: Company A is a joint venture between Company B and Company C where Company C owns a majority share of Company A. Company B is a corporation incorporated in a third-party jurisdiction. Company C is a state-owned enterprise of the PRC or Russia. Company A would be considered “owned by” the PRC or Russia.

Example 17: Company A is majority owned in aggregate by multiple state-owned enterprises and state-owned investment funds of the PRC or Russia. Company A would be considered “owned by” the PRC or Russia.

Example 18: Company A, incorporated in the United States, is a subsidiary of Company B. Company B is a private company incorporated in the PRC or Russia with its principal place of business in the PRC or Russia. Because Company B is subject to the jurisdiction of the PRC or Russia,

Company B's subsidiary, Company A, is controlled by an entity subject to the jurisdiction of the PRC or Russia and would be considered "controlled by" and "subject to the direction of" the PRC or Russia.

Example 19: Company A is a multinational company where a majority of the voting power is held by Company B, a PRC or Russian government investment fund. Company A would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 20: Company A is a holding company organized in a tax-advantaged jurisdiction. Company A is publicly listed on a stock exchange and its corporate voting structure is characterized by Class A and Class B shares. Class B shares having 10 times the voting power of Class A shares. If the aggregate voting power of shareholders subject to the jurisdiction of the PRC or Russia holding either Class A or Class B shares constitutes a majority or a dominant minority of total voting power, then Company A would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 21: Company A, a company that is organized under the laws of the PRC or Russia, owns a minority interest in Company B, a U.S. business. Based on special voting powers vested in that minority interest, Company A maintains certain veto rights that determine important matters affecting Company B, including the right to veto the dismissal of senior executives of Company B. Company B would be considered "controlled by" and "subject to the direction of" Company A, and therefore "controlled by" and "subject to the direction of" the PRC or Russia.

Example 22: Company A is an entity incorporated in a third country and Company B is an entity incorporated in the PRC or Russia. Company A and Company B create a new joint venture, Company C, to design, develop, and manufacture a new product. Company A and Company B own minority shares of the joint venture while Company D, a holding company wholly owned by a PRC citizen, owns the largest minority share. If aggregate voting power of Company B and Company D constitutes majority or dominant minority voting share, Company C would be "controlled by" and "subject to the direction of" the PRC or Russia.

Example 23: Company A has eight members on its board of directors. Company A is characterized by a shareholder and corporate governance structure that requires a 75 percent supermajority for any significant business decision. Three of the members

of the board are citizens of, and therefore subject to the jurisdiction of, the PRC or Russia. Because these three members make up 37.5 percent of the voting power of the board, they can block any supermajority and therefore determine, direct, or decide important matters affecting Company A. Company A would be "controlled by" or "subject to the direction of" the PRC or Russia.

Example 24: The PRC or Russian government, through an investment fund, acquires a 1 percent special management share in Company A. This share grants the PRC or Russian government the right to appoint a director to the board of Company A and veto certain key business decisions, such as major strategic changes or mergers. This share allows the government to influence Company A's operations and strategy. Company A would be "controlled by" the PRC or Russia.

Example 25: Company A maintains its principal place of business in the PRC or Russia. Company A would be "subject to the jurisdiction" of the PRC or Russia.

Example 26: Company A is a publicly listed U.S. corporate entity. Company A has a wholly owned subsidiary, Company B, that is organized under the laws of the PRC or Russia and manufactures goods in the PRC or Russia. Because Company B is organized under the laws of the PRC or Russia, Company B would be subject to the jurisdiction of the PRC or Russia. However, Company A is not subject to the jurisdiction of the PRC or Russia.

Example 27: Company A is privately held and incorporated in the United States. One member of Company A's board of directors, Person X, a former chairman of the board of a large PRC corporation, has known ties to the government of the PRC, owns a large minority share of Company A, and has previously made significant investments in other companies founded by Company A's chief executive officer. Person X also facilitated a large minority investment in Company A by the large PRC corporation where they were previously chairman of the board. Person X's professional background indicates that they are directly or indirectly supervised, directed, controlled, financed, or subsidized by the PRC government. The combination of Person X's close ties to Company A's CEO, Person X's ownership interest and ability to direct investment from large, highly regulated PRC corporate entities, and Person X's close ties to the PRC government indicate that Company A would be "subject to the direction" of the PRC.

Example 28: Company A is an automobile company based in a jurisdiction that is not the PRC or Russia. Company A maintains a supervisory committee established by the company's articles of association that is responsible for supervising the management of the company and is not part of the board of directors. Each member of the committee exercises significant managerial authority over the nature, scope, and attributes of the company's business. An independent member of this committee has known ties to the government of the PRC and previously served as board director for a PRC state-owned enterprise. Since Company A's supervisory committee contains a member that can affect important matters of the company, has ties to the PRC government, Company A is subject to the direction of the PRC.

For additional clarity for determining what is and what is not designed, developed, manufactured, or supplied by the entities mentioned above, BIS offers the following examples below.

Example 29: Company A is a U.S. person. Company B is headquartered in the PRC and is a fabless semiconductor design company that produces systems on chips for vehicle telematics systems. Through a joint development agreement, Company A collaborates with Company B to design a custom cellular microcontroller for integration into a VCS hardware unit that will be imported into the United States. Assuming no other facts, Company A's VCS hardware unit contains components designed by an entity that is subject to the jurisdiction of the PRC. The import of the VCS hardware unit is a prohibited transaction, unless authorized by a general authorization or specific authorization.

Example 30: Company A is a U.S. person. Person B is a PRC citizen residing in the PRC. Company A contracts with Person B to conduct a cybersecurity review of its operating system software design for a piece of VCS hardware that is imported in the United States. Person B completes that review and recommends improvements and changes to Company A's product, which Company A is free to accept or reject. Person B's review of Company A's software does not mean Company A's covered software product was designed by an entity subject to the jurisdiction of the PRC solely on the basis of Person B being a PRC citizen.

Example 31: Company A is domiciled in the PRC and is a joint venture between Company B and Company C. Company B is headquartered in the United States. Company C is headquartered in the PRC. Company A

sources suppliers, including suppliers of VCS hardware and covered software, integrates parts into automotive systems, and conducts prototyping and testing for future model year connected vehicles that Company B will eventually import and sell into the United States. Assuming no other facts, the connected vehicles that Company A prototypes and tests contain VCS hardware and covered software supplied by an entity subject to the jurisdiction of the PRC. Company B's import or sale of the vehicles is a prohibited transaction, unless a general authorization or specific authorization applies.

Example 32: Company A is a PRC company that is an automotive contract assembler and manufacturer for connected vehicles. Company B is an automotive company headquartered in the United States. Company A assembles and manufactures completed connected vehicles, including installing the VCS hardware and covered software, in another country, that Company B will eventually import into the United States. Company B's connected vehicles contain VCS hardware and covered software supplied by an entity that is subject to the jurisdiction of the PRC. Importing the vehicles into the United States is a prohibited transaction, unless a general authorization or specific authorization applies.

Example 33: Company A is an automotive parts company that is domiciled in the PRC or Russia. Company B is a U.S. person. Company A buys VCS hardware that integrates covered software, then customizes and packages that VCS hardware for sale to and import by Company B into the United States. Assuming no other facts, the VCS hardware supplied by Company A is supplied by an entity subject to the jurisdiction of the PRC or Russia. The import of the VCS hardware into the United States is a prohibited transaction, unless a general authorization or specific authorization applies.

For additional clarity in determining whether a transaction involving VCS hardware or covered software designed, developed, manufactured, or supplied by entities described above is prohibited under the final rule, BIS offers the below examples. In offering these examples, BIS emphasizes, and has further clarified this language in the prohibitions, that VCS hardware and covered software would not be considered designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia based solely on the country of citizenship of one or more natural

persons who are employed by, contracted by, or otherwise similarly engaged in such actions through the entity designing, developing, manufacturing, or supplying the VCS hardware or covered software. In particular, BIS confirms that visa holders in the United States would not be considered persons controlled by the PRC or Russia solely based on their citizenship.

Example 34: A U.S. person has a contractual relationship with a foreign person to import a cellular module, and the cellular module will later be integrated into a VCS for a completed connected vehicle. The U.S. person is, under the final rule, a VCS hardware importer. The U.S. person knows the cellular module was manufactured at a facility located in the PRC or Russia and is being imported through a third country. Since the entity manufacturing the module would, at a minimum, be "subject to the jurisdiction" of the PRC or Russia, the import of the module would be a prohibited transaction under the final rule, unless it qualifies for a general authorization or a specific authorization from BIS.

Example 35: A U.S. person imports a TCU that was assembled in a third country, but that contains a microcontroller that is manufactured in the PRC or Russia and is sold to the third-country assembler of the TCU. The U.S. person knows that the microcontroller was manufactured by an entity located in the PRC or Russia. As the microcontroller is included in the definition of VCS hardware, the import of the TCU for a completed connected vehicle would be a prohibited transaction under the final rule unless it qualifies for a general authorization, or a specific authorization granted by BIS.

Example 36: A U.S. person imports a completed connected vehicle, making the U.S. person a connected vehicle manufacturer under the final rule's definition. The completed connected vehicle contains a TCU that operates software supporting off-vehicle connectivity above 450 MHz, and that software is designed, developed, or otherwise supplied (in whole or in part) by an entity located in the PRC or Russia. Under the final rule, the import of the completed connected vehicle would be prohibited unless it was authorized by a general authorization or a specific authorization.

Example 37: A U.S. person who is a connected vehicle manufacturer that manufactures or assembles completed connected vehicles in the United States sells to a dealer within the United States a completed connected vehicle in which the vehicle's ADS software for object

detection, classification, and decision making is proprietary software designed, developed, or supplied by an entity in the PRC or Russia. The sale or transfer of the completed connected vehicle would be a prohibited transaction under the final rule unless it qualifies for a general authorization or specific authorization.

Example 38: A U.S. person who is a connected vehicle manufacturer utilizes foreign VCS and ADS software development teams through various subsidiaries, joint ventures, and contract arrangements, some of which retain servicing obligations and contractual and licensing rights in the software they have developed. One of those software development teams is located in the PRC or Russia, and as such, that software team is subject to the jurisdiction of the PRC or Russia. Given the role of PRC or Russian developers in the creation of the VCS or ADS software and the existence of an ongoing foreign interest (*i.e.*, servicing obligations and contractual and licensing rights), the sale of a completed connected vehicle within the United States that integrates this proprietary covered software would be a prohibited transaction under the final rule, unless it qualifies for a general authorization or specific authorization.

Example 39: Company A, which is a wholly owned subsidiary of a foreign corporation in which a PRC or Russian entity owns a controlling interest, imports completed connected vehicles that incorporate covered software and VCS hardware, none of which was originally designed, developed, manufactured, or supplied by an entity owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. In the rare circumstance where Company A did not participate in the design or development of the covered software or VCS hardware, Company A would submit a Declaration of Conformity for the import of the completed connected vehicles containing covered software and VCS hardware, identified by make, model, and VIN series. However, any subsequent sale by Company A of such completed connected vehicle in the United States would be prohibited. For example, Company A subsequently sells such completed connected vehicles to a dealer in the United States. Because Company A is a person controlled by the PRC or Russia and has direct privileged access to the VCS hardware and covered software prior to the sale, the knowing sale by Company A of the completed connected vehicle with VCS hardware and covered software would be a prohibited transaction under the

final rule, and a specific authorization from BIS would be required before engaging in such a transaction.

Example 40: Company A, a wholly owned subsidiary of a PRC or Russia corporation, manufactures completed connected vehicles in the United States. The completed connected vehicles that Company A manufactures incorporate covered software and VCS hardware provided by Company B, a company that is not owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Because Company A is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, Company A's sale of the completed connected vehicles is a prohibited transaction under the final rule, and a specific authorization from BIS would be required before engaging in such a transaction.

Example 41: Company A is a company that, through any of the scenarios detailed above, is deemed to be owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Company A purchases otherwise completed connected vehicles from Company B, a U.S. company that is not owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Company A transforms these vehicles into autonomous vehicles by integrating hardware and software, including ADS software, on these vehicles. Company A is thus a connected vehicle manufacturer under this rule. Company A seeks to offer a commercial robotaxi service by which customers are able to use a mobile application to hail one of Company A's vehicles incorporating ADS software. Because Company A is a connected vehicle manufacturer owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia and seeks to offer a commercial service utilizing completed connected vehicles incorporating ADS, Company A would require a specific authorization from BIS prior to engaging in such a transaction.

Many commenters recommended that BIS further clarify that, under the rule, VCS hardware or covered software would not be considered as designed, developed, manufactured, or supplied by entities with a nexus to the PRC or Russia if individual contributors holding PRC or Russian citizenship work on the hardware or software outside of the PRC or Russia. Commenters expressed similar concerns about visa holders from the PRC or Russia working in the United States. BIS agrees that participation by individual contributors holding PRC or Russian citizenship outside of the PRC or Russia

should not alone make VCS hardware or covered software subject to the prohibitions in this rule because this scenario presents a lower national security risk than other situations addressed by this rule. BIS has addressed this point in paragraph (b) of section 791.302 (prohibited VCS hardware transactions) and paragraph (c) of section 791.303 (prohibited covered software transactions). BIS further highlights in the examples below.

Example 42: A U.S. person who is a connected vehicle manufacturer utilizes VCS and ADS software development teams around the world through various subsidiaries, joint ventures, and contract arrangements. One of those software development teams is comprised of individuals who are PRC or Russian citizens working in a foreign jurisdiction other than the PRC or Russia for a company that is not owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Although the individuals technically meet the definition of "person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary," assuming no other facts, paragraph (c) of the section 791.303 (Prohibited covered software transactions) makes clear that the sole fact that PRC or Russian citizens work on the connected vehicle manufacturer's software development would not make the sale of a completed connected vehicle within the United States that integrates this VCS or ADS software a prohibited transaction under the final rule.

Example 43: Company A is a European automotive company. Company B is a supply chain consultancy that is domiciled in Singapore and is majority owned by a PRC citizen. Subject to a non-disclosure agreement, Company B reviews Company A's automotive design specifications and recommends specific hardware and software suppliers to Company A. Company A considers Company B's recommendations and obtains hardware or software from the recommended suppliers directly (not through Company B). Assuming no other facts, Company B's review and recommendation of Company A's covered software and VCS hardware suppliers does not mean those products are developed by an entity subject to the jurisdiction of the PRC. The import or sale of Company A's vehicles in the United States would not be a prohibited transaction, but a VCS hardware importer or connected vehicle manufacturer that imports or sells the vehicles into the United States must

comply with any applicable Declaration of Conformity requirements.

To provide further clarification, BIS has added examples to this final rule, such as Example 30, Example 42, and Example 43, to explain that citizenship of natural persons involved in the manufacture or design of a product is not itself determinative of a product being designed, development, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. These examples also help explain the prohibitions described in Section VI subsection (b) *Prohibitions on Certain Transactions Related to Connected Vehicles*.

Numerous commenters urged BIS to provide greater clarity as to the criteria by which regulated entities should deem a person to be owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Several commenters recommended that BIS adopt the criteria described by the Department of Justice's (DOJ) NPRM, *Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons* (89 FR 86116, October 29, 2024), which uses a fifty percent threshold for ownership as one criteria for an entity to be a "covered person", or adopting a more conservative ownership threshold of 25 percent, as stipulated by the Department of Energy's (DOE) Foreign Entity of Concern (FEOC) rules. BIS rejects these suggestions and retains the current definition as published in the NPRM because it retains consistency across all ICTS transactions reviewed by BIS under 15 CFR part 791 Securing the Information and Communications Technology and Services Supply Chain. By contrast, each of the other U.S. government programs identified by commenters differs and addresses national security risks unique to their mandates and missions. For instance, DOE's final guidance applies to the Battery Materials Processing and Manufacturing grant program, authorized by section 40207 of the Bipartisan Infrastructure Law, Public Law 117–58, and the 30D Clean Vehicle tax credit created under the Inflation Reduction Act, Public Law 117–169, which imposes limits on when an entity's battery supply chain includes FEOC. DOE's final guidance was issued to aid stakeholders in identifying FEOCs in their battery supply chains rather than those entities involved in supply chains related to VCS and ADS. DOJ's NPRM on *Provisions Pertaining to Preventing Access to U.S. Sensitive*

Personal Data and Government-Related Data by Countries of Concern or Covered Persons also differs in that it prohibits and restricts certain transactions that could allow persons from countries of concern access to bulk sensitive personal data or to U.S. government-related data. Additionally, BIS rejects the recommendation to define ownership thresholds. While BIS recognizes that thresholds may provide a bright line for industry, BIS maintains that connected vehicle supply chains are complex and opaque, with varying ownership structures of OEMs and connected vehicle suppliers. Bright-line thresholds alone can be limited when dealing with an entity with a PRC or Russia nexus and one who may circumvent the prohibitions by adjusting its ownership structure, while still retaining corporate control or executive management that may be subject to the direction of the PRC or Russia. Retaining the current definition of *owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia*, will allow BIS to address the evolving and unique national security risks across a variety of supply chains for distinct industries, as articulated in Section IV of this rule. Additionally, one commenter requested that BIS further clarify the meaning of *subject to the direction* in this definition. This commenter expressed concern that “direction” diverges from common industry understandings of ownership and control, and that it could be interpreted to include a one-time event. BIS retains the definition of *person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary*, which is consistent with the scope of E.O. 13873 and reflects the possibility that a person may act at the direction of a foreign adversary in situations in which typical corporate ownership or control may not be present. BIS considers “subject to the direction” to typically entail a continuous and ongoing relationship between a regulated person and the PRC or Russian government or entities subject to the jurisdiction of the PRC or Russian government.

One commenter maintained that the ultimate ownership structure of an entity should not subject that entity to the prohibitions of the rule, and the location of covered software and VCS hardware design should instead be determinative. BIS reiterates the threat outlined in the NPRM and in this final rule that entities owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia may be compelled to provide logical access to

their VCS hardware or covered software resulting in the exfiltration of sensitive data or remote manipulation of the vehicle. While the location of covered software and VCS hardware design and development, as well as corporate structure and security practices, will play an important factor in BIS’s decision to issue specific authorizations, BIS declines to amend the rule in response to this comment.

15. Prohibited Transactions

In the NPRM, BIS proposed *prohibited transactions* to mean collectively, the transactions described in section 791.302 (Prohibited VCS hardware transactions), section 791.303 (Prohibited covered software transactions), or section 791.304 (Related prohibited transactions) of this subpart. BIS did not receive any comments directly about this definition. Feedback on prohibited transactions focused on the transactions described in the body of the regulation text. To review the comments and responses on the prohibited transactions in this rule, please review Section VI subsection (b) *Prohibitions on Certain Transactions Related to Connected Vehicles* below.

16. Sale

In the NPRM, BIS proposed *sale* to mean distributing for purchase, lease, or other commercial operations a new completed connected vehicle for a price, to include the transfer of completed connected vehicles from a connected vehicle manufacturer to a dealer or distributor, as those terms are defined in 49 U.S.C. 30102. This definition also applies to the related terms such as *sell* or *selling*. Some commenters recommended that BIS clarify and revise the definition of sale. Commenters highlighted differences between the commercial vehicle market and the passenger vehicle market and emphasized that the NPRM *sale* definition is inadequately scoped for the commercial vehicle market. BIS, after taking all comments into consideration, retained this definition in the final rule but made a related change to the definition of *connected vehicle* to focus on the passenger market by limiting the scope of this final rule to vehicles under 10,001 pounds.

One commenter recommended that BIS clarify that contracting with a third party to manufacture one’s own completed connected vehicles with one’s own VCS or ADS does not constitute a sale. In response, BIS believes that such a transaction could, but would not necessarily always, constitute a sale, and such a determination would depend on the

specifics of the arrangement, including the chain of custody or legal rights over the vehicle while with a third-party manufacturer. BIS generally believes that it is not in the national security interest of the United States to categorically exempt third-party manufacturing from the prohibitions of this rule. For example, the rule would prohibit the sale of completed connected vehicles manufactured by an entity that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, even if that manufacturing is on behalf of a U.S. connected vehicle manufacturer. In this scenario, BIS believes the integration of VCS hardware or covered software by that manufacturer constitutes the “supply” of such ICTS by a prohibited entity. Whether or not the actual transfer of the vehicles from the third-party manufacturer to the U.S. connected vehicle manufacturer occurred would depend on the specifics of the transaction, but if there is a foreign interest in the software (e.g., ongoing contractual arrangements or IP rights), the ultimate sale of those vehicles in the United States would be prohibited. However, if, for example, the third-party manufacturer incorporates prohibited ADS software that is designed, developed, manufactured, or supplied by a PRC or Russian entity, the subsequent transfer of those vehicles to any entity for commercial operations would be prohibited.

One commenter claimed that the definition as written could be interpreted to impose compliance duties on dealers who sell but do not manufacture or import connected vehicles. As written, the prohibitions of the rule apply only to the sale of a completed connected vehicle by a connected vehicle manufacturer. Given that dealers do not perform manufacturing operations on vehicles to transform an incomplete connected vehicle into a completed connected vehicle (nor do they integrate ADS onto an otherwise completed connected vehicle), the sale of vehicles from a dealer to a consumer would not be captured by any of the prohibitions of this rule. BIS emphasizes that instead, given both the definition of *sale* and the prohibitions contained in this rule, it is the sale by the connected vehicle manufacturer to the dealer that would be prohibited if the VCS hardware or covered software is designed, developed, manufactured, or supplied by an entity owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, or if the connected

vehicle manufacturer itself is such an entity. In this case, it is the connected vehicle manufacturer that is subject to the prohibition, and it is the connected vehicle manufacturer that would be subject to civil or criminal penalties should they knowingly violate these prohibitions. As such, BIS stresses that this rule places no additional compliance responsibilities on dealers.

17. Software Bill of Materials

In the NPRM, BIS proposed to define *software bills of materials (SBOM)* to mean a formal and dynamic, machine-readable inventory detailing the software supply chain relationships between software components and subcomponents, including software dependencies, hierarchical relationships, and baseline software attributes, including author's name, timestamp, supplier name, component name, version string, component hash package URL, unique identifier, and dependency relationships to other software components. Based on public comment, BIS has altered its definition of *SBOM* and modified its compliance requirements with respect to SBOMs.

Commenters provided feedback on what BIS should include in the criteria for an SBOM, suggesting how its definition should be changed in the final rule. Multiple commenters recommended that BIS align its *SBOM* definition to the National Telecommunication and Information Administration's (NTIA) "The Minimum Elements for a Software Bill of Materials" (Minimum Elements for an SBOM), a report written in collaboration with the Department of Commerce and authorized under President Biden's E.O. 14028, "Improving the Nation's Cybersecurity," 86 FR 26633 (May 12, 2021), which identifies the prevention, detection, assessment, and remediation of cyber incidents. Many commenters recommended referencing NTIA's Minimum Elements for an SBOM in BIS's SBOM definition. Another commenter specifically advised removing the "component hash" requirement in BIS's SBOM definition to match the NTIA's Minimum Elements for an SBOM. Commenters also recommended revising the definition to only require the detailed elements "if available."

Based on the numerous comments received, BIS opted to align the SBOM definition with the NTIA Minimum Elements for an SBOM requirements rather than reference them directly to avoid any confusion should the NTIA definitions change. In addition, BIS has removed several SBOM elements (e.g., version string, component hash, package

URL, and unique identifier) from the minimum documentation requirements necessary to apply for a Declaration of Conformity or specific authorization. BIS declines to add "if available" to the SBOM requirements included in the final rule with the understanding that this regulation is prospective, allowing industry the opportunity to ensure these minimum requirements are met for any covered software transaction. These changes also reflect comments arguing that the NPRM definition requires information that may be beyond the detail provided by automated scanning tools and would create burdens for manufacturers, and cautioning BIS that industry did not have sufficient time to gather SBOMs as defined in the NPRM by model year 2027. By reducing the minimum documentation requirements for an SBOM, as described above, and removing the requirement to submit an SBOM with Declarations of Conformity (see Section VI.C.1), BIS has significantly reduced the compliance burden for industry, including for small entities. BIS has significantly reduced the compliance burden for industry, including for small entities.

One auto manufacturer recommended that BIS replace "supplier's name" and "author's name" with "person's name" in the definition. While BIS has removed the required baseline software attributes from the definition of SBOM, including the requirements for author's name and supplier name, it declines to replace the term "supplier" and "author" with "person" in the context of SBOMs throughout the remaining regulatory text based on the understanding that a "supplier" or "author" may be either an entity or person. Additionally, this language is inconsistent with E.O. 14028 and NTIA's Minimum Elements for an SBOM, on which BIS bases its SBOM definition. Another commenter stated that if BIS intends for SBOM requirements to include open-source software within covered software, that this be specified in the definition by adding "including open-source software used in covered software, even if the open-source software is outside the definition of covered software." In alignment with the removal of the SBOM submission requirement, BIS will only require retention of minimal documentation related to products for which a Declaration of Conformity is submitted, including documentation or third-party assessments sufficient to identify, at minimum, the author name, timestamp, component name, and supplier name of all proprietary

additions to the development of the covered software.

Commenters provided other feedback about how to use and process SBOMs. A commenter highlighted how SBOMs could be useful to BIS in variety of ways, including: verifying if known vulnerabilities exist using the CPE (Common Platform Enumeration) in the unique identifier against the NVD (National Vulnerability Database); ensuring the supplier names listed in the SBOMs do not match any entity under foreign adversary control, as defined by the proposed rule; confirming that component hashes match those generated from package URLs to verify source code integrity; and using dependency relationships to provide specific guidance to entities on scope to address for achieving conformity when issues arise with identified components. This commenter also recommended that BIS allow a flexible SBOM update method that can be integrated into the frequent software update typical for VCS and ADS without disrupting development cycle. BIS appreciates this feedback; however, given its decision to not require SBOMs at this time, BIS will not take action on these recommendations. NBIS has chosen to define "Software Bill of Materials" or SBOM as a formal record containing the details and supply chain relationships of various components used in building software. Software developers and vendors often create products by assembling existing open-source and commercial software components. The SBOM enumerates these components in a product.

18. United States

In the NPRM, BIS proposed *United States* to mean United States of America, the States of the United States, the District of Columbia, and any commonwealth, territory, dependency, or possession of the United States, or any subdivision thereof, and the territorial sea of the United States. Commenters did not provide feedback on this definition. BIS retains this definition for its final rule.

19. Vehicle Connectivity System

In the NPRM, BIS proposed *Vehicle Connectivity System (VCS)* to mean a hardware or software item for a completed connected vehicle that has the function of enabling the transmission, receipt, conversion, or processing of radio frequency communications at a frequency over 450 megahertz. Public comments informed BIS's modification of *VCS* definition for the final rule, which includes explicit hardware and software exclusions.

Numerous commenters provided feedback on BIS's proposed definition for *Vehicle Connectivity System*. Many commenters urged BIS to narrow the definition to exclude specific radio frequency bands, functions, or devices. Comments regarding specific VCS hardware devices are discussed in the next section, "VCS Hardware."

Multiple commenters took issue with the proposed rule's threshold of 450 MHz and argued that this cutoff is overly broad. For example, some commenters recommended that BIS include an upper limit for the radio frequency band in order to scope out certain ultra-wideband automotive applications, such as some key fobs. Other commenters encouraged BIS to scope out certain convenience functions such as garage door opening or rear seat entertainment. Several commenters also encouraged BIS to explicitly scope out systems that connect internally within the vehicle, supply power to the VCS, exchange data with the VCS, authenticate a user to access or drive a vehicle, or localize a device intended to control vehicle functions.

In response to these comments, BIS has amended the definition of VCS to include a variety of function-based exclusions to exclude certain low-risk use cases and provide industry with greater flexibility. BIS declines to implement an upper bound for the radio frequency as this would unnecessarily constrain the definition of VCS as automotive technology evolves. BIS has accepted the majority of recommendations to exclude certain functions, including automotive sensing (which includes LiDAR, radar, cameras, and ultrawideband); global navigation satellite system (GNSS); and satellite, AM, and FM radio. BIS declines to exclude convenience functions given the difficulty in adequately defining this exemption to address only convenience functions rather than communications functions that present undue risk. Further, many of the "convenience" functions referenced by the commenters are simply systems that use VCS to accomplish a non-driving task, often by communicating non-expressive data with an external device. BIS added a number of VCS exclusions that may exclude certain "convenience" functions, but declines to categorically exclude them all, as the term is broad and eludes concise definition. BIS further believes that the amended definition of VCS *hardware*, particularly the replacement of "supports" to "directly enables," renders unnecessary the exclusion of internal vehicle communications or an exemption for systems that simply exchange data with

the VCS. While BIS believes that this amended definition excludes features that enable vehicle access and user authentication, BIS declines to exclude the hardware and software that enable the localization of a device intended to control vehicle functions, as the vehicle-side hardware and software of that function presents a possible threat vector that could enable the national security risks spelled out in this rule.

A commenter recommended that the definition of VCS be restricted to the electronic control unit or part of an item that supports the VCS external communications capability. Restricting the definition of VCS, and therefore VCS *hardware*, to solely the electronic control unit or "telematics control unit" would be overly narrow and would leave many other components that also support wireless communications that could enable long-range cybersecurity exploits. For example, if an infotainment module or a battery management system included a cellular module for its own wireless communication, those modules could be considered VCS but would not be covered by a regulation that only focused on an "ECU." Furthermore, major subcomponents of ECUs that are software programmable often retain connectivity with their OEMs and continue to receive software updates throughout their lifecycle. Therefore, BIS determined that addressing connectivity systems at the ECU level only would be insufficient.

Commenters urged BIS to clarify the definition of VCS by clarifying that (1) a system that may convert or process radio frequency communications at a frequency over 450 megahertz, but that does not both receive and transmit data either to or from the vehicle, is outside the scope and (2) a system that does not both receive data from external sources and transmit data to an external source is outside the scope. In response to this comment and others that raised similar issues, BIS modified the definition of VCS to add a number of functional exclusions, one of which excludes unidirectional communication systems. However, a subcomponent within an item that directly enables the function of transmission, receipt, conversion, or processing of a connectivity item would nonetheless be defined as VCS even if that subcomponent has only an internal, unidirectional communication purpose. One commenter urged BIS to modify the VCS definition to clarify that: "Items that are either for wired frequency communications (e.g., USB port, OBD port) or for the purpose of distance positioning or imaging only are exempted (e.g., Ultra-Wide Band (UWB),

cameras, and sensors including LiDAR and radar)." BIS understands that wired-frequency communications-related hardware may also pose risks, but they are not as significant as those defined in the final rule's definition of VCS. BIS accepts this recommendation in part and has modified the VCS definition to define specific function-based exclusions, including on that explicitly excludes sensor hardware.

Commenters recommended that the VCS definition align with the Federal Communication Commission (FCC) equipment authorization regulations. BIS attempted, wherever able, to conform and harmonize with preexisting standards in both the automotive and telecommunications industries. In this case, aligning the VCS definition with the scope of the FCC's equipment authorization definition would be overly broad, as the FCC requires declarations of conformity or certification for products that BIS did not intend to be VCS, including unintentional radiators, as defined by 47 CFR 15.3. To keep the definition as narrow as possible to address only those items and components necessary to mitigate the identified national security risks, BIS decided not to rely on the FCC equipment authorization program's scope.

One commenter suggested that BIS amend this term to "Vehicle Communication Device," believing that the term would provide industry with greater clarity on covered items. BIS has decided to retain the original Vehicle Connectivity System term and believes that "Vehicle Communication Device" would unnecessarily constrain covered components, including unintentionally excluding major VCS subcomponents that could directly pose a national security risk as outlined in this rule. However, BIS believes that other changes to the definitions of *Vehicle Connectivity System* and VCS *hardware* substantially address the intent behind this comment. BIS also rejects commenters recommendation to define system. Another commenter urged BIS to reconsider its prohibitions on vehicle connectivity given the U.S Department of Transportation's efforts to deploy Vehicle-to-Everything (V2X) technology. This commenter argued that the proposed rule unnecessarily risks delaying V2X deployments and undermines local, state, and federal investments into V2X infrastructure deployment. BIS appreciates this comment and has been in contact with the Department of Transportation in drafting this regulation. BIS understands that the requirements of this regulation may create new compliance burdens.

However, those requirements seek to ensure automotive supply chain security, which will help secure the future of V2X technology implementation.

BIS has chosen to define *Vehicle Connectivity System* or *VCS* as a hardware or software item installed in or on a completed connected vehicle that directly enables the function of transmission, receipt, conversion, or processing of radio frequency communications at a frequency over 450 megahertz. VCS does not include a hardware or software item that exclusively:

(1) enables the transmission, receipt, conversion, or processing of automotive sensing (e.g., LiDAR, radar, video, ultrawideband);

(2) enables the transmission, receipt, conversion, or processing of ultrawideband communications to directly enable physical vehicle access (e.g., key fobs);

(3) enables the receipt, conversion or processing of unidirectional radio frequency bands (e.g., global navigation satellite systems (GNSS), satellite radio, AM/FM radio); or

(4) supplies or manages power for the VCS.

20. VCS Hardware

In the NPRM, BIS proposed *VCS hardware* to mean the following software-enabled or programmable components and subcomponents that support the function of VCS or are part of an item that supports the function of VCS: microcontroller, microcomputers or modules, systems on a chip, networking or telematics units, cellular modem/modules, Wi-Fi microcontrollers or modules, Bluetooth microcontrollers or modules, satellite navigation systems, satellite communication systems, other wireless communication microcontrollers or modules, and external antennas. VCS hardware does not include component parts that do not contribute to the communication function of VCS hardware. BIS received a variety of comments on VCS hardware that informed the final rule definition.

One commenter encouraged BIS to adopt an entity-based approach, rather than target specific VCS hardware devices, or to introduce an exhaustive list of covered components. BIS declines these suggestions. BIS has determined that an entity-based approach would not adequately mitigate the national security risks outlined in this rule, given the ability of prohibited entities to restructure and ingrain themselves in the connected vehicle supply chain before being subject to an enforcement

action by BIS. Rather, a technology-based approach more broadly covers entities of concern and would not require individual enforcement actions against all PRC or Russian suppliers of covered software or VCS hardware. Some commenters requested that BIS clarify that the list of VCS hardware components is exhaustive, meaning any component not included in the definition would not be captured by the prohibition. BIS declines this recommendation as it believes the modifications to the definition of VCS and VCS hardware will allow industry to appropriately identify covered components, and further believes that limiting the definition to a set list of components would not adequately address the potential for changes in nomenclature in the future or address technological developments in which components that are not listed might directly enable VCS functions.

Commenters requested several changes to the *VCS hardware* definition. As with covered software, numerous commenters requested that BIS refine the definition of *VCS hardware* and replace the phrase “support the function of.” Most commenters making this point suggested that BIS replace this language with “directly enable the function of” or similar language. BIS accepts this recommendation and believes it will allow industry to more easily identify components that are captured by the *VCS hardware* definition. One commenter requested that BIS remove the word “subcomponent” from the definition. BIS rejects this recommendation because VCS hardware subcomponents with a nexus to foreign adversaries facilitate the same risk identified in this regulation.

Many commenters encouraged BIS either to explicitly exclude certain VCS hardware devices from the definition, or, in some cases, to explicitly include a set of devices not originally present in the proposed rule’s definition. As referenced above, commenters encouraged BIS to exclude automotive radar from the definition of *VCS hardware* given its safety-critical nature and its inability to communicate independently of the vehicle. As noted, BIS accepts this recommendation and has amended the definition of *Vehicle Connectivity System* accordingly where it has noted this exclusion. Radar hardware is also excluded in the definition of VCS hardware because its primary function is for sensing rather than communications.

Other commenters urged BIS to include LiDAR as a separate category of VCS hardware, contesting BIS’s decision to exclude the technology from the

proposed rule. One commenter pointed to outside research assessing that certain PRC manufacturers of LiDAR could insert vulnerabilities into the technology and that the reliance of U.S. connected vehicle manufacturers on PRC LiDAR could pose an unacceptable supply chain risk. In response, BIS reaffirms its decision to exclude LiDAR from the definition of *VCS hardware*. While recognizing that foreign adversary-sourced LiDAR may present certain cyber or supply chain risks, BIS continues to assess that the ADS software is the most appropriate avenue through which to address the potential remote manipulation of a connected vehicle at this time. In general, ADS software is responsible for overseeing the autonomous behavior of the car, processing data from sensors in the car, and executing operations based on that data. In contrast, LiDAR software is merely responsible for analyzing and processing the data collected by LiDAR. BIS recognizes that the scope of both data and control over the vehicle is greater for ADS software than LiDAR software, which is why BIS has prioritized ADS software in this regulation. However, BIS emphasizes that it may consider LiDAR separately as part of a separate rulemaking effort or investigation under 15 CFR 791.

Commenters specifically asked that components and subcomponents that do not have the ability to process or modify data be removed from the scope of VCS hardware, such as antennas and tuners. In response to these comments, BIS notes that if a tuner is a passive electronic part that is not software programmable, it may not be covered by this regulation. However, if the tuner is a software-enabled and programmable component that directly enables the function of a VCS item then it would likely be defined as *VCS hardware* and thus regulated by this rule. This also applies to one commenter, who requested that BIS clarify that RF switches and passive oscillation components not be included in the definition of VCS hardware. BIS believes that the clarification that VCS hardware must “directly enable” vehicle communication addresses this comment. Other outstanding questions may be answered on BIS’s FAQ website page or via an advisory opinion.

Commenters requested that BIS define the terms system and modules. BIS accepts this recommendation in part, as it has defined “system” to the extent it has defined *Vehicle Connectivity System* and *Automated Driving System*. Further, the definition of *item* reflects BIS’s stance on the term “system,” insofar as a system can be considered an

item if that system performs a function. Given this portion of the *item* definition, a subsequent definition of “system” would be redundant. With regard to the term “module,” BIS again determines that the definition of *item* is sufficient to provide a known industry benchmark that regulated entities may use to delimit the types of components that fall within the regulated systems. Multiple commenters, particularly in the commercial vehicle sector, urged BIS to reconsider the inclusion of aftermarket VCS devices. BIS believes that certain aftermarket devices, specifically those that fulfill VCS functions, pose a significant national security risk when designed, developed, manufactured, or supplied by PRC or Russian entities. BIS does recognize that the inclusion of aftermarket devices poses particular concerns for the commercial sector, and consequently may consider a separate rulemaking on commercial connected vehicles to address this significant threat in a tailored manner. For the passenger connected vehicle market, BIS emphasizes that aftermarket devices that directly fulfill VCS functions are captured by the VCS hardware prohibition.

Some commenters raised that under the proposed rule, a cellphone that paired with a connected vehicle could be considered aftermarket VCS hardware. BIS believes that the updated definition of *VCS hardware*, particularly the stipulation that the hardware “directly enable the function of” and be “directly connected to” VCS sufficiently clarifies BIS’s intent that cellphones not be captured by this rule. VCS hardware includes aftermarket devices not contained in a completed connected vehicle at sale but that are later integrated into the vehicle to perform VCS functions. Conversely, VCS hardware does not include aftermarket devices whose primary function is not to enable vehicle connectivity. For example, mobile phones that are paired with a connected vehicle are not considered aftermarket VCS hardware as vehicle connectivity is not the primary intended function of the device.

Additionally, just as commenters requested legacy software to be excluded from the definition of covered software, other commenters requested BIS exclude legacy hardware, or “as produced” repairs, from the scope of the regulation. BIS rejects adding a legacy hardware exclusion because of the longevity of hardware and completed connected vehicles in general. As such, excluding hardware designed prior to the effective date of the prohibition but imported after the effective date from the scope of this regulation could result

in national security risks emanating from such hardware for decades. BIS believes that setting the date in the prohibition for January 1, 2029, or model year 2030 and allowing the import of parts meant for vehicles with a model year prior to 2030 provides a reasonable middle ground.

Additionally, BIS assesses that inspecting hardware for embedded vulnerabilities is more burdensome than inspecting software for the same. Legacy hardware could contain persistent undetected vulnerabilities that would continue to enable potential access to or exploitation of vehicles or vehicle data that would be difficult or impossible to mitigate if scaled across a generation of vehicles. Conversely, regulated entities are more likely to discover such vulnerabilities in software during the continuous cycle of software development and testing, and have the means to patch those vulnerabilities across their fleets. BIS emphasizes that VCS hardware importers may engage in otherwise prohibited transactions so long as (1) the import of VCS hardware not associated with a vehicle model year prior to January 1, 2029, or (2) the import of VCS hardware is associated with a vehicle model year prior to 2030, the VCS hardware is imported as part of a connected vehicle with a model year prior to 2030, or the VCS hardware is imported for purposes of repair or warranty for a connected vehicle with a model year prior to 2030. BIS believes this is sufficient time to adjust VCS hardware supply chains, including for legacy VCS hardware.

BIS defines *VCS hardware* to mean software-enabled or programmable components if they directly enable the function of VCS, or are part of an item that directly enables the function of VCS, including but not limited to: microcontroller, microcomputers or modules, systems on a chip, networking or telematics units, cellular modem/modules, Wi-Fi microcontrollers or modules, Bluetooth microcontrollers or modules, satellite communication systems, other wireless communication microcontrollers or modules, external antennas, digital signal processors, and field-programmable gate arrays. VCS hardware does not include component parts that do not contribute to the communication function of VCS hardware (e.g., brackets, fasteners, plastics, and passive electronics, diodes, field-effect transistors, and bipolar junction transistors).

The representative list of VCS hardware included in its definition is not exhaustive but provides a bright line for certain examples where BIS would consider a component to be VCS

hardware. BIS believes this definition appropriately identifies the various components, contained within a TCU or other connected systems of a connected vehicle, that facilitate off-board data transmission, and thus are most likely to pose the risks identified in Section IV.

21. VCS Hardware Importer

In the NPRM, BIS proposed *VCS hardware importer* to mean a U.S. person importing VCS hardware for further manufacturing, integration, resale, or distribution. A connected vehicle manufacturer may be a VCS hardware importer if VCS hardware has already been installed in a connected vehicle when imported by the connected vehicle manufacturer. Commenters’ feedback led BIS to provide a more specific definition in the final rule.

Some commenters highlighted that the proposed rule’s broad definition of both *VCS hardware* and *VCS hardware importer* would capture the import of components whose primary use is not automotive and thus cause severe ancillary effects on other industries. In response, BIS has clarified the definition of *VCS hardware importer* to include only those entities who are importing VCS hardware components that are for use in completed connected vehicles, or that are already incorporated in a connected vehicle (incomplete or completed). BIS further believes that the changes to the definition of *VCS hardware* provide additional clarity on this point.

Other commenters requested that BIS codify its expectation that this definition would capture OEMs and tier one and tier two suppliers. While BIS anticipates that these will be the primary entities who are engaging in the import of VCS hardware components covered by this rule, BIS has opted not to specify this expectation in the rule text given the possibility that other entities may become involved in the import of VCS hardware. BIS emphasizes that parties may submit a request for an advisory opinion on a specific transaction if they are unsure if they qualify as a VCS hardware importer under the terms of this rule.

BIS defines *VCS hardware importer* as a U.S. person who imports:

(1) VCS hardware for further manufacturing, incorporation, or integration into a completed connected vehicle that is intended to be sold or operated in the United States; or

(2) VCS hardware that has already been installed, incorporated, or integrated into a connected vehicle, or a subassembly thereof, that is intended

to be sold as part of a completed connected vehicle in the United States.

BIS anticipates that this definition will primarily capture OEMs, tier one, and tier two suppliers importing VCS hardware into the United States. This definition also delineates that only entities importing VCS hardware with an intention of incorporating it into the U.S. automotive supply chain are subject to this regulation, rather than VCS hardware importers providing products to markets beside the auto industry.

b. Prohibitions on Certain Transactions Related to Connected Vehicles

The NPRM proposed to prohibit three categories of transactions: prohibited VCS hardware transactions, prohibited covered software transactions, and related prohibited transactions (collectively described as *prohibited transactions*). In this section, BIS summarizes the prohibitions proposed in the NPRM and examines public comments on them. This final rule largely retains these same prohibitions, but in response to comments, BIS has added additional examples to provide more clarity for the scope of transactions that fall under this regulation. Many commenters also requested that BIS provide greater clarity regarding the definitions of *VCS hardware*, *covered software*, and *foreign interest* so that auto manufacturers can better understand what constitutes a prohibited transaction. Comments on these definitions as well as BIS's efforts to clarify these definitions are discussed above and should be considered in tandem with this discussion.

In the NPRM, BIS proposed the following language identifying prohibited transactions. First, under prohibited VCS hardware transactions, the NPRM stated:

(a) "VCS hardware importers are prohibited from knowingly importing VCS hardware that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia."

(b) "In the context of this subpart, VCS hardware will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, solely based on the country of citizenship of natural persons who are employed, contracted, or otherwise similarly engaged to participate in the design, development, manufacture, or supply of the VCS hardware."

Second, under prohibited covered software transactions, BIS proposed the following language:

(a) "Connected vehicle manufacturers are prohibited from knowingly importing into the United States completed connected vehicles that incorporate covered software, designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia."

(b) "Connected vehicle manufacturers are prohibited from knowingly selling in the United States completed connected vehicles that incorporate covered software, designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia."

(c) "In the context of this subpart, covered software will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, solely based on the country of citizenship of natural persons who are employed, contracted, or otherwise similarly engaged to participate in the design, development, manufacture, or supply of the [c]overed [s]oftware."

Finally, BIS proposed the following language addressing related prohibited transactions:

"Connected vehicle manufacturers who are persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, are prohibited from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software."

Multiple commenters requested that BIS provide clearer guidance on what constitutes a prohibited transaction, notably (1) to demonstrate the difference between "design" and "develop" (relevant to both the VCS hardware and the covered software prohibitions) and (2) to narrow the scope of the entity responsible for the "design" or "development" of the item when multiple entities are involved in its creation. BIS acknowledges the need for clear guidance on what constitutes a prohibited transaction and has therefore in response to commenters included new examples in explaining the definitions above to clarify the scope of "design and develop" and the entities responsible.

Several commenters voiced that BIS should narrow the scope of the prohibited transactions. For example, one commenter recommended that the covered software prohibition only apply prospectively and not to software developed prior to the effective date of the rule. Another commenter stated that BIS should exclude embedded software similar to firmware, while another commenter stated that BIS should amend its prohibitions to only prohibit the import of VCS hardware if it is integrated into a VCS or a completed connected vehicle. BIS appreciates these

recommendations and has addressed them by clarifying the definitions of ADS, VCS, VCS hardware, and covered software, as described above.

One commenter proposed narrowing the scope of prohibited transactions by adding an exemption to the prohibited transactions for OEMs physically manufacturing connected vehicles in the PRC and Russia if those OEMs met certain security standards such as the independent design of covered software and VCS hardware, verifiable hardware and software integrity, secure key and certificate management, and ongoing monitoring. BIS appreciates this suggestion when issuing specific authorizations, which are discussed in Section VI.c.3 below. However, BIS believes that such mitigations are more appropriately implemented and monitored on a case-by-case basis and therefore declines the suggestion for a blanket exemption.

Other commenters recommended that BIS expand the scope of prohibited transactions to include BMS, vehicle charging equipment, connectivity apps, edge cloud architecture, and core ADS components to better protect national security. BIS regulates VCS and ADS based on feedback from the ANPRM that eliminates these other areas. For example, ANPRM comments emphasized that BMS do not have their own connectivity and require communication through a VCS, thereby making VCS a better system for mitigating the identified risks in this rule. BIS also recognizes that the traditional BMS does not have its own external wireless data link, which is why it rejects commenters' recommendation to include BMS at this time. An additional commenter stated that BIS should avoid "politicization" of technical issues and cancel all prohibitions against the PRC in the rule. BIS declines to make this change due to the national security risks discussed in Section IV above.

One commenter requested that BIS clarify with regard to the preamble's "potential regulatory statement" that the prohibition on the sale of completed connected vehicles by connected vehicle manufacturers who are themselves owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia (related prohibited transactions) applies only when the VCS hardware or covered software within the vehicle is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. BIS has amended the rule to clarify that this prohibition applies to

all vehicles (with VCS hardware or covered software) sold by these connected vehicle manufacturers given the substantial national security risk posed by the provision of these completed connected vehicles by these entities.

Some commenters asked whether ownership alone, regardless of the location of manufacturing or development, falls under this prohibition. Given the legal authorities laid out in Section IV and the threats stemming from those authorities, BIS assesses that a connected vehicle manufacturer that is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia creates an unacceptable risk. The risk applies even if manufacturing or design operations are located in the United States or other non-foreign adversary countries, and BIS assesses that the costs of reducing the risk are justified by the reduced risk to national security.

One commenter suggested that ADS hardware should also be prohibited. This commenter suggested that the supply chain disruptions can be reduced by incorporating a phased implementation, where the prohibitions relating to ADS hardware could be modeled after the VCS hardware exemption. This commenter also emphasized that if ADS hardware is not included in the final rule, industry will have little incentive to develop and manufacture hardware in the United States, leaving the national security risk unmitigated. BIS declines to expand this regulation to prohibit ADS hardware at this time. Much of the hardware that supports or directly enables the ADS function, or that falls within the ADS item definition, are end point sensing devices or internal wired communication devices that often do not have external connectivity. For that reason, BIS maintains that regulating VCS hardware and ADS software is an appropriate means to mitigate the national security concerns at this time. BIS's decision not to include ADS hardware in this rule's prohibitions does not preclude BIS from addressing it in a subsequent rulemaking.

BIS agrees with commenters' focus on the potential impacts of foreign adversary involvement in developing technology for autonomous vehicles and the degree to which PRC and Russian legal and regulatory environments inhibit the transparency that would be necessary to adequately ensure both public safety and U.S. national security. One commenter noted that the lack of data transparency required of PRC autonomous vehicle developers makes it

particularly difficult for the public to assess their safety. BIS appreciates this feedback and notes its alignment with its own risk assessment.

After reviewing and considering all of the comments, in this final rule, BIS has adopted prohibitions consistent with the NPRM: (1) VCS hardware importers are prohibited from knowingly importing into the United States any VCS hardware that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia; (2) connected vehicle manufacturers are prohibited from knowingly selling within the United States, or importing into the United States, completed connected vehicles that incorporate covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia; and (3) connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia are also prohibited from knowingly selling in the United States completed connected vehicles that incorporate covered software or VCS hardware, regardless of whether such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or control of the PRC or Russia. These connected vehicle manufacturers are also prohibited from offering commercial services in the United States that utilize completed connected vehicles that incorporate ADS.

Because of the role connected vehicle manufacturers play in the design and development of the key components in connected vehicles, which are generally built to the manufacturers' specifications, the third prohibition will often be duplicative of the other prohibitions in this final rule. However, as BIS intended in the NPRM and has clarified in this final rule, the third prohibition applies even if connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia were not involved in the design or development of the VCS hardware and covered software. Their sale of those completed connected vehicles constitutes the supply of VCS hardware and covered software and is thus captured by this prohibition. Additionally, in the NPRM, BIS intended to prohibit persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or

Russia from integrating ADS onto otherwise completed connected vehicles and offering them for commercial services, to include rideshare or robotaxi services. For this reason, BIS included in the NPRM's definition of sale that "distributing for . . . other commercial operations" qualifies as a sale (even if it is not for purchase or lease). In order to provide greater clarity to regulated parties, BIS has chosen to explicitly state in the related prohibited transactions provision in section 791.304, that this rule prohibits connected vehicle manufacturers who are themselves owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia from offering commercial services that utilize completed connected vehicles that incorporate ADS. BIS anticipates that this will include both robotaxi and rideshare services. BIS has added Example 41 above to provide further clarity.

As noted above, for the purposes of the final rule, BIS defines the term *person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary* to mean (a) any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary; (b) any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States; (c) any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or (d) any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (a) through (c) possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine,

direct, or decide important matters affecting an entity.

To provide further clarity regarding transactions involving VCS hardware and covered software that are prohibited, BIS has offered examples of persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC and Russia in Section VI subsection (a) above. BIS incorporates the examples provided in the NPRM and has added several new examples to provide further illustration.

c. Compliance

1. Declaration of Conformity

Declarations of Conformity will be a critical tool for advancing the goals of this final rule, and addressing the emergency declared in E.O. 13873 (section 791.306, “General authorizations”). Through extensive engagement with connected vehicle manufacturers and automotive suppliers, BIS has come to understand that connected vehicle supply chains are complex and often opaque, with potentially hundreds of suppliers for a single connected vehicle in a given model year. Given the complexity, the vast number of parts, and the supply-chain opacity, BIS assesses there is a significant risk that VCS hardware and covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries will be incorporated into connected vehicles if connected vehicle manufacturers do not conduct adequate supply chain due diligence or fail to prioritize and prevent the risks BIS has assessed. BIS considered whether to remove the Declarations of Conformity requirement and only require the submission of specific authorization applications for connected vehicles incorporating VCS hardware and covered software imported from PRC and Russia. However, BIS does not believe that this alternative adequately mitigates the risks identified in this rule. Foreign adversaries are not limited to operations within their geographical area and may obtain access to VCS and ADS supply chains through investment and participation in operations in a variety of foreign locations. Current customs and other supply chain reporting, which is focused on country of origin, creates a layer of opacity that can be exploited by adversaries to compromise connected vehicle components that can later be used to threaten United States persons and infrastructure. In other words, current practices for reporting supply chain due diligence do not prioritize the same

national security focus required by this regulation.

As BIS stated in the NPRM and as discussed in further detail below, based on extensive engagement with connected vehicle manufacturers and automotive suppliers, BIS assesses that connected vehicle supply chains often have significant numbers of suppliers for a single connected vehicle in a given model year. Connected vehicle manufacturers typically have strong relationships with their immediate suppliers, including the development of years-long supply contracts that span entire vehicle generations; however, their understanding of the deeper supply chain, such as who is supplying their suppliers (*e.g.*, tier two, tier three) is substantially weaker. Additionally, BIS understands through industry engagement that although the COVID-19 pandemic and associated supply chain crisis forced connected vehicle manufacturers to critically evaluate their hardware supply chains, detailed knowledge of software supply chains remains largely unachieved. Even where it may exist, BIS cannot actively identify a specific supply chain compliance framework for the auto industry that requires due diligence on the national security risks in the auto market’s supply chain. Such complexity and opacity, without a requirement to conduct the necessary due diligence, could result in the incorporation of VCS hardware and covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries, into connected vehicles without the full knowledge of the connected vehicle manufacturer.

Consequently, BIS believes that the requirement to submit annual Declarations of Conformity will serve as an important mechanism that will substantially reduce the risk of the current supply chain opacity by requiring enhanced due diligence into the auto market’s supply chain through a specific national security lens. BIS requires VCS hardware importers and connected vehicle manufacturers to submit Declarations of Conformity to certify their compliance with this regulation, including their completion of due diligence requirements. BIS has considered whether, as an alternative, a recordkeeping approach could adequately address the national security risk posed by connected vehicle technology with a nexus to the PRC and Russia, but recordkeeping is a retroactive activity. It does not create an adequate incentive to change supply

chain business practices to achieve the goals of this rule.

If Declarations of Conformity were entirely replaced by a recordkeeping requirement, manufacturers may have to undergo recalls on parts that have already entered the supply chain. Automotive recalls are difficult to execute, with automakers traditionally struggling to reach a 100 percent completion rate on recalls due to various complications, including customer communication failures and the preowned vehicle market. If a recall fails to remove all of the vulnerable vehicles from the road, the national security threat will continue to persist. As such, the undue risks to national security would not be sufficiently mitigated without proactive due diligence requirements that deter the threat before it enters the U.S. supply chain, rather than reactive measures such as recordkeeping, reporting requirements, or unsatisfactory recalls by VCS hardware importers and covered vehicle manufacturers to secure their supply chains. At the same time, recalls would represent a source of unpredictability for automakers and suppliers, and this cost would likely be passed on to consumers. By contrast, requiring companies to submit Declarations of Conformity to the government will motivate them to conduct supply chain due diligence in order to make the required certifications. Because companies are conducting proactive due diligence, they will be able to detect prohibited components and mitigate risks before they enter the larger connected vehicle ecosystem.

Given the national security risks posed by the ADS and VCS supply chains, BIS requires that industry actively participate in securing the supply chain. By requiring certifications in the Declaration of Conformity, BIS creates an incentive for industry to invest in supply chain review and assessment and to accelerate necessary changes to ensure each regulated entity achieves compliance. The act of requiring affirmative certification encourages the adoption of enhanced supply chain due diligence and begins the process of standardizing how industry will be required to respond to foreign adversary ICTS in the automotive supply chain. Public comments to the ANPRM and the NPRM and information conveyed in BIS’s external engagements indicate that much of the industry does not factor national security issues into their supply chain operations. Ultimately, by requiring connected vehicle manufacturers and VCS hardware

importers to submit Declarations of Conformity, BIS ensures that parties subject to this final rule implement necessary procedures to fully understand their VCS hardware and covered software supply chains. Declarations of Conformity are an important tool in ensuring that parties subject to this final rule comply with the prohibitions on the incorporation of VCS hardware or covered software that has been designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

Apart from encouraging suppliers to re-examine their supply chains, the certification process will also help the U.S. Government execute its responsibility to maintain the national security interests of the American people. Through requirements for recordkeeping and due diligence on the part of declarants, BIS will be able to obtain data which may not otherwise exist in a useable format without such requirements to verify Declarations of Conformity, such as documentation of the tiers of ICTS suppliers (section 791.312, “Recordkeeping”) (section 791.313, “Reports to be furnished on demand”). BIS will further use such information to better inform and identify risks as they evolve within ADS and VCS supply chains. For example, if, through the verification process, BIS determines that a supplier has a nexus to foreign adversary, BIS can highlight to other companies that the supplier is prohibited by using an “Is-Informed” notice. Additionally, if a company previously acting under a Declaration of Conformity must, due to their own discovery of a change in circumstance, cease acting under a Declaration of Conformity, and instead submit an application for a specific authorization, BIS may, upon receipt of said specific authorization, be able to identify supply chain issues impacting other companies acting under a Declaration of Conformity. Receipt of Declarations of Conformity will also help BIS to spot trends in the importation of covered software and VCS hardware with a foreign interest into the U.S., which will allow BIS to appropriately analyze the hardware and software with the largest risk of evasion by prohibited companies. In sum, through receipt of Declarations of Conformity, BIS will be more capable of monitoring the pervasiveness of the risk and gain insight into any additional mitigation measures which may be required to secure the continuously evolving ICTS supply chain, as authorized by E.O. 13873.

The information collected through Declarations of Conformity will be essential for BIS to effectively protect U.S. national security from the risks identified in this rule. BIS has generally found that research using publicly available data is often incapable of revealing whether a supplier has ties to the PRC or Russia. As BIS has detailed extensively in this rule, there are myriad ways in which an entity may be owned by, controlled by, or subject to the jurisdiction of a foreign adversary, and not all of these circumstances will be publicly disclosed. Additionally, regulated entities working directly in the sector will have a far more intimate understanding of the parties with whom they transact, another form of information which is often otherwise undisclosed. BIS will need access to both types of information in order to execute on the goals of this rule. As such, to ensure industry-wide compliance with this rule and maintain the understanding of the connected vehicle sector necessary to conduct enforcement, BIS will require companies to maintain such information, and submit said information in the case that it is otherwise unavailable. Without the Declaration of Conformity certifications, BIS will be unable to receive a fulsome picture of the regulated supply chain and relevant technologies, and it will be left with a needle-in-a-haystack approach when assessing companies’ compliance with this rule. Ultimately, the certification process will bring transparency to an opaque supply chain.

In the proposed rule, BIS proposed including several reporting requirements for connected vehicle manufacturers, connected vehicle importers, and VCS hardware importers that submit Declarations of Conformity. These reporting requirements included, but were not limited to, submitting SBOMs and HBOMs and a list of third-party external endpoints to which the VCS hardware connects, including the country where each endpoint is located and the identity and location of the service provider, as applicable.

After considering public comments, BIS has restructured the Declarations of Conformity requirement to clarify the certification, narrow the reporting requirements, and add recordkeeping elements. The final rule requires that Declarations of Conformity would be submitted in two instances by persons not engaged in prohibited transactions: (1) Declarations by entities engaged in VCS hardware transactions; and (2) Declarations by entities engaged in covered software transactions.

Persons required to submit a Declaration of Conformity need to do so once per model year for units associated with a vehicle model year, or once per calendar year for units not associated with a vehicle model year, and only for the categories of transactions they seek to execute during that period. Several commenters voiced confusion and requested clarification on the timeline for Declarations of Conformity. BIS has extended the timeline for submitting updates to a Declaration of Conformity from 30 to 60 days.

BIS further clarifies the certification statement that connected vehicle manufacturers and VCS hardware importers must make. BIS agrees that the use of terms like “knowingly engaged,” which is past tense, made the timing for submission of a Declaration of Conformity confusing. Therefore, BIS has adjusted the language to require a more straightforward certification: that the VCS hardware or covered software triggering the need for, and described in, the Declaration of Conformity was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

In the final rule, entities must submit to BIS the name and contact information of the VCS hardware importer or connected vehicle manufacturer, as well as additional information outlined in section 791.305, based on whether the entity is engaging in a covered software or VCS hardware transaction. Entities must also certify to BIS that they have conducted due diligence into their supply chain and that their VCS hardware or covered software was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Primary business records documenting these due diligence efforts, which may include the optional use of independent or hired third-party research (section 791.315, “Third-party verification and assessments”), must be maintained by the declarant or a third-party and made available to BIS upon request. HBOMs and SBOMs are no longer required to be submitted as part of a Declaration of Conformity but can function as a method of recordkeeping.

Several commenters expressed fundamental disagreement with BIS’s proposed regulatory approach for connected vehicle supply chains. One commenter suggested that BIS adopt a framework like the NHTSA Federal Motor Vehicle Safety Standards (FMVSS), which allows companies to import restricted components provided

they conduct their own due diligence and risk analysis. NHTSA FMVSS establishes minimum performance requirements for manufacturers and the equipment used to make vehicles, prioritizing safety standards for drivers and passengers. BIS's concern with ADS and VCS technology is broader than that of public safety of drivers and passengers, but also addresses additional concerns, including national security risks posed by adversary countries, such as data exfiltration and remote access control that may compromise critical infrastructure. BIS does not believe that the NHTSA FMVSS provides a framework that is designed to address national security concerns, however, BIS has adopted some similar characteristics of this framework. For example, BIS may allow companies to import restricted components through specific authorizations if those companies show a certain degree of due diligence, risk analysis, and risk mitigation to minimize the threat present in otherwise prohibited ICTS.

One commenter requested withdrawal of the use of the Declaration of Conformity in favor of a presumption of conformance, claiming that a presumption of conformance would reduce regulatory burden, address the national security risk, and remove potential hurdles to innovation posed by the NPRM. BIS rejects utilizing a presumption of conformance. The risks identified in this rulemaking are too great to rely solely on a presumption of conformance by commercial companies, which is only exacerbated by the opacity of the supply chain as discussed above. A presumption of conformance would also allow hardware and software to linger and remain in the U.S. ecosystem for a longer period of time as BIS would not have insight or confirmation of the existence of such hardware or software. Through receipt of declarants' certification regarding VCS hardware or covered software, that they have conducted due diligence to inform this certification, and that they, or a designated third party, maintain documentation related to this certification as part of their Declarations of Conformity, BIS will be able to more accurately and efficiently confirm and verify that no VCS hardware or covered software designed, developed, manufactured, or supplied by persons with a sufficient nexus to the PRC or Russia continues to operate in the United States.

In the final rule, BIS has largely adopted a certification and recordkeeping approach in Declarations of Conformity that significantly lessens

the burden on regulated entities. Entities can now certify to BIS that they have conducted due diligence into their covered software and VCS hardware supply chains without needing to submit such documentation to BIS. A recordkeeping requirement alone would not be sufficient to mitigate the identified risk because it would not create the incentive to change business processes to identify and address risks in their supply chains. Requiring certifications in Declarations of Conformity, on top of a recordkeeping requirement, creates an enforceable incentive for industry to invest in supply chain review and assessment thereby furthering mitigation of the risks identified in this rule.

Commenters also requested that software traceability be included in the compliance requirements of this regulation. BIS believes that in order to determine compliance, entities regulated under this rule will be required to conduct the necessary software traceability as part of their supply chain due diligence. For example, in submitting a Declaration of Conformity, declarants are required to certify both that the covered software was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia and that the declarant has conducted due diligence to inform its certification. If such due diligence determines that certain VCS hardware or covered software was designed, developed, manufactured, or supplied by a foreign adversary, such use of ICTS would be prohibited and the entity would need to apply for a specific authorization. Furthermore, an applicant for a specific authorization may be required to furnish additional information to BIS prior to the granting of a specific authorization, which may require applicants to conduct further due diligence into their software supply chain.

Some commenters criticized the NPRM for being developed in isolation from other automobile trade actions taken by the U.S. government, suggesting that this lack of coordination prevents the streamlining of existing governmental processes related to the automotive industry. BIS emphasizes that the statement in the NPRM that one commenter referenced, which stated that the proposed rule was issued irrespective of other trade policies, does not mean to imply that this action was undertaken without coordination with other government agencies regulating vehicle safety or the trade of vehicles. Rather, BIS emphasizes that this

regulation is being promulgated strictly on national security grounds that exist irrespective of specific trade policy surrounding connected vehicles, which do not adequately (or at all) address the national security risks articulated in this rule. BIS emphasizes that the ANPRM, the NPRM, and this final rule all underwent extensive interagency review and incorporated views of all other relevant Federal agencies. In addition, BIS met weekly with an interagency technical working group as part of its drafting process.

Existing trade actions do not sufficiently address the national security risks identified by BIS in the connected vehicle supply chain. In response to commenters requesting that BIS clarify the role of coordinating agencies or other regulations, such as the FCC Covered List, BIS anticipates that it will continue closely collaborating with relevant government agencies including when adjudicating applications for specific authorizations or determining if and when updates to this rule are necessary. BIS emphasizes that regulated entities will be responsible for verifying compliance with all laws and regulations applicable to the transactions in which they seek to engage but may request an advisory opinion from BIS if unsure that a specific transaction is subject to the prohibitions of this rule.

Commenters raised a series of concerns with the SBOM and HBOM requirements in the Declarations of Conformity requirement. Most of these concerns involved the ambiguity of the SBOM and HBOM requirements described in the NPRM and what should be included in these documents. Commenters argued that the NPRM's HBOM and SBOM requirements are overly burdensome, demanding both regulated entities and BIS to devote substantial resources to meet compliance. Commenters also wanted clarity on when companies would be required to submit an HBOM or SBOM, and for BIS to specify whether they would be required to do so every time an SBOM or HBOM changes. In response to comments, BIS is no longer requiring the submission of SBOMs and HBOMs in Declarations of Conformity. Entities will instead be required to certify to BIS that they have conducted due diligence in analyzing their VCS hardware and covered software supply chains and maintain documentation in support of this certification. The documentation may take the form of an SBOM or HBOM or another appropriate format. Entities must also certify that this documentation can be made available to BIS upon request.

Commenters wanted BIS to describe how it will receive, store, protect, and use SBOMs and HBOMs. Commenters repeatedly raised concerns about the protections of sensitive proprietary information in Declarations of Conformity. Commenters argued that BIS is creating a heightened risk that hostile actors may attempt to exfiltrate sensitive technical specifications, software components, or system designs, leading to significant economic damage and undermining the global competitiveness of U.S. companies if BIS fails to adopt protective measures. Commenters often sought BIS assurance that their data will be protected and secured. Commenters recommended that BIS adopt strict access controls for submitted Declarations of Conformity, particularly those containing classified or sensitive proprietary information. These controls could include encryption of submissions, limiting access to authorized personnel only, and ensuring that proprietary information is not unnecessarily shared during any public disclosure or regulatory review processes. One commenter also requested that BIS delete CBI provided in support of a submission after a period of time.

BIS acknowledges commenters' concerns related to the submission of sensitive information in the Declarations of Conformity. In response, BIS has limited the amount of sensitive information required as part of the submission by eliminating the requirement to submit SBOMs and HBOMs. BIS has also included a section in the rule (section 791.314, "Confidential Business Information") dedicated to the submission of CBI, which would cover the submission of SBOMs or HBOMs if they were ever required for third-party verification purposes. Section 791.314 outlines the confidentiality of information the same as in BIS regulation 15 CFR 791.102 including that information or documentary materials, not otherwise publicly or commercially available, submitted or filed with the Secretary under this part will not be released publicly except to the extent required by law. BIS declines the suggestion to delete CBI after a period of time, as such information may need to be referenced in future investigations due to evolving national security concerns.

Tier one and tier two suppliers often explained that providing SBOMs and HBOMs to customers, such as OEMs, can potentially undermine their business value because it is equivalent to giving their proprietary information to their client. These suppliers would rather submit this information directly

to BIS. In response to these comments, and apart from removing the mandatory submission of SBOMs and HBOMs as part of the Declaration of Conformity process, BIS has allowed connected vehicle manufacturers and VCS hardware importers to rely on third parties as part of their due diligence efforts. If BIS requires the submission of additional documentation in the verification of a Declaration of Conformity, suppliers would be allowed to submit the required documentation directly to BIS.

Commenters offered ideas on how BIS could enact different models to limit the burdens imposed on both BIS and regulated entities, as well as ensure the protection of IP. A handful of commenters suggested implementing the NHTSA self-certification model requiring VCS hardware importers and connected vehicle manufacturers to produce and retain their Declarations of Conformity and provide them to BIS on an as-needed basis. Commenters also suggested implementing other attestation or self-certification programs, including those that could be modeled by Federal agencies, such as U.S. Customs and Border Protection's Certifications of Origin template or the Food and Drug Administration's Importation of Electronic Products declarations. One commenter in particular emphasized that the adoption of these methods would create a streamlined self-certification compliance process that eases production burdens on regulated entities and allows BIS to focus on monitoring for prohibited transactions, rather than processing and maintaining a substantial amount of information through Declarations of Conformity that may not provide meaningful data. As described above, BIS determined that relying entirely on a self-certification system for Declarations of Conformity would be insufficient given the nature of the national security risk and these self-certification models. Self-certification would not give BIS the visibility that Declarations of Conformity provide to track and monitor the connected vehicle supply chain industry, specifically as it relates to the timeliness of identifying potential violations of this rule and the actions BIS would need to take to remedy a national security issue stemming from prohibited covered software or VCS hardware that has entered the U.S. supply chain.

Commenters suggested other ways of narrowing the scope of the Declaration to be less burdensome on regulated entities. For instance, some commenters recommended that BIS change the

requirement to submit a Declaration of Conformity for every model year. While it has not removed the requirement to submit a Declaration of Conformity every model year, BIS has updated the Declaration of Conformity submission requirements to be less burdensome on regulated entities by allowing declarants to submit a confirmation that a prior Declaration of Conformity remains accurate in lieu of submitting a new Declaration of Conformity. Some commenters also requested BIS allow regulated entities to rely on statements, attestations, or affirmations from suppliers regarding the origins of components and software so as to limit reporting requirements and ensure that tiered suppliers did not have to share their intellectual property with their customers. Based on comments, BIS will allow connected vehicle manufacturers to rely on their suppliers' submissions of supply chain information to BIS, if an agreement between the connected vehicle manufacturer and supplier permits such sharing of information. Commenters suggested that entities should be able to simply provide a comprehensive list of all imported VCS and ADS fleet-wide for a given model year. BIS accepts this suggestion as the Declaration of Conformity procedures would allow for connected vehicle manufacturers or VCS hardware importers to submit a single comprehensive submission. Other commenters strongly recommended that BIS abandon the universal submissions requirements of SBOM and HBOM and instead require them only in the event of an investigation or audit. BIS acknowledges commenters' feedback, and in response has adjusted SBOM and HBOM submission requirements. BIS accommodates the requests to forego the submissions of HBOMs, SBOMs, and other proprietary information, and rely more on a certification-based model as commenters suggested.

As such, for the purposes of submitting a Declaration of Conformity, BIS has clarified that a certification is a written statement or attestation, made in relation to section 791.305(a) of this rule, to the U.S. Government, signed by a duly authorized designee, certifying under the penalties provided in 18 U.S.C. 1001, that the information provided is accurate and complete in all material respects to the best knowledge of the designee on behalf of the entity filing the Declaration of Conformity. BIS further clarified that for the purposes of a Declaration of Conformity, a duly authorized designee is:

(i) In the case of a partnership, any general partner thereof;

(ii) In the case of a corporation, the chief executive officer, or any officer with the authority to bind the corporation;

(iii) An employee with authority to make certifications on behalf of the company as designated by a person in (i) or (ii); and

(iv) In the case of an entity lacking partners and officers, any individual manager, or designated agent who has been explicitly authorized by the board of directors or equivalent to sign contracts and make legally binding agreements on behalf of the entity.

BIS concluded that this approach provides the declarant with clear instructions as to who may make certifications as part of Declarations of Conformity. While the requirements for a certification have certain guidelines, BIS has still provided companies with flexibility to internally determine who may make these statements. BIS acknowledges that adopting a more certification-based model for Declarations of Conformity, as commenters suggested, requires an increased level of trust in such certifications on the part of BIS. BIS's guidelines as to who can make a certification ensures that only duly authorized individuals can attest to an entity's compliance and that supply chain security is a priority within the connected vehicle industry.

BIS has additionally allowed for connected vehicle manufacturers and VCS hardware importers to rely on third parties as part of their due diligence requirements for a Declaration of Conformity. This could include a VCS hardware importer or connected vehicle manufacturer relying on assessments from suppliers, provided that they have arranged for suppliers to furnish documentation and third-party assessments (as applicable) to BIS upon request. Further, BIS confirms that the Declaration of Conformity requirement will be satisfied by VCS hardware importers and connected vehicle manufacturers who submit a compiled Declaration of Conformity that covers the covered entity's entire fleet for the given model year, so long as it appropriately identifies the minimum required information (including, without limitation, the FCC ID Number of the hardware, if known, and the makes, models, and trims of vehicles covered by the Declaration of Conformity).

Commenters raised concerns about the efficiency of the compliance process and provided solutions to promote processing in a timely manner. Commenters suggested that Declarations of Conformity be replaced with dialogue

between BIS and entities subject to regulation. Another commenter urged BIS to consider clarifying the applicability of the Declaration of Conformity requirement for import purposes in order to avoid a huge surge in advisory opinion requests, particularly for importers. To help with expediency, one commenter recommended that BIS use best-in-class documentation and verification standards to ensure that submission of compliance materials does not hinder the pace of commerce. This commenter also suggested that BIS allow companies to digitally present import and compliance documentation proactively via their due diligence processes. BIS took these comments under consideration when re-assessing the requirements in the Declarations of Conformity. While BIS did not accept all of the commenter's suggestions, BIS believes that the updated Declaration of Conformity provisions and clarifications in the final rule will increase the rule's efficiency. BIS believes that the Declaration of Conformity requirement will be integral to the expedient administration of this rule because it will incentivize industry compliance and help BIS administer this rule when reviewing industry compliance.

Commenters advised BIS to reconsider the timeline submission requirements of Declarations of Conformity. Many commenters advised increasing the Declaration of Conformity submission deadline from 30 days to 60 days to provide manufacturers and importers adequate time to prepare, verify, and submit updates. Another commenter requested more details on the timeline required for regulated entities to submit their initial Declarations of Conformity, urging BIS to provide more time for entities to initially review their supply chains. Commenters also recommended that BIS clarify that manufacturers or importers must submit amended Declarations of Conformity within 30 days if they discover errors, omissions, or other issues in previously submitted documents. BIS acknowledges commenters' concerns and has increased the submission deadline for Declarations of Conformity to 60 days in all instances. Connected vehicle manufacturers and VCS hardware importers must submit digital documentation of their compliance at least 60 days prior to the first import or first sale of each model year of a completed connected vehicle that incorporates covered software and the first import of VCS hardware for each

model year or calendar year, as applicable.

Commenters provided feedback on the "material" change requirements of Declarations of Conformity. Comments included conflicting opinions on when industry should be responsible for providing an updated Declaration of Conformity. One commenter requested that material changes be limited to the first submission because hardware can be used for several different makes, models, and trims. Another commenter suggested that a material change submission should require an updated Declaration of Conformity within 60 days. Several commenters suggested that BIS remove the requirement for annual certification and instead only require recertification if there is a material change to the model year. Separate from this, another commenter identified that the NPRM placed no limit on how far into the future automakers will have to declare material changes, suggesting that material changes be limited to 10 years to align with the document retention limit. One commenter also advised that BIS clarify when the material change clock starts, specifying it to be when the declarant first knows of the material change. More broadly, commenters urged BIS to define "material" change and provide examples.

BIS has clarified the scope of a "material" change, which is limited to the "discovery, by the declarant, of an omission, inaccuracy, or error in the information provided to the Department in a prior Declaration of Conformity that could reasonably mislead as to the true source of VCS hardware or covered software in question." BIS accepts the suggestion that connected vehicle manufacturers and VCS hardware importers must notify BIS of any material change to the information conveyed in a previously submitted Declaration of Conformity by submitting a revised Declaration of Conformity within 60 days following the discovery of such change. BIS clarifies that covered software updates alone do not constitute a material change. BIS declines to remove the annual certification requirements for Declarations of Conformity as the information certified in an annual certification is more robust than that considered to be a "material" change. However, BIS confirms that connected vehicle manufacturers and VCS hardware importers may submit a confirmation that a prior Declaration of Conformity remains accurate by associating the relevant new model year of vehicles (if known) to an existing Declaration of Conformity. In addition,

BIS confirms that the declarant's obligation to inform BIS of material changes to the information on which a Declaration of Conformity depends ceases 10 years after submission of the original Declaration of Conformity for that model year or calendar year.

Commenters also respectfully questioned whether a 10-year retention requirement for Declarations of Conformity is reasonable, appropriate, or practicable for the connected vehicle industry given that rate of technological advancement, ultimately recommending a shorter retention period. One commenter suggested to require only keeping records that would be retained in a normal course of the business. BIS declines to adjust the 10-year recordkeeping requirement so as to maintain consistency with the statute of limitations clause of IEEPA.

Additionally, BIS understands that the connected vehicle industry generally maintains a minimum standard of 10-year spare parts availability. As such, BIS believes the 10-year recordkeeping requirement contained in this rule represents a relatively small additional burden to the industry. BIS agrees with the commenter's request to narrow the scope of recordkeeping to primary business records and has modified the final rule accordingly.

Commenters shed light on a handful of other areas of improvement for the Declarations of Conformity. For example, one commenter requested that an incorrectly submitted Declaration of Conformity in good faith should not be considered a "violation" and should be excluded from the penalties listed in the BIS proposed rule. BIS acknowledges commenters' concerns and would advise commenters to review section 791.305(k) which subjects any person who submits false information in a Declaration of Conformity, with knowledge that such information is false, and engages in a prohibited transaction, to potential penalties. Furthermore, in response to commenters, BIS has provided an opportunity for connected vehicle manufacturers and VCS hardware importers who incorrectly submit a Declaration of Conformity in good faith to submit an updated Declaration of Conformity to BIS within 60 days of discovery of an error or omission in a previously submitted Declaration of Conformity.

Other commenters highlighted a contradiction between the NPRM's discussion text and its regulation text about third-party research requirements. Commenters provided several examples of text to update this language. BIS appreciates this notification and has

adjusted the discussion and regulation text to indicate that the use of third-party research is not required but may be used by declarants to fulfill due diligence requirements as part of the submission of a Declaration of Conformity.

Commenters also pointed out that requiring importers and manufacturers to record all third-party external endpoints that VCS hardware connects is not possible because these connection points are inherently in the control of third parties, such as app providers. Further, to limit third-party external endpoints in order to create a complete list, VCS hardware manufacturers would need to develop and operate completely closed ecosystems, which is inconsistent with consumer demand. Ultimately, commenters recommend that BIS delete the requirement to record all third-party external endpoints or narrow the information requested to that which is in the possession and control of the VCS hardware manufacturer or importer. BIS agrees with these commenters and has removed reporting requirements related to external endpoints from the final rule.

Commenters urged BIS to consider how it could streamline the approach for tier one, tier two, tier three, and below suppliers. One commenter recommended that BIS provide guidance on establishing a shared responsibility framework, making tier one and tier two suppliers equally accountable for compliance of their components in order to accelerate due diligence efforts. Another commenter advised that BIS form a volunteer certification process for VCS hardware suppliers to help streamline the process of compliance at the OEM level. Another commenter suggested that BIS provide additional clarity on how OEMs should interface with tier three suppliers and below, which was not contemplated in the NPRM. In an effort to create a semi-shared responsibility framework, BIS has allowed connected vehicle manufacturers and VCS hardware importers to rely on third-party assessments (including assessments from suppliers) as a part of the due diligence requirements for the submission of a Declaration of Conformity. If declarants rely on assessments from suppliers, declarants must certify that they have taken all possible measures, either contractually or otherwise, to ensure any necessary documentation and assessments from suppliers will be furnished to BIS upon request either by the declarant, or, in cases including CBI, directly by the supplier. BIS declines to create a

volunteer certification process for VCS hardware suppliers at this time but may consider issuing a general authorization at a later date if applicable. With regard to interfacing with tier three suppliers and below, BIS declines to prescribe the nature by which OEMs conduct the required due diligence to allow each regulated entity the flexibility to align with their unique business model.

As noted above, one commenter argued that BIS's broad definition of foreign interest would mean that a publicly traded company with some foreign shareholders would be required to submit a Declaration of Conformity. As explained above, BIS does not intend for every publicly traded company with minority foreign shareholders who do not affect management or control over the company to submit Declarations of Conformity if no other foreign interest exists. Therefore, BIS has created an exemption to the Declarations of Conformity requirement in section 791.305(l) for circumstances where the only foreign interest arises when a foreign person owns equity of a public company but does not affect the company's management or control.

One commenter sought clarification on whether the NPRM requires that all OEMs must prepare and submit a Declaration of Conformity even when no foreign interest is involved. BIS clarifies that if VCS hardware or the addition of covered software to a completed connected vehicle involves components in which there is no foreign interest, then it would not fall within the scope of this rule. However, if there is a foreign interest in that VCS hardware or covered software transaction, then it would require a Declaration of Conformity or specific authorization.

1. The sections below explain in greater detail the types of Declaration of Conformity that are required under the final rule.

i. VCS Hardware

The Declarations of Conformity described in section 791.305(a)(1) require VCS hardware importers to provide information on the specific VCS hardware that the declarant plans to import into the United States for a given model year, or, for units not associated with a model year, a given calendar year. FCC regulations at 47 CFR 2.925 require any electronic device that emits RF waves, including those imported into the United States, to have an FCC ID number. The FCC ID is used to identify and certify that the device meets the necessary regulatory standards for wireless communication. BIS will require the Declaration of Conformity to contain the FCC ID

number(s) of the VCS hardware if known. BIS will also require the Declaration of Conformity to list any subcomponents in the VCS hardware that also have an FCC ID number if applicable. The final rule additionally requires VCS hardware importers to provide the make and model of the connected vehicle(s) for which the VCS hardware is intended or already integrated, if known. The VCS hardware importer submitting a Declaration of Conformity must certify that the VCS hardware was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, has conducted due diligence (with or without the use of third-party assessments), and maintains any supporting documentation (either through an HBOM or otherwise) and third-party assessments (as applicable). Declarants must also specify who maintains the supporting documentation or assessments and certify that the declarant has arranged for suppliers to furnish any documentation or third-party assessments upon request by BIS.

ii. Covered Software

The Declarations of Conformity described in section 791.305(a)(2) applies to connected vehicle manufacturers that import or sell completed connected vehicles in the United States that incorporate covered software, including U.S.-based OEMs and foreign-headquartered OEMs with operations in the United States. Section 791.305(a)(2) requires covered entities to provide information to BIS on the make, model, trim, and Vehicle Identification Number (VIN) series applicable to the completed connected vehicles that incorporate covered software. Persons submitting a Declaration of Conformity for covered software must certify that the covered software was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, has conducted due diligence (with or without the use of third-party assessments), and maintains any supporting documentation (either through an SBOM or otherwise) and third-party assessments (as applicable). Declarants must also specify who maintains the supporting documentation or assessments and certify that the declarant has authorized suppliers to furnish any documentation or third-party assessments upon request by BIS.

iii. Procedures To Submit Declarations of Conformity

The NPRM contemplated that VCS hardware importers and connected vehicle manufacturers submitting a Declaration of Conformity would be required to submit the Declaration of Conformity to BIS annually, 60 days prior to the first sale or first import of a VIN series of completed connected vehicles comprised of a single model year, or 60 days prior to the import of VCS hardware covered by the Declaration of Conformity. The NPRM also provided that VCS hardware importers and connected vehicle manufacturers may, at their discretion, submit a combined Declaration of Conformity, or may submit separate Declarations of Conformity (e.g., one Declaration covering import of VCS hardware and another covering import of completed connected vehicles). Declarations of Conformity covering both the import or manufacture of completed connected vehicles and the import of VCS hardware should be submitted by the earlier of the two reporting dates. Additionally, the NPRM stipulated that in the event of material changes that impact the content of the Declaration of Conformity, VCS hardware importers or connected vehicle manufacturers would be required to submit an updated Declaration of Conformity and an updated HBOM or SBOM within 30 days of such a change.

The final rule provides that connected vehicle manufacturers shall submit a Declaration of Conformity at least 60 days prior to the first import or first sale of each model year of completed connected vehicle that incorporates covered software. VCS hardware importers shall submit a Declaration of Conformity at least 60 days prior to the first import of VCS hardware for each model year for units associated with a vehicle model year, or calendar year for units not associated with a vehicle model year. BIS has chosen not to stipulate combined versus individual Declaration of Conformity submissions if an entity engages in both covered software and VCS hardware transactions at this time, but entities may do so if they choose for submission efficiency. The final rule also clarifies that connected vehicle manufacturers and VCS hardware importers must notify BIS of any material change to the information conveyed in a previously submitted Declaration of Conformity by submitting a revised Declaration of Conformity within 60 days following the discovery of such change. A declarant's obligation to inform BIS of

material changes to a Declaration of Conformity ceases 10 years after the original submission. The final rule defines "material changes" as any omissions, inaccuracies, or errors in the information provided to BIS in a prior Declaration of Conformity that could reasonably mislead as the true source of VCS hardware or connected software in question. Additionally, the final rule stipulates that, in lieu of submitting a new Declaration of Conformity, a declarant may, if applicable, submit a confirmation that an existing Declaration of Conformity remains accurate and encompasses relevant new model year of vehicles (if known). Declarants shall follow the electronic filing instructions on BIS's website.

2. General Authorizations

In the NPRM, BIS provided for four general authorizations, which would have allowed VCS hardware importers and connected vehicle manufacturers to engage in otherwise prohibited transactions in certain low risk use cases without need to notify BIS. These general authorizations would have applied if (1) the connected vehicle manufacturer or VCS hardware importer produced fewer than 1,000 connected vehicles or VCS hardware units; (2) the completed connected vehicle was used on public roadways for fewer than 30 calendar days in a year; (3) the completed connected vehicle or VCS hardware was used solely for purposes of display, testing, or research; or (4) the completed connected vehicle was imported solely for repair, alteration, or competition off public roads and would have been exported within one year of import. Persons availing themselves of a general authorization, while not required to notify BIS, would have been required to monitor their usage of the authorization for any change in use and would have been subject to audit and inspection by BIS. VCS hardware importers and connected vehicle manufacturers who were themselves owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia would have been ineligible for a general authorization.

Commenters nearly universally supported BIS's decision to include a provision for general authorizations while raising a variety of concerns or suggestions related to general authorizations, which are discussed below. However, it is important to note that in this final rule, BIS has amended the provision to allow BIS to issue general authorizations on its website and in the **Federal Register**, rather than provide for predetermined general authorizations in this rule. Several

commenters encouraged BIS to consider issuing more general authorizations, including to consider issuing general authorizations for connected vehicle manufacturers who meet a certain set of robust security standards to mitigate the national security risks described in this notice. BIS's decision to provide for the issuance of general authorizations as and when it determines, rather than enumerate four specifying categories of general authorizations in this rule, will enable BIS to more nimbly and quickly issue general authorizations as appropriate, without the need for a lengthy rulemaking process to issue or amend such general authorizations. BIS anticipates that it will issue a set of general authorizations shortly after publication of this rule that align with the general authorizations outlined in the NPRM. This will include general authorizations for small businesses; for connected vehicles used infrequently on public roads; for display, testing, or research purposes; and for repair, alteration, or competition.

The following is a summary of public comments received regarding the general authorizations provisions and BIS's response.

Commenters urged BIS to raise the cap for the small business general authorization from 1,000 vehicles or units to 5,000 vehicles or units in order to align with other regulatory authorities. BIS acknowledges that differing standards exist across regulation and legislation that define small manufacturers. BIS is continuing to consider this threshold but anticipates that it will retain the 1,000-vehicle threshold because this aligns with the high-volume manufacturer definition found in Vehicle Identification Number (VIN) requirements in 49 CFR 565. BIS emphasizes that this general authorization threshold will apply to U.S. production, not global production. BIS anticipates that it will limit this general authorization to all entities under common control so as to prevent the misuse of this general authorization by numerous subsidiaries of a single entity that are purpose-built to circumvent the prohibitions of this rule. Some commenters urged BIS to clarify that vehicles assembled in the United States for export to foreign markets qualify for a general authorization. BIS does not intend for this rule to capture vehicles manufactured exclusively for export outside of the United States and anticipates that it will issue a general authorization to this effect shortly after publication of this rule. One commenter recommended that BIS implement a general authorization for re-imported

hardware. The commenter highlighted that the prohibitions could capture hardware that is manufactured in the United States, exported abroad to locations other than the PRC or Russia for integration, and then imported back into the United States. BIS does not anticipate that it will institute a general authorization to this effect as it believes that such a transaction is already permitted under the terms of the rule. In this scenario, the supply chains in question "do not involve the PRC or Russia," as the commenter noted. In this scenario, products are not designed, developed, manufactured or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, and thus are permitted. Further, this final rule substantially reduces the burden of submitting Declarations of Conformity for imported VCS hardware, so BIS believes that BIS's decision to decline to add this general authorization will not negatively affect the manufacture of VCS hardware in the United States that is later reimported. Another commenter requested BIS add a general authorization exempting hardware "for general communications purposes" that is "not integrated into a VCS." BIS believes that modifications of the terms VCS and VCS hardware eliminate the need for this general authorization, as the revisions clarify that hardware that does not "directly enable" VCS, is not destined for VCS, or is not already incorporated in VCS is not captured by the rule.

Commenters identified challenges with the software prohibition timeline (discussed below). To remedy this challenge, commenters recommend that BIS provide time-limited general authorization for its software prohibition. Given that BIS has amended the definition of covered software to exclude software developed prior to one year following the effective date of this rule, BIS believes such a general authorization to be unnecessary at this time.

General authorizations allow certain VCS hardware importers and connected vehicle manufacturers to engage in otherwise prohibited transactions without the need to notify BIS prior to engaging in the transaction. When issuing a general authorization, BIS will publish this decision on its website (<https://www.bis.gov/OICTS>) and will also publish the decision in the **Federal Register**. Notices regarding individual general authorizations may contain specific instructions that persons must follow if they wish to avail themselves of a general authorization, which could include filing regular reports with BIS

regarding their use of the general authorization. However, BIS anticipates that most general authorizations will not require reports to BIS. Under the amended provisions for general authorizations, VCS hardware importers and connected vehicle manufacturers availing themselves of general authorizations must monitor their use of such authorizations, and, within 30 days of discovering a change in circumstance, conduct an inquiry as to if the general authorization still applies. Should the importer or manufacturer determine the general authorization no longer applies, it must, within an additional 30 days, cease all prohibited conduct and submit a report to BIS detailing the incident and proposing remediation.

BIS may, at its discretion, contact VCS hardware importers or connected vehicle manufacturers to determine if the party is availing itself of a general authorization. If the party confirms that it is indeed availing itself of one or more general authorizations, BIS reserves the right to request documentation to verify compliance with these provisions. Such documents would include the primary documentation upon which the VCS hardware importer or connected vehicle manufacturer has relied to determine that it is eligible (and has remained eligible) for the general authorization(s). For more information, see "Reports to be furnished on demand."

A connected vehicle manufacturer or VCS hardware importer that is a subsidiary, joint venture, affiliate, or other entity subject to the ownership, control, jurisdiction, or direction of the PRC or Russia would be ineligible for general authorizations and is required to apply for a specific authorization before engaging in an otherwise prohibited transaction.

3. Specific Authorizations

In the NPRM, BIS proposed a specific authorization process by which VCS hardware importers and connected vehicle manufacturers could apply to engage in an otherwise prohibited transaction. Commenters provided a variety of feedback on the specific authorization criteria. One commenter suggested that BIS specify requirements for conducting proof of concept testing in the United States with Chinese network access device technologies only available from the PRC. Multiple commenters recommended that BIS consider utilizing industry or government standards and frameworks when granting specific authorizations. These recommended standards include NIST standards, the ISO/SAE 21434 Standard, UNR155, the "Proposal for

Recommendations on Uniform Provisions Concerning Cyber Security and Software Updates” by the World Forum for Harmonization of Vehicle Regulations in April 2026, and the Multiple Independent Levels of Security (MILS) standards. Although not within the scope of the NPRM, one commenter recommended that BIS develop standards with NIST for vehicle to cloud interfaces and incorporate this as part of the specific authorizations process. BIS agrees with commenters that standards and assessments should be considered when reviewing specific authorization applications. In the final rule, BIS lists several examples of documentation that could be used to support the information contained in a specific authorization application, including the ISO/SAE 21434 Threat Analysis and Risk Assessments. However, BIS intends to leave the documentation that can be used to support the information contained in a specific authorization application broad to give applicants flexibility in how they wish to support their application.

Commenters recommended different forms of preclearance procedure to ensure auto manufacturers and suppliers have advance approval for the use of certain covered software. One commenter recommended that BIS establish a process for companies to obtain preclearance for certain covered software items, such as base code that is not specifically designed or developed for automotive applications. In addition to allowing preclearance with respect to certain covered software, BIS could require companies seeking preclearance to meet specified cybersecurity standards and risk mitigation measures specific to ensuring the integrity of the relevant code, including third-party vulnerability testing as applicable. Another commenter suggested that this preclearance could replace specific authorizations for companies that demonstrate that they meet the provided preclearance requirements. BIS appreciates these recommendations but finds conducting a case-by-case review to be a more effective method of risk management. BIS notes, however, that VCS hardware importer or connected vehicle manufacturers may request an advisory opinion that may inform a specific authorization at any time in accordance with section 791.310 and may apply for a specific authorization as early as sufficient information is known to fulfill the requirements of section 791.307. BIS also retains the right to issue a general authorization at a later date.

Multiple commenters urged BIS to establish with more clarity as to how frequently specific authorizations must be submitted. In response, specific authorizations will generally be approved for a duration of no less than one (1) model year or calendar year. At the time of issuance, BIS will advise specific authorization applicants the duration of any approved specific authorizations. BIS clarifies that in situations in which BIS may make an exception to approve a specific authorization for less than one (1) model or calendar year such as for model years that are actively being sold or imported as of the effective date of the rule, for situations in which supply chains are affected by force majeure events, or due to an unexpected change in the supply chain during model year production. BIS believes these exceptions will allow companies to continue to operate while a long-term solution is pursued. BIS anticipates that each specific authorization granted under an exception will be superseded by a more permanent and long-term specific authorization.

Commenters asked that BIS be more transparent about its specific authorization procedures, such as its approach to public disclosure and preferential status. In response to these comments BIS has indicated that it will not publicly disclose any approved specific authorizations. With regards to commenters’ request for preferential status to auto manufacturers headquartered in, incorporated in, or otherwise organized under the laws of an allied country, BIS believes that granting this preferential status will not limit the risk posed by foreign adversaries that are intertwined within supply chains. Therefore, BIS will not provide preferential treatment to companies on the sole basis of being headquartered in, incorporated in, or otherwise organized under the laws of a non-foreign adversary.

Another commenter argued that BIS should also include a mechanism for an emergency authorization such as in cases of supply chain disruption, natural disaster, or other temporary emergencies. BIS has accepted this feedback and incorporated it into the regulation text, allowing for the ability to grant exceptions to the default minimum one-year specific authorization and for durations of less than one year in response to force majeure events. BIS believes this change will allow companies to continue to operate while a long-term solution is pursued. BIS anticipates that each specific authorization granted under an exception will be superseded by a more

permanent and long-term specific authorization. In addition to force majeure events, BIS recognizes that other potential exigencies may arise causing supply chain challenges for companies, thus requiring a specific authorization to mitigate national security risk while BIS collaborates with companies to integrate them into the standard specific authorization process. BIS has included these additional scenarios which it believes cover a wide scope of exceptions so as to be flexible with companies regulated under this rule: 2027 Model Years that include covered software and are actively being sold or imported as of the effective date of this rule; as a result of a corporate merger, investment, acquisition, joint venture, or conversion of equity (such as from debt) that occurs during model year production; as a result of the closure or relocation of facilities involved in the production of covered software or VCS hardware; and other instances as determined by BIS. BIS envisions that specific authorizations granted under an exception will be shorter than one year in length and include proactive measures such as more frequent reporting requirements while BIS works with companies that are actively implementing or modifying corporate security policies or control measures for a more permanent solution and for which BIS would be more comfortable in granting a standard specific authorization.

Commenters additionally recommended that BIS adopt a portfolio phased approach for both software and hardware compliance. One commenter in particular highlighted that BIS could require OEMs to need only a portion of their portfolio to be compliant in the first year and then increasing each year after (e.g., 33 percent the first year, 66 percent the second year, 100 percent the third year). BIS appreciates this as a recommendation and will consider it as a compliance approach when issuing specific authorizations.

Based upon this review of commenters’ feedback and further consideration, BIS has modified the specific authorization process to provide more clarity to industry. VCS hardware importers and connected vehicle manufacturers wishing to engage in an otherwise prohibited transaction who are ineligible for an exemption or general authorization will have to apply for and receive a specific authorization to engage in the otherwise prohibited transaction. The purpose of specific authorizations is to allow BIS on a case-by-case basis to determine the nature and scope of the undue or unacceptable risk to U.S. national

security posed by transactions involving VCS hardware and covered software, including the extent of foreign adversary involvement in the transactions, as well as potential mitigations.

VCS hardware importers and connected vehicle manufacturers must not engage in an otherwise prohibited transaction until BIS grants the application for a specific authorization. If a party engages in a prohibited transaction prior to receiving a specific authorization from BIS, that transaction would constitute a violation of this final rule. Specific authorization requests will be reviewed on a case-by-case basis, and a decision regarding the application will be provided within 90 days unless BIS determines and notifies the applicant within the 90-day period that additional time is required. Applications for a specific authorization must contain detailed information on the proposed transaction, including each party to the transaction, an overview of the covered software and/or the VCS hardware designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, information on the connected vehicles in which the VCS hardware of covered software will be integrated, the intended use of the covered software and/or VCS hardware, and documentation to support the information contained in the application. Persons seeking a specific authorization will submit an application according to instructions available on the BIS website. Applicants should take care to submit to BIS only one copy of an application pertaining to each transaction for which they seek specific authorization to avoid processing delays. BIS may request additional information from an applicant about any matter related to the specific authorization request. In rare situations, as part of its review of an application for specific authorization, BIS may, in its sole discretion, request an oral briefing by the applicant and any other relevant parties. At any point between initial submission of an application for specific authorization and a final decision issued by BIS, an applicant may submit additional information to bolster the application or provide clarity on any aspect thereof.

When reviewing applications for a specific authorization, BIS will consider factors that may pose undue or unacceptable risks, particularly as they relate to transactions that could result in the exfiltration of connected vehicle or U.S. persons' data, or the remote manipulation or operation of a connected vehicle. Examples of factors

that BIS may consider include: ISO/SAE 21434 Threat Analysis and Risk Assessments; the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture, or supply of the VCS hardware or covered software; security standards used by the applicant and if such standards can be validated by BIS or a third party; and other actions or proposals the applicant offers to implement as a way to mitigate undue or unacceptable risk.

BIS's decision regarding any application for specific authorization will apply only to the actual parties and transaction outlined in the application and described in the decision notice. Additionally, the decision notice from BIS to the applicant(s) may contain any conditions that must be met by the parties for a transaction to be authorized. Such conditions, which are subject to revision by BIS, may include technical controls (*e.g.*, software validation) or operational controls (*e.g.*, physical and logical access monitoring procedures), that are either permanent or temporary. These controls will focus on the supply chain element that involves a link to a foreign adversary to mitigate any undue or unacceptable risk posed by the transaction. For connected vehicle manufacturers owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, a specific authorization may include a requirement that all VCS hardware and covered software be assembled and integrated into the connected vehicle in the United States. In the approval letter for specific authorization, BIS will determine the effective date and duration of the authorization on a case-by-case basis. As a default, specific authorizations will be approved for a duration of no less than one (1) calendar year, except on a case-by-case basis under certain exceptions including model years that are actively being sold or imported as of the effective date of the rule, for situations in which supply chains are affected by force majeure events, or due to an unexpected change in the supply chain during model year production.

Applicants with denied authorizations would not be precluded from submitting new applications for specific authorizations for different transactions involving different parties and/or different covered software or VCS hardware. BIS will reconsider a previously denied application for a specific authorization only if the applicant demonstrates a material change in circumstances.

4. Exemptions

In the NPRM, BIS delineated several exemptions to the proposed rule. First, VCS hardware importers could engage in prohibited transactions described in section 791.302 without a general or specific authorization, and would be exempt from submitting Declarations of Conformity with respect to all other transactions, as described in section 791.305, provided that (1) the import of the VCS hardware occurred prior to January 1, 2029 for VCS hardware units not associated with a vehicle model year, or (2) the VCS hardware was associated with a vehicle model year prior to 2030 or the VCS hardware was imported as part of a connected vehicle with a model year prior to 2030. Second, connected vehicle manufacturers could engage in prohibited covered software transactions described in section 791.303 without a general or specific authorization and would be exempt from submitting Declarations of Conformity with respect to all other transactions described in section 791.305, provided that the completed connected vehicle that incorporates covered software described in section 791.303(a)(1) was manufactured prior to model year 2027. Third, it was contemplated in the NPRM that connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia could engage in prohibited transactions without a general or specific authorization, and would be exempt from submitting Declarations of Conformity for all other transactions, provided that the completed connected vehicle that incorporated VCS hardware and/or covered software was manufactured prior to model year 2027. The final rule has maintained this existing list of exemptions while adding a specific exemption for parts that are imported for purposes of warranty or repair of a completed connected vehicle with a model year prior to 2030.

Many commenters requested that BIS extend the software and hardware prohibition timelines in the rule so that industry has sufficient time to adjust their supply chains. For example, one commenter claimed that the proposed timelines do not account for existing contracts between manufacturers and suppliers. Commenters requested compliance timeline extensions ranging from one to five years for the software prohibition to go into effect, and one to six additional years for the hardware prohibition to go into effect. Alternatively, multiple commenters

recommended incorporating a phased-in approach for both the software and hardware prohibitions. In contrast, two commenters recommend that BIS shorten the implementation timeline due to the national security, privacy, and safety risks posed by the software and hardware transactions. Due to the national security risk being addressed by this regulation as discussed in Section IV, BIS has declined to extend the proposed software and hardware implementation timelines. For situations in which connected vehicle manufacturers or VCS hardware importers anticipate this regulation will impact connected vehicles or VCS hardware currently under production, those connected vehicle manufacturers or VCS hardware importers may apply for a specific authorization. Furthermore, with the exclusion of legacy software from the definition of covered software, BIS anticipates the regulatory burden to be lessened for industry, allowing regulated entities to more easily comply with the timeline.

Regarding exemptions, commenters recommended that BIS clarify whether systems which include their own communication but are only operational during parking are covered by the regulation. BIS declines to confirm whether systems which include their own communication but are only operational during parking are covered by the regulations, as this would require a case-by-case analysis. BIS advises industry to reference the definition of Vehicle Connectivity System.

Lastly, multiple commenters urged BIS to clarify that spare, replacement, or warranty parts imported after January 1, 2029, but for integration into a vehicle with a model year prior to 2030 which are exempted from the rule. BIS understands that connected vehicle manufacturers may have warranty or repair obligations that extend years past the date of manufacture of the vehicle. BIS does not intend for this rule to interfere with those obligations, and BIS believes the rule as written adequately allows for the import of otherwise prohibited VCS hardware if it is for a vehicle with a model year prior to 2030. Some commenters envisioned a scenario in which a VCS hardware importer may wish to import a specific component after January 1, 2029, but the component is not yet “associated” with a model year and would thus be prohibited. In response, BIS has amended the exemptions to clarify that VCS hardware components imported for repair or warranty purposes for a vehicle model year prior to 2030 are exempt.

5. Appeals

In the NPRM, BIS proposed a process by which any person whose application for a specific authorization is denied, whose specific authorization is suspended or revoked, or who has received a written notification of ineligibility for a general authorization may appeal that decision to the Under Secretary. Commenters suggested that BIS expand the appeals section and create a detailed framework for navigating the process, including procedures for a software supplier to participate in a connected vehicle manufacturer’s appeal. Commenters also suggested that BIS be specific in defining a “reasonable time” for appealing decisions. In response to comments, BIS has included a provision that allows third parties to submit amicus filings in support of parties undergoing an informal appeals hearing if, for example, their technology is the subject of the appeal. BIS also specified that 45 days is the reasonable amount of time to file an appeal and is consistent with 15 CFR 756.2(c).

Based on commenters’ feedback, BIS has further clarified the appeals process. In the final rule, the appeals process remains a mechanism by which any person whose application for a specific authorization is denied, whose specific authorization is suspended or revoked, or who has received a written notification of ineligibility for a general authorization may appeal that decision to the Under Secretary. Appeals must be submitted in writing by email or mail to the Office of the Under Secretary within 45 days of the date on the notice of the adverse administrative action by BIS. The appeal must detail how the party submitting the appeal has been directly and adversely affected by BIS’s action, and the reasons BIS’s action should be reversed or otherwise modified. The Under Secretary, at his or her discretion, may delegate to the Deputy Under Secretary of Commerce for Industry and Security or another BIS official responsibility to review and decide appeals, including arranging, at the official’s discretion, informal hearings with relevant parties regarding the appeal.

On their own accord or at the request of the Under Secretary or designated reviewing official, appellants may submit supplementary information in support of their appeal. However, the Under Secretary or designated reviewing official generally will not consider additional information submitted on an appellant’s own accord more than 30 days after submission of the original appeal. Appellants may also

request an in-person informal hearing in writing at the time of submission. A hearing is not required, and the Under Secretary or designated official may, at his or her sole discretion, grant or deny a request for an informal hearing. Parties not subject to the administrative action under appeal may submit an amicus filing in support of an appellant as part of a granted informal hearing.

6. Advisory Opinions

In the NPRM, BIS proposed the inclusion of an advisory opinion provision in order to provide interested parties greater clarity about how to comply with the proposed rule on an as-needed basis. Commenters supported BIS’s inclusion of an advisory opinion mechanism in the rule. Some commenters urged BIS to set a deadline by which BIS must respond to a request for an advisory opinion. In response, BIS has implemented a 60-day deadline for advisory opinion requests unless BIS determines that additional time is needed. BIS also emphasizes the timely issuance of an advisory opinion will depend upon prompt responses by the requester in the event that BIS requests additional documents or information to inform the advisory opinion. BIS may publish on its website an advisory opinion that may be of broad interest to the public, with redactions where necessary to protect CBI. To solicit an advisory opinion from BIS, persons will be required to submit a written request to BIS by email or through a portal that will be available on the BIS website. BIS will not accept advisory opinion requests submitted by mail. A request for an advisory opinion must contain contact information for the submitter as well as all current information on the prospective transaction to assist BIS in making a determination.

In response to the NPRM’s stipulation that advisory opinion requests be only for real and not hypothetical transactions, some commenters suggested that BIS allow an initial period after the rule comes into effect during which BIS will allow advisory opinion requests for hypothetical transactions. One commenter also recommended that BIS use the advisory opinion mechanism to create a trusted supplier program for connected vehicle manufacturers and VCS hardware importers. Another commenter urged BIS to issue advisory opinions for hypothetical transactions to avoid compliance challenges and high costs. BIS declines these suggestions, as such reviews for hypothetical transactions could burden the department for transactions that may never materialize and for which the binding opinion risks

being made on incomplete facts. The intent of limiting advisory opinion requests to actual transactions is to allow BIS to provide thorough responses to each request that would ultimately bind the Department with regard to that transaction. Permitting entities to submit requests for vague, unspecified transactions would likely result in an untenable influx of requests and therefore undermine BIS's ability to provide comprehensive responses to each request. BIS emphasizes that a transaction need not have been initiated or executed in order to qualify for an advisory opinion request. Indeed, where a regulated entity believes that the transaction may be prohibited, the entity should request an advisory opinion before initiating or executing the transaction. BIS stresses that an advisory opinion request must contain real, specified parties to the transaction and real, specified VCS hardware or covered software in order for BIS to issue the opinion.

One commenter requested that BIS allow suppliers or other relevant parties to submit information in support of an advisory opinion request in order to avoid the forced transfer of IP from the supplier to the customer who is seeking the advisory opinion. In response, BIS has clarified that interested parties may submit information directly to BIS in support of an advisory opinion request.

Another commenter recommended that BIS hold compliance forums to assist regulated persons in implementing the provisions of this rule. BIS will take this suggestion under advisement and will consider holding such forums after the publication of this rule. BIS further anticipates posting guidance and responses to frequently asked questions on its website (<https://www.bis.gov/OICTS>) to assist the public in complying with the rule.

Multiple commenters addressed the concept of preclearance and urged BIS to consider implementing such a process in parallel to the advisory opinion program. While BIS declines to institute a preclearance program given the need to adequately address the national security concerns posed by otherwise prohibited transactions, BIS has emphasized in the advisory opinion stipulations that a regulated entity may rely upon an advisory opinion issued by BIS in seeking a specific authorization or submitting an appeal to BIS to the extent that the facts and assertions made in the request remain truthful and accurate. BIS also believes that the exclusion of legacy software and refinement of the open-source software exclusion further address this commenter's point. Finally, BIS

reiterates that it may publish certain advisory opinions, in accordance with the CBI section of this rule, in the case that it may be of general interest to regulated entities or relating to a supplier with which many entities wish to transact.

7. "Is-Informed" Notices

BIS received no comments on the proposed "Is-Informed" notice provision and retains the same "Is-Informed" notice provision for the final rule (section 791.311, "Is-Informed notices").

BIS may notify connected vehicle manufacturers or VCS hardware importers, either through direct letters or through a **Federal Register** notice meant to inform a broader set of persons, that a transaction involving certain covered software, VCS hardware, or entities, requires a specific authorization because it would constitute a prohibited transaction according to the terms of this final rule. Any person who engages in a transaction covered by an "Is-Informed" notice without first receiving a specific authorization from BIS would have knowledge that such transaction is prohibited and would therefore be in violation of the rule. "Is-Informed" notices may only be delivered by or at the direction of the Under Secretary or a BIS official designated by the Under Secretary.

8. Recordkeeping, Reporting Requirements, and Confidential Business Information

BIS made a few notable changes from the NPRM to the final rule. First, BIS no longer requires submission of SBOMs and HBOMs, mitigating concerns about the retention of CBI and complexity of reporting requirements. Additionally, BIS has reworked the estimates of compliance costs in response with comments. As described below in more detail, BIS estimates that the initial cost of compliance will increase, but the annual cost to conduct ongoing due diligence and resubmit Declarations of Conformity will be less due to the decreased reporting requirements. BIS declined, however, to change the timeline for the retention of business records, as it is in line with IEEPA authority.

Commenters urged BIS to provide explicit assurance for protecting CBI and limit the scope of recordkeeping requirements. Some commenters provided suggestions that delineated how BIS should protect CBI and limited recordkeeping requirements. Other commenters advised that BIS establish robust protections for CBI and sought

that BIS provide more information on how the agency will identify and redact CBI in published advisory opinions. Several commenters also expressed that recordkeeping requirements of the regulation were unduly burdensome and requested that BIS restructure the requirements. One commenter suggested narrowing the scope to "primary business records, such as contracts, import records, bills of sale, essential correspondence, and other key documents specified for compliance assessment." BIS understands the concerns surrounding CBI and burden posed by recordkeeping requirements. Accordingly, BIS has determined that the final rule will not require the submission of SBOMs and HBOMs. BIS notes that CBI still may be submitted pursuant to other provisions of the final rule, but not to the extent proposed in the NPRM.

A commenter urged BIS to adopt robust CBI protections given that requests for an advisory opinion will almost certainly contain proprietary information. BIS believes this comment is addressed by its addition of a new section of the rule detailing the submission of CBI. Furthermore, entities submitting CBI should refer to 15 CFR 791.102, which outlines the circumstances under which the Secretary of Commerce may authorize the disclosure of CBI materials submitted to BIS. BIS emphasizes that any information submitted as confidential will be handled in compliance with applicable laws and regulations, to ensure proper handling and to prevent unauthorized disclosure. The CBI will be used exclusively for investigative, enforcement, or regulatory purposes.

One commenter requested that BIS provide guidance on how suppliers should mark CBI in their submissions and implement a secure CBI portal. In response, BIS encourages the commenter to refer to section 791.314, which captures the CBI submission and procedures, including how the CBI files should be marked "CONFIDENTIAL BUSINESS INFORMATION" at the top of the page. Submission will occur as indicated on the BIS website, initially via email, and eventually through a submission portal which will be described in more detail on the BIS website once available.

Another commenter asked if all reports to be furnished on demand are covered in the 10-year recordkeeping requirement. BIS requires that primary business records be retained for 10 years and furnished to BIS upon request. Based on this feedback, BIS confirms that all reports to be furnished on

demand are covered by the 10-year requirement.

Commenters provided conflicting feedback on the time requirements of recordkeeping. One commenter suggested that recordkeeping requirements be lowered to five years. Another commenter suggested increasing it to fifteen years. Another commenter noted 10-year recordkeeping requirements but said the information collected should be limited. BIS agrees that recordkeeping should be limited solely to primary business records related to the execution of a transaction. However, BIS declines to adjust the 10-year recordkeeping requirement so as to maintain consistency with IIEPA.

One commenter suggested that suppliers should be responsible for recordkeeping. BIS underscores that the primary compliance responsibility is on the connected vehicle manufacturer and VCS hardware importer. However, when submitting a Declaration of Conformity, entities must certify that they have arranged for suppliers to furnish any documentation and third-party assessments (as applicable) upon request by BIS.

One commenter requested information on “permissible locations for data centers.” BIS declines to explicitly name permissible locations for data centers for vehicle-external data storage but may consider the location of a data center as it relates to the design, development, manufacturing, and supplying of covered software or VCS hardware for applicants of specific authorizations.

Several commenters expressed that BIS’s recordkeeping cost estimates are inaccurate. A few commenters argued that the initial range of “\$30,964 and \$38,554 per regulated entity, followed by estimated yearly costs of \$16,133 to \$80,667” to comply with the rule was underestimated. One commenter noted that two staff members managing this regulation compliance would prevent BIS from sufficiently processing all Declarations of Conformity and relevant materials. After reviewing the comments and re-analyzing the cost to entities to read the rule, understand the rule, and conduct initial due diligence, BIS re-estimates that this initial cost is between \$56,671 and \$77,055. Additionally, BIS re-estimates that the estimated yearly costs to re-conduct due diligence and potentially re-submit a Declaration of Conformity is between \$24,200 and \$48,400. While BIS agrees that its initial estimate of conducting due diligence with the rule was understated due to the complexity of automotive supply chains, BIS estimates that the annual cost to re-conduct due diligence and

potentially re-submit Declarations of Conformity is reduced due to the decreased reporting requirements. Additional information on these new estimates can be found in the *Paperwork Reduction Act* section of this final rule, and the accompanying Final Regulatory Impact Analysis.

A few commenters also noted that the estimates do not reflect BIS’s own suggestion that regulated entities provide evidence of due diligence “to include independent or hired third-party research.” BIS clarifies that third-party research and assessments is optional when submitting a Declaration of Conformity. However, BIS notes that third-party verification may be required as a condition for the approval of a specific authorization.

Commenters suggested implementing lists of trusted countries or suppliers in order to reduce the due diligence burden on connected vehicle manufacturers and VCS hardware importers. The publication of a list of trusted countries or suppliers would complicate compliance for BIS. The broad application of trusted countries or suppliers undercuts BIS’s ability to address each transaction on a case-by-case basis with proportionate mitigation measures, as may be necessary. Creating a preapproved list of countries and suppliers would also lead to a more uncertain regulatory environment as BIS may be required to update such a list from time to time as the threat environment evolves.

BIS has chosen to require connected vehicle manufacturers and VCS hardware importers to maintain complete records related to any transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required by this rule, for a period of 10 years. This recordkeeping requirement applies regardless of whether the transaction is subject to a general authorization or specific authorization, or whether the connected vehicle manufacturer or VCS hardware importer has not yet sought an authorization. Records subject to the recordkeeping requirement include all information pertinent to transactions completed pursuant to a general authorization or submitted when applying for a specific authorization, as well as business records related to the execution of the transaction, such as contracts, import records, bills of sale, relevant correspondence, and all other files specified in sections 791.312 and 791.313 to assess compliance with the rule.

All connected vehicle manufacturers and VCS hardware importers are

required to submit records when requested by BIS related to any transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required by this rule, whether or not said transaction was carried out under a general authorization, specific authorization, or without an authorization from BIS. As such, BIS may request business records, before, during, or after the transaction in question has taken place.

In response to numerous public comments requesting deeper commitments by BIS to protect CBI as well as greater clarity regarding how BIS will protect CBI, BIS has included a new section in this final rule detailing relevant measures BIS will take. Under these new provisions, entities submitting information that they wish to receive CBI protections should clearly mark any pages containing such CBI in their submission. Additionally, the entity requesting CBI handling should submit a statement to BIS that justifies non-disclosure by citing the specific legal authority on which the entity believes BIS should rely, such as Exemption 4 of the Freedom of Information Act (FOIA) as codified at 5 U.S.C. 552(b)(4), or other relevant authorities. As stated above, BIS will maintain confidential information in accordance with 15 CFR 791.102.

9. Third Party Verification and Assessments

In response to numerous public comments, BIS decided to further clarify the voluntary use of third-party assessments. Several comments indicated that for many of the rule’s regulated entities, companies would need to outsource to third parties to maintain compliance and assist in preparing documentation for recordkeeping and submission of Declarations of Conformity. BIS emphasized that the use of third parties to maintain compliance with this rule is generally voluntary but may be required by BIS as a condition for granting a specific authorization. While regulated entities may use a third party to assist with compliance checks, the final rule does stipulate that such third parties may not be a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Additionally, any reports produced by these third parties would be subject to the final rule’s recordkeeping requirements.

d. Enforcement

BIS notes as a threshold matter that it has reordered the enforcement sections

of this rule to flow more naturally and to provide readers with a better sense of the chronology and sequencing of enforcement actions as compared to the structure in the NPRM. The reorder of these sections in the regulatory text has no bearing on the substance of the sections nor the rule as a whole. BIS's consideration of comments related to the enforcement provisions is discussed in the sections that follow.

1. Penalties

One commenter requested that BIS provide greater clarity on how it will determine whether a civil or criminal penalty will be assessed, as well as provide means by which an entity may rectify an error before a penalty is assessed. In response, BIS emphasizes, as detailed below, that the penalties in this rule are derived from IEEPA, and the individual nature of the violation will determine both the type of penalty and the amount to be assessed. Additionally, this rule contains multiple paths through which VCS hardware importers and connected vehicle manufacturers may rectify errors. For example, BIS may issue an "Is-Informed" notice to a party informing them that a specific authorization is needed to continue with a certain transaction. As provided below, BIS may also issue a pre-penalty notice outlining BIS's intention to issue a penalty and providing the party with the opportunity to respond and present any potentially mitigating or exculpatory evidence or remediation proposals. Lastly, in response to a request from a commenter, BIS has included in this rule a clarification that it will take into account voluntary self-disclosures of potential violations when deciding to issue a penalty.

IEEPA provides the authority for this rulemaking. Thus, persons who violate, attempt to violate, conspire to violate, or knowingly cause a violation of this rule will be subject to civil and/or criminal penalties under IEEPA (50 U.S.C. 1705), depending on the circumstances of the violation. Potential violations of this final rule that would be subject to penalties include, but are not limited to, engaging in a prohibited transaction without an applicable general authorization or specific authorization, or failure to abide by the conditions enumerated in a specific authorization. Willfully providing false or fictitious information to the U.S. Government may be subject to criminal fines, imprisonment, or both. A civil penalty may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any exemption, authorization, order,

regulation, directive, instruction, or prohibition issued under IEEPA and this rule.

Under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the specific maximum civil penalty will be adjusted by notice in the **Federal Register** effective each calendar year by the Office of the Secretary of the Department of Commerce. At the time of publishing of this final rule, the maximum civil penalty for violations of IEEPA is \$368,136 per violation and the maximum criminal penalty is \$1,000,000.

Under the final rule, should BIS have reason to believe that a violation has occurred and intends to issue a civil monetary penalty, it will inform the alleged violator through a written notice of the intent to impose a penalty (pre-penalty notice). BIS will generally transmit the pre-penalty notice electronically but may additionally mail notice. The recipient of a pre-penalty notice may respond in writing to BIS to provide additional information or otherwise contest the penalty. BIS must receive this response within 30 days of the transmission of the original pre-penalty notice. A response to a pre-penalty notice does not constitute a formal appeal, but it allows the recipient of the pre-penalty notice to contest facts set forth by BIS in the pre-penalty notice, provide exculpatory evidence, or otherwise respond to the violation alleged in the pre-penalty notice. BIS may seek to initiate settlement discussions in the pre-penalty notice or may conduct separate outreach following transmission of the pre-penalty notice. Recipients of a pre-penalty notice may additionally request to initiate settlement discussions in their response to BIS or may conduct separate outreach to do so.

Following the delivery of the pre-penalty notice, and after considering any responses from the alleged violator, BIS will inform the alleged violator in writing as to whether it has found that a violation in fact occurred. Should BIS find that a violation has indeed taken place and no settlement has been reached, BIS will issue a final penalty notice to the violator specifying the violation and determining the specific civil monetary penalty to be imposed. This penalty may not be appealed following the procedures in section 791.309, as it is a final agency action that the violator may contest in the appropriate U.S. District Court.

Should a violator fail to pay the penalty as specified in the final penalty notice or fail to make alternative payment arrangements approved by BIS, BIS may refer the matter to the

Department of the Treasury for administrative collection or to the Department of Justice for collection via civil suit in U.S. District Court.

2. Finding a Violation

BIS did not receive any feedback on this in the NPRM and retains its approach for "finding a violation" in its final rule.

Under the final rule, there may be cases in which BIS determines that a violation has taken place but that a civil monetary penalty is not appropriate. In such cases, BIS would issue a finding of violation that identifies the violation. The finding of violation could also contain an administrative response other than a civil monetary penalty, such as an order to cease and desist from conduct or activities that are prohibited by the final rule. Consistent with the procedures listed above regarding a pre-penalty notice, recipients of a finding of violation may file a response within 30 days contesting the facts of the finding of violation and/or providing information relevant to BIS's determination of whether a violation has occurred. BIS will consider any new information and inform the party in writing whether a violation has or has not occurred. A recipient that does not respond within 30 days of receipt of the finding of violation will be deemed to have waived the right to respond. Any action taken in a finding of violation issued by BIS constitutes a final agency action that is not subject to appeal following the procedures in section 791.309.

3. Severability

BIS did not receive any feedback on this in the NPRM and retains its approach to "Severability" in its final rule.

This rule implements, and is fully consistent with, governing law. However, in the event of legal challenge, BIS intends for the provisions of the final rule to be severable from each other. If a court holds that any provision in the final 15 CFR 791, subpart D, is invalid or unenforceable, BIS intends that the remaining provisions of the final 15 CFR 791, subpart D, as relevant, would continue in effect to the greatest extent possible. In addition, if a court holds that any such provision is invalid or unenforceable as to a particular person or circumstance (such as the recordkeeping or Declarations of Conformity requirements), BIS intends that the provision would remain in effect as to any other person or circumstance. Each provision of the final rule and application thereof serves an important, related, but distinct

purpose; provides a distinct benefit separate from, and in addition to, the benefit provided by other provisions and applications; is supported by evidence and findings that stand independent of each other; and is capable of operating independently such that the invalidity of any particular provision or application would not undermine the operability or usefulness of other aspects of the final rule. Depending on the circumstances and the scope of the court's order, BIS believes that the remaining provisions of the final rule likely could continue to function sensibly independent of any provision or application held invalid or unenforceable. For example, the prohibitions related to transactions involving VCS hardware could continue to apply as intended, even if a court finds that the prohibitions on transactions involving ADS are invalid. Similarly, the final rule could be applied with respect to relevant hardware and software designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC, even if a court finds its application with respect to relevant hardware and software from Russian-linked persons is invalid.

e. Other Commentary

1. Coordination With Interagency and Industry

Commenters urged BIS to consider its overlap with other government agencies in a variety of ways. One commenter suggested that BIS conduct a conflict-of-laws analysis to ensure there is no overlap with the Committee on Foreign Investment in the United States (CFIUS) authorities. In response, BIS clarifies that its authorities are different from CFIUS authorities, the latter of which apply to certain foreign investments in the United States and are coordinated by the Department of the Treasury.

One commenter urged BIS to coordinate more closely with the NHTSA, the Federal Motor Carrier Safety Administration (FMCSA), and industry when finalizing the rule. Additional commenters advised BIS to evaluate its overlapping authorities with other government bodies. Another commenter claimed that the telecommunications supply chain is subject to overlapping authorities and regulations and therefore BIS should ensure the rule is narrowly tailored to connected vehicles. BIS acknowledges these suggestions and notes for commenters that it has robustly engaged with its interagency partners to deconflict any overlap in authorities. As

noted previously, BIS's ICTS authorities are explicitly focused on addressing unique national security risks from foreign adversary involvement in the ICTS supply chain such as those articulated in Section IV of this rule and differ from other programs in the U.S. government. BIS has coordinated with interagency partners and industry to inform the development of this final rule and has worked with them to ensure this rule does not conflict with but complements other governmental efforts.

2. Global Standards/Regulations for Consideration

Multiple commenters stated that BIS should consider adopting the United Nations regulations concerning cybersecurity and software update management, such as UN Regulation 155 and UN Regulation 156. Other commenters proposed utilizing standards and frameworks including ISO/SAE 21434, ISO 26262, CISA's Autonomous Ground Vehicle Security (TISAX), Auto-ISAC Cybersecurity Best Practices, NHTSA's Cybersecurity Best Practices for the Safety of Modern Vehicles, 2024 Technical Requirements for Vehicle Overall Information Security (GB44495), and the United Nations World Forum for Harmonization of Vehicle Regulations (WP.29). In response, BIS wants to voice its appreciation for the commenters' input and thoughts on incorporating these standards into its regulation format. However, after consideration, BIS does not assess these standards as sufficient methods to mitigate the identified risk within the connected vehicle supply chain. These standards and frameworks all have different scopes that do not accurately match BIS's goal of mitigating national security risk posed by the connected vehicle technology supply chain when containing a nexus with adversary countries.

However, some of these standards and frameworks may offer support for the compliance process. For example, when processing specific authorizations, BIS will take into consideration existing cybersecurity measures employed by the entity, such as the implementation of UN Regulation 156, which involves software update and software update management systems, or SAE Standard 21434, as they relate to the unique ICTS transaction. BIS's review for specific authorizations will be conducted on a case-by-case basis, and BIS therefore does not see it beneficial to provide blanket clearance for any one cybersecurity standard at this time. In addition to advocating for BIS to consider international standards, one

commenter asked BIS to reconsider the impact of its regulation, arguing that it will hinder the United States' ability to meet its 2030 goal under the Paris Agreement. This commenter urged BIS to prepare an environmental assessment of the rule. Given that the focus of BIS's authority is limited to national security threats from adversary countries, an environmental evaluation is neither pertinent nor required.

Commenters also sought clarification on how BIS would consider international standards to which adversary countries had input. One commenter asked BIS to clarify that vehicle technologies would not be prohibited simply because they had been developed according to international standards in which the PRC had been a party. A separate commenter stated that BIS should clarify that the participation of Chinese or Russian citizens in international technical standards-setting would not deem the VCS hardware subject to that standard as captured by the rule. BIS appreciates these comments but notes that PRC or Russia support in an international standard development process does not fall within the scope of this regulation.

3. Stakeholder Meetings

Between September 24 and December 13, 2024, BIS conducted 35 meetings with industry stakeholders to gather information, follow up on ambiguous comments, and better understand current business practices in the U.S. connected vehicle supply chain.²

In each meeting, BIS encouraged the participant(s) to submit written comments to the public docket. For the most part, commenters in these meetings offered views that they previously or subsequently submitted in written comments. BIS summarizes below additional points not addressed in written comments. In many of the meetings, participants provided BIS with confidential business information relating to their design and manufacturing of completed connected vehicles and/or components to provide context for points made in written submissions.

Across all meetings, stakeholders generally reiterated information submitted in written comments regarding specific authorizations; advisory opinions; Declarations of Conformity; definitions of terms such as *person owned by, controlled by, or*

² These meetings included 20 meetings held after the close of the comment period. BIS met with all stakeholders who requested meetings until the draft final rule was submitted to OMB for coordinated interagency review under Executive Order 12866.

subject to the jurisdiction or direction of a foreign adversary and foreign interest; a whitelist for approved components; unconventional ownership structures; and commercial trucking. As stated above, BIS has addressed each of these issues in the final rule by: clarifying the process for specific authorizations (Section VI.c.3) and advisory opinion requests (Section VI.c.6); greatly reducing the burden for Declarations of Conformity (Section VI.c.1), including exclusion of SBOMs and HBOMs; updating the definition of *covered software* (Section VI.a.5); and providing more examples regarding the definition of a *person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary* (Section VI.a.14) and *foreign interest* (Section VI.a.8); providing more examples on unconventional ownership structures (Section VI.a.14); and scoping the rule to address only those vehicles under 10,001 pounds (Section VI.a.3). For the reasons stated above, BIS declines to implement a whitelist (Section VI.a.12).

Finally, a stakeholder expressed interest in whether like-minded countries would be encouraged to adopt similar provisions to this regulation. BIS notes that throughout the rulemaking process it has been working closely with international allies and partners and has experienced high interest. BIS also participated in a meeting with interested foreign governments convened by the Department of State and the White House on July 31, 2024, to jointly address the national security risks associated with connected vehicles.

f. Classification

1. Executive Order 12866

Executive Order 12866, as reaffirmed by Executive Order 13563 and amended by Executive Order 14094, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, and distributed impacts and equity). This final rule has been designated a significant regulatory action by the Office of Information and Regulatory Affairs (OIRA) under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094.

2. Unfunded Mandates Reform Act of 1995

This final rule would not produce a Federal mandate (under the regulatory provisions of title II of the Unfunded Mandates Reform Act of 1995) for state,

local, and Tribal governments or the private sector.

3. Executive Order 13132 (Federalism)

This final rule does not contain policies having federalism implications requiring preparations of a Federalism Summary Impact Statement.

4. Executive Order 12630 (Governmental Actions and Interference With Constitutionally Protected Property Rights)

This final rule does not contain policies that have takings implications.

5. Executive Order 13175 (Consultation and Coordination With Indian Tribes)

The Department has analyzed this final rule under Executive Order 13175 and has determined that the action would not have a substantial direct effect on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal law.

6. National Environmental Policy Act

The Department has reviewed this rulemaking action for the purposes of the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*). It has been determined that this final rule would not have a significant impact on the quality of the human environment.

7. Paperwork Reduction Act

There are several changes between the NPRM and the final rule regarding information collection requirements. First, BIS has significantly decreased the reporting requirements in the Declaration of Conformity provision, including eliminating the need to submit SBOMs/HBOMs or a list of third-party external endpoints to which the VCS hardware connects. These provisions have been replaced with certification and recordkeeping requirements, with specific documentation and assessments on due diligence only needing to be submitted to BIS upon request. Additionally, BIS has removed the submission of an SBOM/HBOM for advisory opinion requests. Lastly, BIS has specified in the final rule that only primary business records relating to VCS hardware and covered software need to be maintained. These changes have significantly reduced the recurring annual cost and burden hour estimates.

Several commenters noted that the initial estimation to read the rule, understand the rule, and conduct initial due diligence in preparation to comply with the rule was significantly underestimated. One commenter noted

that the approximately \$39,000 per entity estimate to initially read and understand the rule and comply with its requirements is under-representative of the scope of activity required by the new proposed restrictions, compliance activities, and certification requirements. It was also noted that one of the main compliance tasks for OEMs would be the supply chain due diligence, which is time consuming and resource intensive. After internal deliberation, BIS agrees with commenters that the initial estimations to read the rule, understand the rule, and conduct initial due diligence in preparation to comply with the rule were likely underestimated, most significantly is the initial time burden for entities.

The initial time burden hour estimate for operations managers in the Preliminary Regulatory Impact Analysis was between 50 to 70 hours. BIS now estimates that the burden hour estimate for operations managers is between 100 to 160 hours. BIS evaluates that the burden hours for operations managers is essentially doubled compared to the estimation in the proposed rule due to improved insight into the complexities surrounding mapping supply chains and the initial efforts that will need to be invested in preparing to comply with the rule. BIS assesses that this updated hour estimate more accurately reflects these activities.

The initial burden hour estimate for lawyers in the Preliminary Regulatory Impact Analysis was between 80 and 100 hours. BIS now estimates that the burden hour estimate for lawyers is between 160 and 200 hours. Similarly to operations managers, BIS evaluates that the burden hours for lawyers is doubled compared to the estimation in the proposed rule due to improved insight into the legal efforts needed to (1) ensure that complex supply chains are compliant with the requirements outlined in the rule, and to (2) establish the reporting and recordkeeping practices as prescribed in the rule. The increase in lawyer burden hours also accounts for potential outside counsel engagement if a company does not have the proper in-house legal support or expertise.

Lastly, the initial burden hour estimates in the Preliminary Regulatory Impact Analysis assumed a time burden of 50 to 70 hours for engineers. This estimation remains the same in this final rule. After internal deliberation, BIS estimates that the burden to read the rule, understand the rule, and conduct initial due diligence in preparation to comply with the rule will largely fall on operations managers and lawyers.

Therefore, BIS did not increase the engineer burden hour estimate.

In the NPRM and Preliminary Regulatory Impact Analysis, BIS estimated that the cumulative initial burden (in hours) placed on applicable entities would be 180 to 240 hours and that the initial cost burden for these entities would be between \$30,964 and \$38,554. This estimate took into account the one-time initial cost (in hours) per entity to comply with the rule, including reading and understanding the rule's provisions. Every subsequent year, BIS estimated that the total annual cost burden (in hours) for applicable entities to implement the rule would be 100 to 500 hours and that the total annual cost burden for applicable entities to implement the rule would be \$16,133 to \$80,667 a year. In the final rule and final Regulatory Impact Analysis, BIS re-estimates that the cumulative initial burden (in hours) placed on applicable entities is between 310 and 430 hours to initially read the rule, understand the rule, and conduct initial due diligence in preparation to comply. The re-estimated cost burden for these entities to read the rule, understand the rule, and conduct initial due diligence is between \$56,671 and \$77,055. Every subsequent year after the publication of the final rule, the Department anticipates that the total annual burden (in hours) for connected vehicle manufacturers and VCS hardware importers to re-conduct due diligence into their VCS hardware or covered software supply chains and potentially re-submit a Declaration of Conformity will be 150 to 300 hours. BIS estimates that the total annual cost burden for a connected vehicle manufacturer or VCS hardware importer to re-conduct due diligence into their VCS hardware or covered software supply chains and potentially re-submit a Declaration of Conformity will be \$24,200 to \$48,400 per year.

BIS has also re-calculated the expected cost to the U.S. Government. Consistent with the proposed rule, BIS estimates that it will take staff an average of 20 hours to review and, if applicable, respond to each Declaration of Conformity, specific authorization application, or advisory opinion request. However, BIS has corrected the calculation by removing the 20 percent overhead addition, as overhead is already captured in staff wages. For this final rule, BIS has increased the expected legal support personnel from one to two employees in response to comments related to staffing needs in managing compliance with the rule. The re-estimated annual cost to the U.S. Government in the final rule is

\$1,299,728, a slight decrease from the \$1,437,982 estimate in the NPRM.

Some commenters to the NPRM expressed that BIS did not provide adequate time to review the costs of the rule. BIS acknowledges the short publication timeline of this rule, but also recognizes that the national security risks the rule addresses are severe. BIS also aims to address national security risks in a way that does not unduly burden the industry, as reflected by changes in the final rule. In its efforts to reduce associated costs and compliance burden, BIS has revised the final rule to reduce information submission requirements and expand on provisions that are designed to help the industry comply with the rule. For example, BIS has dramatically reduced the information submission requirements by removing the HBOM and SBOM submission requirements, which not only meets the industry where they are but also reduces the cost of this regulation. BIS has also established a process for issuing advisory opinions to assist parties who are unsure how the requirements in this rule affect them, and a process for requesting specific authorizations if a party believes that certain transactions prohibited by this rule should be permitted to go forward. BIS also notes that the delayed implementation of this rule will provide additional time for the industry to come into compliance with its requirements and seek specific authorizations or advisory opinions, as applicable. Also, BIS emphasizes that it will continue to engage with industry following publication of this rule to educate and facilitate compliance.

One commenter also indicated concerns about "the costs of hardware compliance, particularly regarding aftermarket suppliers in the trucking industry." BIS has since chosen to exclude commercial vehicles from this regulation and intends to propose a subsequent rule to address specific national security risks tailored towards this sector.

Commenters urged BIS to re-evaluate the broader impact of the regulation and noted the potential impact the rule would have on the automotive supply chain. BIS has been working to carefully scope the rule so that it does not place an undue burden on industry or the broader automotive supply chain. One commenter expressed concern about similar actions potentially being taken by other governments. BIS notes that this rule is focused on the domestic market within the United States.

As described above, BIS agrees with commenters who indicated the initial compliance cost estimates described in

the NPRM were understated. However, BIS believes that subsequent annual costs will be lower due to the decreased reporting requirements in this final rule. BIS has revised this PRA section to account for compliance costs new to the final rule, the initial cost to comply with the rule, and lower annual cost to comply with the rule due to decreased reporting requirements.

One commenter wanted to ensure that the rule does not impair the ability for American consumers to access the data from their own vehicles. BIS notes that this concern is not implicated by this final rule. Relatedly, a few commenters shared the view that the rule will limit consumer choice and innovation, is a form of economic protectionism, and is overly broad. BIS has worked to carefully scope this rule and notes that there are numerous firms both in the United States and abroad who are leading the development of innovative products. Moreover, BIS believes that it has narrowed the scope of this rule to the extent possible by solely focusing on VCS hardware and connected software designed, developed, manufactured, or supplied by entities with a sufficient nexus to the PRC and Russia. This rule leaves the remainder of the global market out of scope.

The collections of information contained in this final rule have been submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) (PRA) under control number 0694-0145. This final rule will create new information collection requirements, which are subject to review and approval by OMB under the PRA.

For regulated entities whose covered software or VCS hardware is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, the entity would be responsible for attesting to BIS that due diligence has been conducted through the submission of a Declaration of Conformity. Entities must submit to BIS the name and contact information of the VCS hardware importer or connected vehicle manufacturer, and additional pieces of information, if known, based on the type of declaring entity. Entities must also certify to BIS that they have conducted due diligence into their supply chain and can attest that their covered software and VCS hardware is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or

Russia. A Declaration of Conformity will need to be submitted to BIS each calendar year or for every new connected vehicle model year.

Regulated entities whose covered software or VCS hardware is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia can apply for a specific authorization to engage in an otherwise prohibited transaction. In the application, an entity must submit information substantial enough to demonstrate to BIS that the otherwise prohibited transaction does not pose undue and unacceptable risk to U.S. national security. For example, entities may submit ISO/SAE 21434 Threat Analysis and Risk Assessments, including an assessment on the applicant's ability to limit PRC or Russian government access to, or influence over, the design, development, manufacture, or supply of the VCS hardware or covered software; security standards used by the applicant with respect to the VCS hardware or covered software; and/or other actions or proposals such as technical controls (e.g., software validation) or operational controls (e.g., physical and logical access monitoring procedures) the applicant intends to take to mitigate undue or unacceptable risk. Because specific authorization applications can vary in the level of specificity and volume of submitted materials, BIS cannot accurately estimate the costs and burden hours associated with an entity applying for a specific authorization.

Specific authorizations are reviewed and approved by BIS on a case-by-case basis. The final rule specifies that BIS may stipulate a variety of measures as conditions for the issuance of a specific authorization based on the level of risk that needs to be mitigated. For example, BIS may require the submission of annual third-party assessments as a condition. This condition would incur annual costs for an entity that seeks to engage in an otherwise prohibited transaction. Due to the variety of mitigating factors that BIS may impose when issuing specific authorizations, BIS cannot accurately estimate the costs and burden hours associated with an entity adhering to the conditions in a specific authorization.

There are several other compliance costs that regulated entities may incur from the rule, including the submission of advisory opinion requests and recordkeeping. Advisory opinions are voluntary requests that VCS hardware importers and connected vehicle manufacturers may submit to BIS to seek guidance on whether a prospective

transaction is subject to a prohibition of the rule. BIS sought comments on the potential number of advisory opinions that regulated entities may submit and did not receive any. Additionally, all regulated entities are required to retain primary business records under the recordkeeping requirements in the rule. For instance, entities subject to a Declaration of Conformity will need to maintain primary business records related to their covered transactions, while entities subject to approved specific authorizations may need to record keep additional documentation based on the conditions of a specific authorization. Due to these varying circumstances, BIS cannot accurately estimate the costs and burden hours associated with recordkeeping or submitting voluntary advisory opinion requests.

As noted above, BIS estimates that it will take regulated entities between 310 and 430 hours to initially read the rule, understand the rule, and conduct initial due diligence in preparation to comply. Every subsequent year after the publication of the final rule, the Department anticipates that the total annual burden (in hours) for connected vehicle manufacturers and VCS hardware importers to re-conduct due diligence into their VCS hardware or covered software supply chains and potentially re-submit a Declaration of Conformity will be 150 to 300 hours.

Based on analysis conducted in the accompanying final Regulatory Impact Analysis, BIS assesses that there are 27 to 215 entities potentially impacted by the rule. This range has been updated since the proposed rule to account for the removal of the commercial market from this regulation (narrowing the scope from NAICS: 3361 Motor Vehicle Manufacturing to NAICS: 33611 Automobile and Light Duty Motor Vehicle Manufacturing). The estimated cost burden for these entities to read the rule, understand the rule, and conduct initial due diligence is between \$56,671 and \$77,055. Every subsequent year, BIS estimates that the total annual cost burden for a connected vehicle manufacturer or VCS hardware importer to re-conduct due diligence into their VCS hardware or covered software supply chains and potentially re-submit a Declaration of Conformity will be \$24,200 to \$48,400 per year (average of operations manager, engineer, and lawyer hourly salaries [\$484/hour/3 = \$161.33] * [150 and 300 hours]). This broad range accounts for the varying levels of information that entities need to update in a Declaration of Conformity per model year. For example, a material change in the covered software or VCS

hardware could lead to the entity conducting more due diligence and then submitting a new Declaration of Conformity. Alternatively, where there are no material changes to the covered software or VCS hardware for a subsequent model year or calendar year, the connected vehicle manufacturer or VCS hardware importer can submit a confirmation that the previously submitted information remains accurate.

The estimated annual Federal salary cost to the U.S. Government to review and, if applicable, respond to Declarations of Conformity, specific authorization applications, and advisory opinion requests after the rule is fully implemented is \$971,800 [an estimated total of 430 Declarations of Conformity, specific authorization applications, and advisory opinion requests per year * hourly GS-13 staff rate of \$113/hour * average of 20 hours to review each Declaration of Conformity, specific authorization application, or advisory opinion request]. The \$113 per staff member per hour cost estimate for this information collection is consistent with the GS-scale salary data for a GS-13 Step 1 (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf>) multiplied by a factor of 2 to include the cost of benefits and overhead. While BIS expects the time to review and, if applicable, respond to Declarations of Conformity, specific authorization applications, and advisory opinion requests to vary, 20 hours is our best estimate of this average.

The total estimated annual cost to the U.S. Government is \$1,299,728. The calculation is as follows: Annual Federal Salary Cost [\$971,800] + Legal Support (two GS-15 Step 1 employees (multiplied by 2 to include the cost of benefits and overhead) @50% of their time) [\$327,928] = \$1,299,728.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a valid control number assigned by OMB. Approved information collection requests may be viewed at <https://www.reginfo.gov/public/do/PRAMain>.

8. Regulatory Flexibility Act

In compliance with Section 604 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, the Department has prepared a final regulatory flexibility analysis (FRFA) for this final rule. The FRFA describes the economic impacts the action may have on small entities. Public comments to the initial regulatory flexibility analysis (IRFA) and BIS's response is captured in subsection 2 below.

1. *A statement of the need for, and objectives of, the rule.* Connected vehicles contain a growing number of connected components. While these components provide greater safety and convenience through features like Wi-Fi, Bluetooth, cellular telecommunication, and satellite connectivity, the incorporation of progressively complex hardware and software systems enabling vehicle connectivity has also increased the attack surfaces through which malign actors and foreign adversaries may exploit vulnerabilities to gain access to vehicles. ICTS integral to connected vehicles present an undue or unacceptable risk to U.S. national security when those systems are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. The PRC and Russia are able to leverage legal and regulatory regimes to compel private companies subject to their jurisdiction, including carmakers and vehicle importers, to cooperate with state security and intelligence services. Cooperation could include providing data, logical access, encryption keys, and other vital technical information, as well as installing backdoors or bugs on equipment or in software updates, ultimately making vehicle equipment exploitable by foreign adversaries. Such privileged access potentially enables the PRC and Russia to exfiltrate sensitive data collected by connected vehicles through their components and allows remote manipulation for vehicles driven by U.S. persons.

2. *A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the final rule as a result of such comments.* BIS received minimal comments on the IRFA. One commenter noted that BIS should allow flexibility in the rulemaking approach where minimal or negligible risk is present, citing the IRFA. BIS agrees that there should be flexibility where minimal or negligible risk is present. To accomplish this, the rule's general and specific authorization mechanisms allow VCS hardware importers and connected vehicle manufacturers to engage in otherwise prohibited transactions if they meet certain requirements or conditions as will be identified by BIS. Another commenter noted that the NPRM, Preliminary Regulatory Impact Analysis, and IRFA did not adequately take into account the disruption the rule could cause to the availability of relevant

hardware and software. BIS acknowledges this commenter's concern, and notes that although the market for component systems this rule targets has very limited publicly available data, BIS has presented its best estimates for the regulatory impact of this rule and updated its assumptions and calculations in the Regulatory Impact Analysis based on publicly available information and comments to the NPRM.

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 final rule as a result of the comments.* BIS did not receive comments from the Chief Counsel for Advocacy of the Small Business Association in response to the proposed rule.

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.* BIS anticipates that the entities primarily responsible for compliance with this regulation will be connected vehicle manufacturers and VCS hardware importers. BIS assesses, based on publicly available information, that the U.S. connected vehicle supplier network is dominated by a small set of manufacturers, likely none of which would qualify as small entities. Additionally, BIS received no comments on the number of firms that engage in covered software and VCS hardware transactions in the United States. Based on information available, BIS currently estimates that there will be 27 to 215 connected vehicle manufacturers and VCS hardware importers potentially affected by this rule. This range is the U.S. Census Bureau Statistics of U.S. Businesses' estimate for the number of firms operating at least one establishment in NAICS 33611: Automobile and Light Duty Motor Vehicle Manufacturing, with the low estimate being the number of firms with 500 or more employees in total nationwide and the high estimate being all firms (this therefore includes an estimate of 188 firms with fewer than 500 employees). In comparison, the Small Business Administration's (SBA) small business size standard for NAICS 336110: Automobile and Light Duty Motor Vehicle Manufacturing (covering both manufacturer and supplier activities) uses 1,500 employees or fewer. Despite having this small entity estimate of 188, BIS does not have knowledge of which of these entities engage, or have the potential to engage, in covered software and VCS hardware

transactions. Therefore, BIS is unable to estimate how many entities captured in the 27 to 215 range are small entities and engage in covered software and VCS hardware transactions, and cannot estimate the percentage of connected vehicle manufacturers and VCS hardware importers that qualify as small entities.

We also note that it is possible that an affected entity may be considered a small entity using SBA's size standard based on employee counts for the automobile manufacturing industry, but could nevertheless have large sales or import volumes, which is BIS's primary concern because the national security risks are due to the number of connected vehicles on public roads rather than the size of the entities supplying them. For example, it is possible that a VCS hardware importer with fewer than 1,500 employees could be importing tens of thousands of VCS hardware units in a calendar year.

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.* As stated above, connected vehicle manufacturers and VCS hardware importers will bear the majority of the final rule's compliance costs. However, BIS maintains the flexibility to grant general authorizations to small entities that produce or import connected vehicles or VCS hardware units below a certain threshold each calendar year. The maintenance of records in support of the general authorization would be a compliance requirement for these small entities.

This rule requires regulated entities that cannot avail themselves of a general authorization to examine their automotive supply chain and ensure that their covered software and VCS hardware is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Entities that do not have supply chains that contain covered software and VCS hardware designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia must attest to BIS that this due diligence has been conducted through the submission of a Declaration of Conformity. A Declaration of Conformity entails both reporting and recordkeeping elements. Entities must submit to BIS the name and contact information of the VCS hardware

importer or connected vehicle manufacturer, and additional information, if known, based on the type of declaring entity. Entities must also certify to BIS that they have conducted due diligence into their supply chain and can attest that their covered software and VCS hardware is not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. Primary business records documenting these due diligence efforts, including the optional use of independent or hired third-party research, must be maintained by the declarant and made available to BIS upon request.

Entities that do manufacture or import covered software and VCS hardware designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia have the option of applying for a specific authorization. Specific authorizations will be reviewed by BIS on a case-by-case basis and, if granted, may require greater reporting requirements depending on BIS's assessment of the national security risks posed by the transaction. For example, BIS could require annual third-party verification as a condition for the issuance of a specific authorization.

BIS is requiring the maintenance of primary business records related to any transaction subject to a specific authorization, Declaration of Conformity, or general authorization for a period of 10 years, consistent with IEEPA's statute of limitations. Primary business records include contracts, import records, commercial invoices, bills of sale, essential correspondence, and any other records requested by BIS to assess compliance with this rule.

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 which affect the impact on small entities was rejected.* In the NPRM, BIS listed specific circumstances that would qualify for a general authorization, which would allow regulated entities to engage in otherwise prohibited transactions in certain lower-risk cases. Commenters suggested a variety of additional circumstances that BIS should consider qualifying for a general

authorization. In the final rule, rather than provide predetermined general authorizations in the rule itself, BIS will instead separately issue general authorizations under any circumstances that it feels presents lower risk, allowing BIS to maintain the flexibility to grant as many general authorizations as possible and appropriate. For example, BIS may issue a general authorization to further minimize the impact of this rule on small entities that produce or import connected vehicles or VCS hardware units below a certain threshold each calendar year. If small entities do not qualify for a general authorization but feel they have been adversely affected by the rule, they can apply for a specific authorization related to their specific circumstances. Additionally, the requirements associated with submitting a Declaration of Conformity have been significantly reduced from those proposed in the NPRM, minimizing the economic impact on all submitting entities. Finally, based on public comments to the NPRM, many of the reporting requirements have been converted to recordkeeping and certification provisions. These changes will make Declarations of Conformity less burdensome for all regulated entities.

List of Subjects in 15 CFR Part 791

Business and industry, Communications, Computer technology, Critical infrastructure, Executive orders, Foreign Persons, Investigations, National security, Penalties, Technology, Telecommunications.

Elizabeth L.D. Cannon,

Executive Director, Office of Information and Communications Technology and Services, Bureau of Industry and Security, United States Department of Commerce.

For the reasons set out in the preamble, 15 CFR 791, is amended as follows:

PART 791—SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN

■ 1. The authority citation for part 791 continues to read as follows:

Authority: 50 U.S.C. 1701*et seq.*; 50 U.S.C. 1601*et seq.*; E.O. 13873, 84 FR 22689; E.O. 14034, 86 FR 31.

■ 2. Amend part 791 by adding subpart D, consisting of § 791.300 through § 791.321, to read as follows:

Subpart D—ICTS Supply Chain: Connected Vehicles

Sec.

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§ 791.300 Purpose and scope.

The inclusion in connected vehicles of certain ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of certain foreign adversaries poses undue or unacceptable risks to U.S. national security. To address these undue or unacceptable risks, it is the purpose of this subpart to:

(a) Prohibit ICTS transactions that involve certain software and hardware that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the People's Republic of China (PRC) or the Russian Federation (Russia), as defined in § 791.4, and that directly enable connected vehicle Automated Driving Systems (ADS) or Vehicle Connectivity Systems (VCS), as defined in this subpart;

(b) Implement Declarations of Conformity to provide a mechanism for connected vehicle manufacturers and VCS hardware importers to communicate to BIS that they have conducted supply chain due diligence, and to confirm that no prohibited transactions, as defined in this subpart, have knowingly occurred;

(c) Provide for the issuance of general authorizations for certain transactions that would otherwise be prohibited by this subpart, but where certain factors described in the authorizations reduce the risk to an acceptable level;

(d) Provide a mechanism to apply for specific authorizations for certain transactions that would otherwise be prohibited by this subpart, where the undue or unacceptable risks can be

reasonably mitigated, based on criteria and conditions that are specifically constructed for each applicant; and

(e) Incentivize connected vehicle manufacturers, VCS hardware importers, and related suppliers to adopt and enhance measures to help secure the U.S. ICTS supply chain for connected vehicles.

§ 791.301 Definitions.

The following definitions apply only to this subpart. For additional definitions applicable to all of part 791, see 15 CFR 791.2. If a term is defined differently in this subpart than in 15 CFR 791.2, the definition listed in this section will apply to this subpart.

Automated Driving System means hardware and software that, collectively, are capable of performing the entire dynamic driving task for a completed connected vehicle on a sustained basis, regardless of whether it is limited to a specific operational design domain (ODD).

Completed connected vehicle means a connected vehicle that requires no further manufacturing operations to perform its intended function. For the purposes of this subpart, the integration of an Automated Driving System into a connected vehicle constitutes a manufacturing operation for a completed connected vehicle.

Connected vehicle means a vehicle driven or drawn by mechanical power and manufactured primarily for use on public streets, roads, and highways, that integrates onboard networked hardware with automotive software systems to communicate via dedicated short-range communication, cellular telecommunications connectivity, satellite communication, or other wireless spectrum connectivity with any other network or device. A vehicle operated only on a rail line is not included in this definition. For the purposes of this subpart, a connected vehicle with a gross vehicle weight rating of more than 4,536 kilograms (10,000 pounds) is not included in this definition.

Connected vehicle manufacturer means a U.S. person who:

(1) Manufactures or assembles completed connected vehicles in the United States for sale in the United States;

(2) Imports completed connected vehicles for sale in the United States; and/or

(3) Integrates ADS software on a completed connected vehicle for sale in the United States. A connected vehicle manufacturer may also be a VCS hardware importer, as defined herein, if VCS hardware has already been

installed in a connected vehicle when the connected vehicle manufacturer imports it.

Covered software means the software-based components, including application, middleware, and system software, in which there is a foreign interest, executed by the primary processing unit or units of an item that directly enables the function of Vehicle Connectivity Systems or Automated Driving Systems at the vehicle level. Covered software does not include firmware, which is characterized as software specifically programmed for a hardware device with a primary purpose of directly controlling, configuring, and communicating with that hardware device. Covered software also does not include open-source software, which is characterized as software for which the human-readable source code is available in its entirety for use, study, re-use, modification, enhancement, and redistribution by the users of such software, unless that open-source software has been modified for proprietary purposes and not redistributed or shared.

Covered software also does not include software subcomponents that were designed, developed, manufactured, or supplied prior to March 17, 2026, as long as those software subcomponents are not maintained, augmented, or otherwise altered by an entity owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary after March 17, 2026.

Declarant means the U.S. person submitting a Declaration of Conformity to BIS.

FCC ID Number means the unique alphanumeric code identifying a product subject to certification by the Federal Communications Commission composed of a:

- (1) Grantee code; and
- (2) Product code.

Foreign interest, for purposes of this subpart, means any interest in property of any nature whatsoever, whether direct or indirect, by a non-U.S. person.

Hardware Bill of Materials (HBOM) means a formal record the supply chain relationships of parts, assemblies, and components required to create a physical product, including information identifying the manufacturer, and related firmware.

Import means, in the context of this subpart, with respect to any article, the entry of such article into the United States Customs Territory. It does not include admission of an article from outside the United States into a foreign-trade zone for storage pending further assembly in the foreign-trade zone or

shipment to a foreign country. This definition also applies to related terms such as *importing* or *imported*.

Item means a component or set of components with a specific function at the vehicle level. A system may also be considered an item if it implements a function.

Knowingly means having knowledge of a circumstance (the term may be a variant, such as “know,” “reason to know,” or “reason to believe”), to include not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person’s willful avoidance of facts.

Model year means the year used to designate a discrete vehicle model, irrespective of the calendar year in which the vehicle was actually produced, provided that the production period does not exceed 24 months.

Person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary means:

(1) Any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary;

(2) Any person, wherever located, who is a citizen or resident of a foreign adversary or a country controlled by a foreign adversary, and is not a United States citizen or permanent resident of the United States;

(3) Any corporation, partnership, association, or other organization with a principal place of business in, headquartered in, incorporated in, or otherwise organized under the laws of a foreign adversary or a country controlled by a foreign adversary; or

(4) Any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary, to include circumstances in which any person identified in paragraphs (1) through (3) of this definition possesses the power, direct or indirect, whether or not exercised, through the ownership of a majority or a dominant minority of the total outstanding voting interest in an entity, board representation, proxy voting, a special share, contractual arrangements, formal or informal arrangements to act in concert, or other means, to determine,

direct, or decide important matters affecting an entity.

Prohibited transactions mean, collectively, the transactions described in § 791.302 (Prohibited VCS hardware transactions), § 791.303 (Prohibited covered software transactions), or § 791.304 (Related prohibited transactions) of this subpart.

Safe means, in the context of this subpart, distributing for purchase, lease, or other commercial operations a new completed connected vehicle for a price, to include the transfer of completed connected vehicles from a connected vehicle manufacturer to a dealer or distributor, as those terms are defined in 49 U.S.C. 30102. This definition also applies to the related terms such as *sell* or *selling*.

Software Bill of Materials (SBOM) means a formal record containing the details and supply chain relationships of various components used in building software. Software developers and vendors often create products by assembling existing open source and commercial software components. The SBOM enumerates these components in a product.

United States means the United States of America, the States of the United States, the District of Columbia, and any commonwealth, territory, dependency, or possession of the United States, or any subdivision thereof, and the territorial sea of the United States.

Vehicle Connectivity System (VCS) means a hardware or software item installed in or on a completed connected vehicle that directly enables the function of transmission, receipt, conversion, or processing of radio frequency communications at a frequency over 450 megahertz. VCS does not include a hardware or software item that exclusively:

(1) enables the transmission, receipt, conversion, or processing of automotive sensing (e.g., LiDAR, radar, video, ultrawideband);

(2) enables the transmission, receipt, conversion, or processing of ultrawideband communications to directly enable physical vehicle access (e.g., key fobs);

(3) enables the receipt, conversion or processing of unidirectional radio frequency bands (e.g., global navigation satellite systems (GNSS), satellite radio, AM/FM radio); or

(4) supplies or manages power for the VCS.

VCS hardware means software-enabled or programmable components if they directly enable the function of and are directly connected to Vehicle Connectivity Systems, or are part of an item that directly enables the function

of Vehicle Connectivity Systems, including but not limited to: microcontroller, microcomputers or modules, systems on a chip, networking or telematics units, cellular modem/modules, Wi-Fi microcontrollers or modules, Bluetooth microcontrollers or modules, satellite communication systems, other wireless communication microcontrollers or modules, external antennas, digital signal processors, and field-programmable gate arrays. VCS hardware does not include component parts that do not contribute to the communication function of VCS hardware (e.g., brackets, fasteners, plastics, and passive electronics, diodes, field-effect transistors, and bipolar junction transistors).

VCS hardware importer means a U.S. person who imports:

(1) VCS hardware for further manufacturing, incorporation, or integration into a completed connected vehicle that is intended to be sold or operated in the United States; or

(2) VCS hardware that has already been installed, incorporated, or integrated into a connected vehicle, or a subassembly thereof, that is intended to be sold as part of a completed connected vehicle in the United States.

§ 791.302 Prohibited VCS hardware transactions.

(a) VCS hardware importers are prohibited from knowingly importing into the United States VCS hardware that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(b) In the context of this subpart, VCS hardware will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, based solely on the country of citizenship of one or more natural persons who are employed by, contracted by, or otherwise similarly engaged in such actions through the entity designing, developing, manufacturing, or supplying the hardware.

§ 791.303 Prohibited covered software transactions.

(a) Connected vehicle manufacturers are prohibited from knowingly importing into the United States completed connected vehicles that incorporate covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the

jurisdiction or direction of the PRC or Russia.

(b) Connected vehicle manufacturers are prohibited from knowingly selling within the United States completed connected vehicles that incorporate covered software that is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(c) In the context of this subpart, covered software will not be considered to be designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, based solely on the country of citizenship of one or more natural persons who are employed by, contracted by, or otherwise similarly engaged in such actions through the entity designing, developing, manufacturing, or supplying the software.

§ 791.304 Related prohibited transactions.

Connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, are prohibited from knowingly selling in the United States completed connected vehicles that incorporate VCS hardware or covered software, regardless of whether such VCS hardware or covered software is designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia. These connected vehicle manufacturers are also prohibited from offering commercial services in the United States that utilize completed connected vehicles that incorporate ADS.

§ 791.305 Declaration of Conformity.

(a) *Requirements*—(1) *VCS hardware*: A VCS hardware importer must submit a Declaration of Conformity to BIS prior to importing VCS hardware, unless otherwise specified by this subpart. The Declaration of Conformity for VCS hardware shall include:

(i) The name and address of the VCS hardware importer, to include identifying information for an individual point of contact (including name, email address, and phone number);

(ii) If known, the FCC ID Number associated with the VCS hardware and, if applicable, of the subcomponents contained therein;

(iii) If known, the make and model of the connected vehicle(s) for which the VCS hardware is intended, or already integrated;

(iv) A certification that the VCS hardware described in the Declaration of Conformity was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(v) A certification that the declarant has conducted due diligence (with or without the use of third-party assessments) to inform the above certification, and the declarant or a delegated third party maintains documentation (either through an HBOM or otherwise) and third-party assessments (as applicable) in support of the above certification, which can be made available upon request by BIS;

(vi) Identification as to who maintains the documentation and third-party assessments (as applicable) as certified above;

(vii) A certification that the declarant has taken all possible measures, either contractually or otherwise, to ensure any necessary documentation and assessments from suppliers will be furnished to BIS upon request either by the declarant, or, in cases including confidential business information, directly by the supplier; and

(viii) If applicable, an indication as to whether the submission is an update to a prior Declaration of Conformity, and if so, the date of the last submission.

(2) *Covered software*: A connected vehicle manufacturer must submit a Declaration of Conformity to BIS prior to importing or selling in the United States completed connected vehicles that incorporate covered software, unless otherwise specified by this subpart. The Declaration of Conformity for covered software shall include:

(i) The name and address of the connected vehicle manufacturer, to include information identifying an individual point of contact (including name, email address, and phone number);

(ii) The make, model, trim, and Vehicle Identification Number (VIN) series applicable to the completed connected vehicles that incorporate the covered software;

(iii) A certification that the covered software described in the Declaration of Conformity was not designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia;

(iv) A certification that the declarant has conducted due diligence (with or without the use of third-party assessments) to inform the above certification, and the declarant or a delegated third party maintains documentation (either through an

SBOM or otherwise) and third-party assessments (as applicable) that are sufficient to identify, at minimum, the author name, timestamp, component name, and supplier name of all proprietary additions to the development of the covered software, which can be made available upon request by BIS;

(v) Identification as to who maintains the documentation and third-party assessments (as applicable) as certified above;

(vi) A certification that the declarant has taken all possible measures, either contractually or otherwise, to ensure any necessary documentation and assessments from suppliers will be furnished to BIS upon request either by the declarant, or, in cases including confidential business information, directly by the supplier; and

(vii) If applicable, an indication as to whether the submission is an update to a prior Declaration of Conformity and the date of the last submission.

(b) *Certification*. A certification is a written statement or attestation within a Declaration of Conformity in § 791.305(a) above to the U.S. Government, signed by a duly authorized designee, certifying under the penalties provided in 18 U.S.C. 1001, that the information provided is accurate and complete in all material respects to the best knowledge of the designee on behalf of the entity filing the Declaration of Conformity.

(1) For purposes of this section, a duly authorized designee is:

(i) In the case of a partnership, any general partner thereof;

(ii) In the case of a corporation, the chief executive officer, or any officer with the authority to bind the corporation;

(iii) An employee with authority to make certifications on behalf of the company as designated by a person in (i) or (ii); and

(iv) In the case of an entity lacking partners and officers, any individual manager, or designated agent who has been explicitly authorized by the board of directors or equivalent to sign contracts and make legally binding agreements on behalf of the entity.

(c) *Additional Information*. BIS may request additional information after receipt of a Declaration of Conformity.

(d) *Reliance on Third-Party Assessments*. Declarants are permitted to utilize assessments produced by third parties to assist and prepare a Declaration of Conformity, in addition to ensuring ongoing compliance with this rule, as long as such entities conform to § 791.315 of this subpart.

(e) *Material Changes*. The following events will require an update to a previously submitted Declaration of Conformity:

(1) The discovery, by the declarant, of an omission, inaccuracy, or error in the information provided to BIS in a prior Declaration of Conformity that could reasonably mislead as to the true source of VCS hardware or covered software in question.

(2) Covered software updates alone do not constitute a material change unless an additional condition above is true.

(f) *Change in circumstance*. If the connected vehicle manufacturer or VCS hardware importer determines that articles subject to a Declaration of Conformity are no longer eligible, it must, within 30 days, cease any prohibited conduct and submit a specific authorization application, pursuant to § 791.307(m).

(g) *Deadline to Submit Declarations of Conformity*. Connected vehicle manufacturers and VCS hardware importers shall submit Declarations of Conformity prior to the first sale of the subject connected vehicle in the United States, prior to the import of VCS hardware as specified in this section, and following discovery of a material change that makes a prior Declaration of Conformity no longer accurate.

(1) Connected vehicle manufacturers shall submit a Declaration of Conformity at least 60 days prior to the first import or first sale of each model year of completed connected vehicle that incorporates covered software. Declarants may submit a single Declaration of Conformity for all connected vehicles that use the same covered software, grouped by make, model, and VIN series.

(2) VCS hardware importers shall submit a Declaration of Conformity at least 60 days prior to the first import of VCS hardware for each model year for units associated with a vehicle model year, or calendar year for units not associated with a vehicle model year. VCS hardware importers may submit a single Declaration of Conformity detailing all VCS hardware models that will be imported in the model year or calendar year.

(3) Connected vehicle manufacturers and VCS hardware importers must notify BIS of any material change to the information conveyed in a previously submitted Declaration of Conformity by submitting a revised Declaration of Conformity within 60 days following the discovery of such change. A declarant's obligation to inform BIS of material changes to the information ceases 10 years after submission of the

original Declaration of Conformity for that model year or calendar year.

(h) *Annual updates to Declarations of Conformity.* If applicable, connected vehicle manufacturers and VCS hardware importers may, in lieu of submitting a new Declaration of Conformity, submit a confirmation that the prior Declaration of Conformity remains accurate and that associates the relevant new model year of vehicles (if known) in lieu of submitting a new Declaration of Conformity.

(1) Where there are no material changes to the covered software for a subsequent model year of completed connected vehicles, the connected vehicle manufacturer may submit a confirmation no later than one year after the previous submission, certifying that the prior information remains accurate, and that associates the new relevant model year of vehicles to an existing Declaration of Conformity.

(2) Where there are no material changes to the VCS hardware for a subsequent model year of completed connected vehicles (if known) or calendar year, the VCS hardware importer may submit a confirmation no later than one year after the previous submission, certifying that the prior information remains accurate, and that associates the new relevant model year of vehicles (if known) to an existing Declaration of Conformity.

(i) *Submission Instructions.* The declarant shall follow the electronic filing instructions on BIS's website, <https://www.bis.gov/OICTS>.

(j) *Verification.* BIS, in its sole discretion, may choose to verify Declarations of Conformity that have been submitted by VCS hardware importers and connected vehicle manufacturers.

(k) *Connected vehicle introduced by means of false information in the Declaration of Conformity.* Any person who submits false information in a Declaration of Conformity, with knowledge that such information is false, and engages in one or more prohibited transactions, may incur penalties as defined in § 791.318.

(l) *Exemptions.* No Declaration of Conformity is required if the only foreign interest in a transaction arises from a foreign person's equity ownership of a U.S. person, whether through ownership of public shares or otherwise. This exemption has no effect on transactions where a foreign interest arises from a foreign entity's design, development, manufacture, or supply of VCS hardware or covered software for a U.S. person or where equity ownership allows a foreign person to exercise control over the U.S. person. Further,

this exemption has no effect on the analysis of whether or not an entity is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

§ 791.306 General authorizations.

(a) *Overview.* VCS hardware importers and connected vehicle manufacturers may rely on a general authorization to engage in an otherwise prohibited transaction if they meet the stated requirements or conditions identified in the general authorization and are not subject to the restrictions identified in this section. Records demonstrating compliance with the terms of general authorizations must be retained for a period of 10 years, as specified in § 791.312, and be made available to BIS upon request.

(b) *General course of procedure.* BIS may issue general authorizations for certain types of transactions subject to the prohibitions contained in this subpart. In determining whether to issue a general authorization, BIS may consider any information or material BIS deems relevant and appropriate, classified or unclassified, from any Federal department or agency, or from any other source. BIS will publish general authorizations it issues under this subpart on its website (<https://www.bis.gov/OICTS>), and will also publish them in the **Federal Register**.

(c) *Relationship with specific authorizations.* BIS will not grant specific authorizations for transactions in which a general authorization is applicable.

(d) *Instructions.* Persons availing themselves of certain general authorizations may be required to file reports and statements in accordance with the instructions specified by BIS in each general authorization. Failure to fulfill instructions provided in a general authorization may nullify the authorization and result in a violation of the applicable prohibitions that may be subject to BIS enforcement action.

(e) *Change in circumstance.* Unless otherwise prescribed by BIS, within 30 days of discovering a change in circumstance, the VCS hardware importer or connected vehicle manufacturer must assess if it still qualifies for the general authorization.

(1) If the connected vehicle manufacturer or VCS hardware importer determines that articles subject to a general authorization have been used outside the conditions of the general authorization, it must, within 30 days of such a determination, cease any prohibited conduct, conduct an internal inquiry, and submit to BIS a report identifying any prohibited transactions,

the number of connected vehicles or VCS hardware units implicated, and proposed remedial measures.

(f) *Verification.* BIS may, at its discretion, seek verification from VCS hardware importers and connected vehicle manufacturers as to whether they are relying on a general authorization, and if so, may request documentation to verify compliance with this subpart.

(g) *Restrictions.* VCS hardware importers and connected vehicle manufacturers may not avail themselves of any general authorization if any one or more of the following apply:

(1) BIS has notified, either directly or through an advisory opinion, the VCS hardware importer or connected vehicle manufacturer is not eligible for a general authorization; or

(2) The VCS hardware importer or connected vehicle manufacturer is owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

§ 791.307 Specific authorizations.

(a) *Prohibited transactions authorized.* Upon receipt of a valid and complete application, BIS may grant specific authorizations to permit a VCS hardware importer or connected vehicle manufacturer to engage in an otherwise prohibited transaction.

(b) *Policy.* It is the policy of BIS not to review applications for specific authorizations for transactions that are otherwise permitted by a general authorization.

(c) *Applications for specific authorizations.* Applications for specific authorizations shall include, at a minimum, a description of the nature of the otherwise prohibited transaction(s), including the following:

(1) The identity of the parties engaged in the transaction, including relevant corporate identifiers and information sufficient to identify the ultimate beneficial ownership of the transacting parties;

(2) An overview of the VCS hardware or covered software that is designed, developed, manufactured, or supplied by a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia, including persons responsible for assembling and packaging VCS hardware or covered software;

(3) If known, the make, model, and trim of the connected vehicle(s) in which the VCS hardware or covered software will be integrated;

(4) The intended function of the VCS hardware or covered software;

(5) Documentation to support the information contained in the

application, such as any ISO/SAE 21434 Threat Analysis and Risk Assessments (if available);

(6) An assessment of the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture, or supply of the VCS hardware or covered software;

(7) Security standards used by the applicant with respect to the VCS hardware or covered software; and

(8) Other actions and proposals such as technical controls (e.g., software validation) or operational controls (e.g., physical and logical access monitoring procedures) the applicant intends to take to mitigate undue or unacceptable risk, if applicable.

(d) *Application submission procedures and timing.* VCS hardware importers or connected vehicle manufacturers who seeks to engage in an otherwise prohibited transaction must submit an application for a specific authorization in writing prior to engaging in the transaction, and await a decision from BIS prior to engaging in the transaction. Specific authorization submissions must be delivered to BIS as specified on its website, <https://www.bis.gov/OICTS>.

(e) *Additional conditions.* Only one application for a specific authorization should be submitted to BIS for each otherwise prohibited transaction; multiple parties submitting an application for a specific authorization for the same transaction may result in processing delays.

(f) *Information to be supplied.* An applicant may be required to furnish additional information as BIS deems necessary to assist in making a decision. BIS may request an oral briefing by the applicant and any other relevant parties. The applicant may present additional information concerning an application for a specific authorization at any time before BIS issues its decision regarding the application.

(g) *Review and decisions.*

Applications for specific authorizations will be reviewed on a case-by-case basis, and conditions to be applied to each specific authorization may vary as needed to mitigate any risk that arises as a result of the otherwise prohibited transaction. Such review will include an evaluation of the risks and potential mitigation measures proposed by the applicant for the particular transaction. The risks that BIS may consider include, but are not limited to, risks of data exfiltration from, and remote manipulation or operation of, the connected vehicle and the extent and nature of foreign adversary involvement in the design, development,

manufacture, or supply of the VCS hardware or covered software. Mitigation may include the applicant's ability to limit PRC or Russian government access to, or influence over the design, development, manufacture, or supply of the VCS hardware or covered software; security standards used by the applicant and if such standards can be validated by BIS or a third party; and other actions or proposals the applicant intends to take to mitigate undue or unacceptable risk. BIS will advise each applicant in writing of the decision respecting the filed application. Decisions regarding specific authorizations will not be made publicly available.

(h) *Processing period.* BIS will provide a decision regarding an application for a specific authorization within 90 days unless BIS determines, in its sole discretion, and notifies the applicant within that 90-day period, that additional time is required. Failure or delays by the applicant in submitting additional information requested by BIS may delay or prevent BIS's ability to issue a specific authorization.

(i) *Scope.* (1) Unless otherwise specified in the authorization, a specific authorization applies only to the transaction:

(i) Between the parties identified in the specific authorization;

(ii) With respect to the otherwise prohibited transaction(s) described in the authorization; and

(iii) If the conditions specified in the specific authorization are satisfied. The applicant must inform any other parties identified in the specific authorization of the authorization's scope and specific conditions.

(2) As a condition for the issuance of any specific authorization, BIS may require the applicant to submit third-party assessments or SBOMs/HBOMs as may be prescribed in the specific authorization or otherwise communicated to the applicant by BIS. Reports should be sent in accordance with the instructions provided in the applicable specific authorization.

(3) Any materially false or misleading representation in or otherwise associated with the application, or in any document submitted in connection with the application under this section, shall cause the specific authorization to be deemed void as of the date of issuance, and the applicant may incur penalties as specified in § 791.318.

(j) *Verification.* BIS may establish, in its sole discretion as conditions for receiving a specific authorization, any compliance, auditing, or verification requirements.

(k) *Effect of denial.* BIS's denial of a specific authorization may be appealed as described in § 791.309. BIS's denial of a prior specific authorization does not preclude parties from filing an application for a specific authorization for a separate otherwise prohibited transaction. The applicant may at any time, by written correspondence, request reconsideration of the denial of an application based on new material facts or changed circumstances.

(l) *Effect of specific authorization.* (1) No specific authorization issued under this subpart, or otherwise issued by BIS, permits or validates any prohibited transaction effectuated prior to the issuance of such specific authorization unless specifically provided for in the specific authorization.

(2) No regulation, ruling, instruction, or authorization permits any prohibited transaction under this subpart unless the regulation, ruling, instruction or authorization is issued by BIS and specifically refers to this subpart. No regulation, ruling, instruction, or authorization referring to this subpart shall be deemed to permit any prohibited transaction prohibited by any provision of this subpart unless the regulation, ruling, instruction, or authorization specifically refers to such provision. Any specific authorization permitting any otherwise prohibited transaction has the effect of removing those prohibitions from the transaction, but only to the extent specifically stated by the terms of the specific authorization. Unless the specific authorization otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(3) Nothing contained in this subpart shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain an authorization from another department or agency of the U.S. Government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency.

(4) Specific authorizations will be approved for a duration of no less than one (1) model year or calendar year except as provided in § 791.307(m).

(m) *Exceptions.* BIS may approve specific authorizations for a period of less than one (1) calendar year on a case-by-case basis under the following circumstances:

(1) 2027 model years that include covered software and are actively being

sold or imported as of the effective date of this rule;

(2) Covered software and VCS hardware supply chains that are affected by force majeure events;

(3) As a result of a corporate merger, investment, acquisition, joint venture, or conversion of equity (such as from debt) that occurs during model year production;

(4) As a result of the closure or relocation of facilities involved in the production of covered software or VCS hardware; and

(5) Other instances as determined by BIS.

(n) *Records.* Persons receiving a specific authorization are required to maintain records for a period of 10 years, as required in § 791.312, as well as to submit reports and statements in accordance with the instructions specified in each specific authorization.

(o) *Amendment, modification, or rescission.* Except as otherwise provided by law, any specific authorization or instructions issued thereunder may be amended, modified, or rescinded by BIS at any time.

§ 791.308 Exemptions.

(a) VCS hardware importers may engage in prohibited transactions described in § 791.302 without an authorization as required under §§ 791.306 and 791.307, and are exempt from submitting Declarations of Conformity with respect to all other transactions, as described in § 791.305 provided that:

(1) For VCS hardware units not associated with a vehicle model year, the import of the VCS hardware occurs prior to January 1, 2029; or

(2) The VCS hardware is associated with a vehicle model year prior to 2030, the VCS hardware is imported as part of a connected vehicle with a model year prior to 2030, or the VCS hardware is imported for purposes of repair or warranty for a connected vehicle with a model year prior to 2030.

(b) Connected vehicle manufacturers may engage in prohibited transactions described in § 791.303 without authorization as required under §§ 791.306 or 791.307 and are exempt from submitting Declarations of Conformity with respect to all other transactions, as described in § 791.305, provided that the completed connected vehicle that incorporates covered software described in § 791.303(a)(1) was manufactured prior to model year 2027.

(c) Connected vehicle manufacturers who are owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia may engage in

prohibited transactions described in § 791.304 without authorization as required under §§ 791.306 or 791.307, and are exempt from submitting Declarations of Conformity to all other transactions, provided that the completed connected vehicle that incorporates VCS hardware and/or covered software was manufactured prior to model year 2027.

§ 791.309 Appeals.

(a) *Scope.* Any person claiming to be directly and adversely affected by any of the listed administrative actions taken by BIS pursuant to this subpart may appeal to the Under Secretary for reconsideration of that administrative action. Only the following types of administrative actions are subject to the appeals procedures described in this subpart:

(1) Denial of an application for a specific authorization;

(2) Suspension or revocation of an issued specific authorization; or

(3) Determination of ineligibility for a general authorization.

(b) *Designated appeals reviewer and coordinator.* The Under Secretary may delegate to the Deputy Under Secretary of Commerce for Industry and Security or to another BIS official the authority to review and decide the appeal, and to exercise any other function of the Under Secretary under this section. In addition, the Under Secretary may designate any employee of BIS to be an appeals coordinator to assist in the review and processing of an appeal under this subpart. The responsibilities of an appeals coordinator may include presiding over informal hearings.

(c) *Appeals procedures—(1) Filing.* An appeal under this subpart must be submitted to the Under Secretary by email or at the following address: Bureau of Industry and Security, U.S. Department of Commerce, Room 3898, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230 no later than 45 days after the date appearing on the written notice of administrative action.

(2) *Content of appeal.* The appeal must include a full written statement in support of the appellant's position. The appeal must include a precise statement of the reasons that the appellant believes that the administrative action has a direct and adverse effect and should be reversed or modified. The Under Secretary or the designated official may request additional information that would be helpful in resolving the appeal, and may accept additional submissions from the appellant. The Under Secretary or the designated official will not ordinarily

accept any submission filed voluntarily more than 30 days after the filing of the appeal.

(3) *Request for informal hearing.* In addition to the written statement submitted in support of an appeal, an appellant may request, in writing, at the time an appeal is filed, an opportunity for an informal hearing. A hearing is not required, and the Under Secretary or the designated official may grant or deny a request for an informal hearing at the Under Secretary or the designated official's sole discretion. Any hearings will be held in the District of Columbia unless the Under Secretary or the designated official determines, based upon good cause shown, that another location would be preferable.

(d) *Informal hearing procedures—(1) Presentations.* If a hearing request is granted, the Under Secretary or the designated official may provide an opportunity for the appellant to make an oral presentation at an informal hearing based on the materials previously submitted by the appellant or made available by BIS. The Under Secretary or the designated official may require that any facts in controversy be covered by an affidavit or testimony given under oath or affirmation.

(2) *Evidence.* The rules of evidence prevailing in courts of law do not apply, and all evidentiary material deemed by the Under Secretary or the designated official to be relevant and material to the proceeding, and not unduly repetitious, will be received and considered.

(3) *Procedural questions.* The Under Secretary or the designated official has the authority to limit the number of people attending the hearing, to impose any time or other limitations deemed reasonable, and to determine all procedural questions.

(4) *Transcript.* A transcript of an informal hearing shall not be made, unless the Under Secretary or the designated official determines that the national interest or other good cause warrants it, or if the appellant requests a transcript. If the appellant requests, and the Under Secretary or the designated official approves the taking of, a transcript, the appellant will be responsible for paying all expenses related to production of the transcript.

(5) *Report.* Any person designated by the Under Secretary to conduct an informal hearing shall submit a written report containing a summary of the hearing and recommended action to the Under Secretary.

(e) *Amicus filings.* At the request of the appellant, parties not subject to the administrative action under appeal may submit amicus filings in support of the appellant prior to any informal hearing.

(f) *Decisions.* In addition to the documents specifically submitted in connection with the appeal, the Under Secretary or the designated official may consider any recommendations, reports, or other relevant documents available to BIS in determining the appeal, but shall not be bound by any such information, nor prevented from considering any other relevant information, or consulting with any other person or groups, in making a decision. The Under Secretary or the designated official may adopt any other procedures deemed necessary and reasonable for considering an appeal, including by providing the appellant with an interim or proposed decision and offering the appellant an opportunity to provide comments. The Under Secretary or the designated official shall decide an appeal within a reasonable time after receipt of the appeal. The decision shall be issued to the appellant in writing and contain a statement of the reasons for the action and address any arguments contrary to the decision presented by the appellant. The decision of the Under Secretary or the designated official shall be final.

(g) *Effect of appeal.* Acceptance and consideration of an appeal shall not affect any administrative action, pending or in effect, unless the Under Secretary or the designated official, upon request by the appellant and with opportunity for a response, grants a stay.

§ 791.310 Advisory opinions.

(a) VCS hardware importers and connected vehicle manufacturers may request an advisory opinion from BIS to determine whether a prospective transaction is subject to a prohibition, or requirement under this subpart. The requestor must have a direct financial interest in the substance of the question(s) presented, and the submission must include the name of the parties to the transaction.

(b) Requests for advisory opinions must be delivered to BIS as specified on its website, <https://www.bis.gov/OICTS>.

(c) Persons submitting advisory opinion requests are encouraged to provide as much information as possible to assist BIS in making a determination, to include the following information:

(1) The name, title, telephone, and email address of the submitter;

(2) The submitter's complete address, comprised of street address, city, state, country, and postal code;

(3) All available information identifying the parties to the prospective transaction;

(4) Information regarding the VCS hardware and/or covered software and any descriptive literature, brochures,

technical specifications, or papers that provide sufficient technical detail to enable BIS to verify whether the prospective transaction would constitute a prohibited transaction as defined in this subpart;

(5) For connected vehicle manufacturers: the make, model, and trim level, or other identifying information of the completed connected vehicle;

(6) For VCS hardware importers: the identification of the system; and, if known, the make, model, and trim of the group of completed connected vehicles for which the equipment is intended; and

(7) Any other information that the submitter believes to be material to the prospective transaction.

(d) BIS may consider third-party materials on a case-by-case basis as part of its review of an advisory opinion request. Each person that submits an advisory opinion request or information in support of another party's advisory opinion request shall provide any additional information or documents that BIS may thereafter request in its review of the matter.

(e) BIS shall issue an advisory opinion within 60 days of the request unless it notifies the requester within that 60-day period that more time is required. Failure or delays by the applicant in submitting additional information requested by BIS may delay or prevent BIS's ability to issue an advisory opinion.

(f) Each advisory opinion can be relied upon by the requesting party or parties to the extent the disclosures made pursuant to this subpart were accurate and complete and to the extent the disclosures continue to reflect circumstances accurately and completely after the date of the issuance of the advisory opinion. An advisory opinion will not restrict enforcement actions by any agency other than BIS. It will not affect a requesting party's obligations to any other agency or under any statutory or regulatory provision other than those specifically discussed in the advisory opinion.

(g) BIS may publish on its website an advisory opinion that may be of broad interest to the public, with redactions where necessary to protect Confidential Business Information.

(h) BIS may, at its sole discretion, decline to issue an advisory opinion within 60 days after receipt of the request.

§ 791.311 "Is-Informed" notices.

(a) BIS may inform VCS hardware importers or connected vehicle manufacturers either individually by

specific notice or, for larger groups, through a separate notice published in the **Federal Register**, that a specific authorization is required because an activity could constitute a prohibited transaction.

(b) Specific notice that a specific authorization is required may be given only by, or at the direction of, the Under Secretary or a BIS official designated by the Under Secretary.

§ 791.312 Recordkeeping.

(a) Except as otherwise provided herein, or through subsequent communication with BIS, VCS hardware importers, connected vehicle manufacturers, and/or third-party assessors (if applicable) shall keep all primary business records related to the execution of each transaction for which a Declaration of Conformity, general authorization, or specific authorization would be required under §§ 791.305, 791.306, or 791.307. Primary business records include contracts, import records, commercial invoices, bills of sale, corporate policy documentation, and reports produced by third parties created for the purposes of compliance with this rule. Regardless of whether these transactions are effectuated pursuant to a general authorization, specific authorization, or otherwise, such records shall be available for examination for at least 10 years after the date of such transactions.

(b) Third-party assessors are required to maintain all records relating to third-party verification or assessment of a U.S. person's compliance with this rule.

§ 791.313 Reports to be furnished on demand.

(a) VCS hardware importers and connected vehicle manufacturers must furnish, under oath, in the form of reports or as otherwise specified by BIS, and at any time as may be required by BIS, complete information regarding any transaction involving the import of VCS hardware or the import or sale of completed connected vehicles incorporating covered software. This requirement applies regardless of whether such transaction is affected pursuant to a general or specific authorization or otherwise, subject to the provisions of this subpart. BIS may require that such reports include the production of any books, contracts, letters, papers, or other hard copy or electronic documents relating to any transactions, in the custody or control of the persons required to make such reports. Reports being submitted to BIS pursuant to this section must be retained for a period of 10 years, as specified in § 791.312.

(b) BIS may, through any person or agency, conduct investigations, hold hearings, administer oaths, examine witnesses, receive evidence, take depositions, and require by subpoena the attendance and testimony of witnesses and the production of any books, contracts, letters, papers, and other hard copy or electronic documents relating to any matter under investigation, regardless of whether any report has been required or filed in connection therewith.

(c) Persons providing records to BIS pursuant to this section shall follow the electronic filing instructions on BIS's website, <https://www.bis.gov/OICTS>.

§ 791.314 Confidential Business Information.

(a) *Confidential business information.* Confidential Business Information is defined in 19 CFR 201.6.

(b) *Submission procedures.* Any information or material submitted to BIS which the entity or any other party desires to submit in confidence as a part of a Declaration of Conformity, specific authorization application, advisory opinion request, record to be furnished on demand, or is otherwise Confidential Business Information should be contained within a file beginning its name with the characters "CBI." Any page containing Confidential Business Information must be clearly marked "CONFIDENTIAL BUSINESS INFORMATION" on the top of the page. Any pages not containing Confidential Business Information should not be marked. By submitting information or material identified as Confidential Business Information, the entity or other party represents that the information is exempted from public disclosure, either by the Freedom of Information Act (5 U.S.C. 552 *et seq.*) or by another specific statutory exemption. Any request for Confidential Business Information treatment must be accompanied at the time of submission by a statement justifying non-disclosure and referring to the specific legal authority claimed.

(c) *Confidentiality of information.* Confidentiality of information is subject to 15 CFR 791.102.

§ 791.315 Third-Party Verification and Assessments.

(a) *Overview.* U.S. persons subject to this subpart may hire, consult, or otherwise contract with a third-party to ensure compliance with this rule. In certain cases, the use of a third-party assessor will be mandated in the terms of an approved specific authorization.

(b) *Third-Party Assessors.* U.S. persons should determine whether a third-party assessor is qualified and

competent, such as through industry certification or standard, to examine, to verify, and attest to the U.S. person's compliance with and the effectiveness of the security requirements implemented for VCS hardware or covered software transactions.

(1) The third-party assessor cannot be a person owned by, controlled by, or subject to the jurisdiction or direction of the PRC or Russia.

(2) In determining the reasonableness of an entity's reliance on a third-party assessment, BIS will consider the independence of the third-party, including any financial incentives between the third-party and the entity.

(c) *Scope.* The use of a third-party assessor for U.S. persons submitting Declarations of Conformity is voluntary; however, if utilized, BIS recommends such third-party assessments to:

(1) identify and examine the VCS hardware importer or connected vehicle manufacturer's VCS hardware and covered software supply chains in relation to the prohibitions in this subpart;

(2) examine compliance relating to each Declaration of Conformity, general authorization, or specific authorization pursuant to which an entity is conducting transactions;

(3) use a reliable methodology to conduct the third-party verification; and

(4) acknowledge that the assessment may be used by the U.S. government to verify compliance.

(d) *Assessment.* To utilize third-party verification to fulfill the due diligence requirement for a Declaration of Conformity, the third-party assessor should prepare and submit a written report to the VCS hardware importer or connected vehicle manufacturer. The third-party assessment should at minimum:

(1) identify the suppliers of each relevant component and describe the nature of any foreign interest;

(2) describe the methodology undertaken, including the policies and other documents reviewed, personnel interviewed, and any facilities, equipment, or systems examined;

(3) describe the effectiveness of the VCS hardware importer or connected vehicle manufacturer's corporate policies related to compliance with this rule;

(4) for VCS hardware importers or connected vehicle manufacturers conducting transactions under the auspices of a general authorization or specific authorization, describe any vulnerabilities or deficiencies in the implementation of the authorization; and

(5) recommend any improvements or changes to policies, practices, or other aspects to maintain compliance with this subpart, as applicable to each transaction.

(e) *Recordkeeping.* The third-party assessor must comply with all recordkeeping requirements, pursuant to § 791.312.

§ 791.316 Finding of Violation.

(a) *When issued.* (1) BIS may issue an initial finding of violation that identifies a violation if BIS:

(i) Determines that there has occurred a violation of any provision of this subpart, or a violation of the provisions of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary pursuant to this subpart or otherwise under IEEPA;

(ii) Considers it important to document the occurrence of a violation; and

(iii) Concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial finding of violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter.

(b) *Response—(1) Right to respond.* An alleged violator may contest an initial finding of violation by providing a written response to BIS.

(2) *Deadline for response; default determination.* A response to an initial finding of violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial finding of violation will become final and will constitute final agency action. The violator may seek judicial review of that final agency action in Federal district court.

(i) *Computation of time for response.* A response to an initial finding of violation must be electronically transmitted on or before the 30th day after the date of delivery by BIS.

(ii) *Extensions of time for response.* If a due date falls on a Federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of BIS, only upon specific request to BIS.

(3) *Form and method of response.* A response to an initial finding of violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a

representative thereof, contain information sufficient to indicate that it is in response to the initial finding of violation, and include the BIS identification number listed on the initial finding of violation. A digital signature is acceptable.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the provisions of this subpart did not occur and/or why a finding of violation is otherwise unwarranted under the circumstances. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. BIS will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a finding of violation is warranted.* If, after considering the response, BIS determines that a final finding of violation should be issued, BIS will issue a final finding of violation that will inform the violator of its decision and may include a responsive administrative action other than a civil monetary penalty. Any action taken in a final finding of violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in Federal district court.

(2) *Determination that a finding of violation is not warranted.* If, after considering the response, BIS determines a finding of violation is not warranted, then BIS will inform the alleged violator of its decision not to issue a final finding of violation.

§ 791.317 Pre-penalty notice; settlement.

(a) *When required.* If BIS has reason to believe that there has occurred a violation of any provision of this subpart or a violation of the provisions of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary pursuant to this subpart or otherwise under IEEPA and determines that a civil monetary penalty is warranted, BIS will issue a pre-penalty notice informing the alleged violator of BIS's intent to impose a monetary penalty. A pre-penalty notice shall be in writing and issued either electronically or by mail to the alleged violator. The pre-penalty notice may be issued whether or not another agency has taken any action with respect to the matter. BIS will consider any voluntary disclosures of a violation prior to issuing such notice.

(b) *Response*—(1) *Right to respond.* An alleged violator may respond to a pre-penalty notice in writing to BIS.

(2) *Deadline for response.* A response to a pre-penalty notice must be made within 30 days as set forth below. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a pre-penalty notice must be electronically transmitted on or before the 30th day after the date of delivery by BIS.

(ii) *Extensions of time for response.* If a due date falls on a Federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of BIS, only upon specific request to BIS.

(3) *Form and method of response.* A response to a pre-penalty notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof, contain information sufficient to indicate that it is in response to the pre-penalty notice, and include the BIS identification number listed on the pre-penalty notice. A digital signature is acceptable.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the provisions of this subpart did not occur and/or why a civil monetary penalty is otherwise unwarranted under the circumstances. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. BIS will consider all relevant materials submitted in the response.

(c) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with BIS prior to a written submission regarding the specific allegations contained in the pre-penalty notice must be preceded by a written letter of representation, unless the pre-penalty notice was served upon the alleged violator in care of the representative.

(d) *Settlement.* Settlement discussions may be initiated by BIS, the alleged violator, or the alleged violator's authorized representative.

§ 791.318 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to violations of the provisions of any general authorization, specific authorization, regulation, order,

directive, instruction, or prohibition issued by or pursuant to the direction or authorization of the Secretary of Commerce (Secretary) pursuant to this subpart or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued under this subpart.

(2) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any exemption, general authorization, specific authorization, regulation, order, directive, instruction, or prohibition issued under this subpart is subject to criminal penalties and may, upon conviction, be fined not more than \$1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410, as amended, 28 U.S.C. 2461 note).

(c) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(d) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the U.S. Government, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(e) Violations of this subpart may also be subject to other applicable laws and therefore may be subject to additional penalties not specified in this section.

§ 791.319 Penalty imposition.

(a) If, after considering any written response to the pre-penalty notice and any relevant facts, including voluntary disclosure of a violation, BIS determines that there was a violation by the alleged violator named in the pre-penalty notice and that a civil monetary penalty is appropriate, BIS may issue a penalty notice to the violator containing a determination of the violation and the imposition of the monetary penalty.

(b) The issuance of the penalty notice shall constitute final agency action. The violator may seek judicial review of that final agency action in Federal district court.

§ 791.320 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this subpart or make payment arrangements acceptable to BIS, the

matter may be referred for administrative collection measures by the United States Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a Federal district court.

§ 791.321 Severability.

If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person or

circumstance, or stayed pending further agency action or judicial review, the provision is to be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding will be one of utter invalidity or unenforceability, in which event the provision will be severable from this part and will not affect the remainder thereof.

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Part XI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling: Front-of-Package Nutrition Information; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2024–N–2910]

RIN 0910–AI80

Food Labeling: Front-of-Package Nutrition Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) proposes to require front-of-package nutrition labels on most foods that must bear a Nutrition Facts label. This action, if finalized, would require the display of a compact informational box containing certain nutrient information on the principal display panel. The box would provide consumers, including those who have lower nutrition knowledge, with standardized, interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. We also propose to amend certain nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies.

DATES: Either electronic or written comments on the proposed rule must be submitted by May 16, 2025. Submit comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by May 16, 2025.

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 May 16, 2025. 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–2024–N–2910 for “Food Labeling: Front-of-Package Nutrition Information.” 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.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the “Providing Accountability Through Transparency Act,” 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.

Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if your comments are received by May 16, 2025. Submit your comments on FDA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to FDA using the docket identified at the beginning of this rulemaking. FDA will respond to any information collection-related comments in the final rule. You may also send your information collection-related comments to OMB's Office of Information and Regulatory Affairs using the interface at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently Under Review—Open for Public Comments” or by using the search function. The title of this proposed collection is “Food Labeling: Front-of-Package Nutrition Information.”

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Claudine Kavanaugh, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450; or Deirdre Jurand or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRASStaff@fda.hhs.gov.

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- B. Content (Proposed § 101.6(a)(2))
- C. Format (Proposed § 101.6(a)(3))
- D. No Other Information Allowed in the Nutrition Info Box (Proposed § 101.6(a)(4))
- E. Special Labeling Provisions (Proposed § 101.6(b))
- F. Exemptions (Proposed § 101.6(c))
- G. Low Sodium and Low Saturated Fat Nutrient Content Claims (Revised §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3))
- H. Authority Citation
- I. Conforming Amendments
- J. Technical Amendments
- VI. Proposed Effective/Compliance Dates
- VII. Preliminary Economic Analysis of Impacts
- VIII. Analysis of Environmental Impact
- IX. Paperwork Reduction Act of 1995
- X. Federalism
- XI. Consultation and Coordination With Indian Tribal Governments
- XII. References

I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

This proposed rule, if finalized, would amend our regulations by adding a requirement for certain nutrition information to appear in a compact informational box on the principal display panel or bulk food labeling (for

purposes of this document, referred to collectively as the front of the food package, principal display panel, or similar) of most foods bearing a Nutrition Facts label (by statute, “food” is defined as, among other things, articles used for food or drink for man (21 U.S.C. 321(f))). The scientific literature on nutrition labeling, including on the Nutrition Facts label, demonstrates that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative significance in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages. The box we are proposing would give consumers additional standardized context on the front of most food packages about certain nutrients that appear on the Nutrition Facts label and allow them to compare this nutrition information across foods. An example of the proposed front-of-package (FOP) nutrition information box (Nutrition Info box) that reflects all proposed requirements is as follows:

Nutrition Info		
Per serving		% Daily
5 cookies		Value
Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	10%	Med
FDA.gov		

The proposed rule would provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. We also propose to amend the nutrient content claim definitions for low sodium (which includes the terms “low sodium,” “low in sodium,” “little sodium,” “contains a small amount of sodium,” and “low source of sodium”) and low saturated fat (which includes the terms “low in saturated fat,” “low saturated fat,” “contains a small amount of saturated fat,” “low source of saturated fat,” and “a little saturated fat”) to align with current

nutrition science and to avoid within-label inconsistencies.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule, if finalized, would:

- Require most foods that must display a Nutrition Facts label to bear an FOP Nutrition Info box on the principal display panel that details and interprets the relative amount of certain nutrients to limit (*i.e.*, saturated fat, sodium, and added sugars) in a serving of the food;
- Detail how to determine the interpretive descriptions (*i.e.*, “Low,” “Med,” and “High”) of such nutrients for the Nutrition Info box;

• Specify the required contents of the Nutrition Info box, such as the headings and nutrients;

• Specify the required format of the Nutrition Info box, such as placement, size, and use of dividing lines to separate information;

• Detail special labeling provisions for certain foods to modify or alternatively display the Nutrition Info box;

• Specify certain foods that are exempt from the requirement to display the Nutrition Info box;

• Provide examples of Nutrition Info boxes;

• Revise the low sodium and low saturated fat nutrient content claim definitions; and

• Establish a compliance date of 3 years after the final rule's effective date for businesses with \$10 million or more in annual food sales, and a compliance date of 4 years after the final rule's effective date for businesses with less than \$10 million in annual food sales.

C. Legal Authority

We are issuing this proposed rule consistent with the Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101–535, 104 Stat. 2353, Section 2(b)(1) (21 U.S.C. 343 note (1990))) and sections 403(f) and 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). We are also issuing this proposed rule consistent with our authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act (21 U.S.C. 371(a), 21 U.S.C. 343(a)(1), and 21 U.S.C. 321(n), respectively).

D. Costs and Benefits

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box on the front of most foods bearing a

Nutrition Facts label. The proposed rule would also amend the low sodium and low saturated fat nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. The proposed rule, if finalized, may result in industry reformulating products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

We quantify costs to the packaged food industry from updating labeling to meet the proposed requirements. Annualized costs from relabeling over 10 years would range from \$66 million to \$154 million at a 2 percent discount rate, with a primary estimate of \$105 million per year. Although reformulation is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation, as the rule may result in some food manufacturers reformulating some food products. We estimate that the annualized costs of reformulation over 10 years would range from \$125 million

to \$377 million at a 2 percent discount rate, with a primary estimate of \$227 million. Combined, we estimate the annualized costs of the proposed rule over 10 years would range from \$191 to \$530 million at a 2 percent discount rate, with a primary estimate of \$333 million. Note that, in general, this rule would impose few requirements on retailers. If a food that a retailer manufactures or packages either bears nutrition information or makes nutrition claims, and therefore is required to bear a Nutrition Facts label, the food would be subject to this rule's requirements.

Benefits of this proposed rule, if finalized, would come from the value consumers receive from the information provided by the interpretive FOP label on food packages. If some packaged food manufacturers chose to reformulate products to maintain current nutrient content claims or move into a “Low” or “Med” interpretive description, consumers whose nutritional intake changes accordingly would also benefit from a healthier food supply.

TABLE 1—SUMMARY OF THE BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[Millions of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes
Benefits: Annualized monetized benefits. Annualized quantified, but non-monetized, benefits.							
Unquantified benefits.	The benefits of this proposed rule would come from the value consumers receive from the information provided in the interpretive label on food packages.						
Costs: Annualized monetized costs. Annualized quantified, but non-monetized, costs. Unquantified costs.	\$333	\$191	\$530	2023	2	2025–2034	Although reformulation is not a requirement or goal of the proposed rule, reformulation costs are estimated to be 68% of total quantified costs. Costs may, at least partially, be passed through to consumers in the form of price increases.
Transfers: Annualized monetized Federal budgetary transfers. Other annualized monetized transfers.							
Net Benefits: Annualized monetized net benefits.							
Category	Effects			Notes			
Effects on State, local, or Tribal governments.							
Effects on small businesses	The total discounted cost of the proposed rule per entity (including large firms) is approximately \$100,253. We cannot estimate the exact cost per small entity because we do not know how many UPCs on average are owned by small entities as defined using the SBA definition.						
Effects on wages.							
Effects on growth.							

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Dietary Guidelines	Dietary Guidelines for Americans.
<i>Dietary Guidelines, 2020–2025</i>	<i>Dietary Guidelines for Americans, 2020–2025.</i>
DRV	Daily Reference Value.
DV	Daily Value.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOP	Front-of-package.
G	Gram(s).
GDA	Guideline Daily Amount.
HHS	U.S. Department of Health and Human Services.
IOM	Institute of Medicine (now NASEM).
Med	Medium.
Mg	Milligram(s).
NASEM	National Academies of Sciences, Engineering, and Medicine.
NLEA	Nutrition Labeling and Education Act of 1990.
OMB	Office of Management and Budget.
PRIA	Preliminary Regulatory Impact Analysis.
RACC	Reference Amount Customarily Consumed.
RDI	Reference Daily Intake.

III. Background

The United States faces a growing prevalence of preventable diet-related chronic diseases and conditions (for purposes of this document, we use the term “diseases” to cover both diseases and conditions), which can include hypertension, cardiovascular disease, type 2 diabetes, and certain forms of cancer. These diseases are leading causes of death and disability in the United States (Ref. 1). Data show that about one in 10 Americans has diabetes, and 90 to 95 percent of those have type 2 diabetes (Ref. 2); at least one in three people will have cancer in their lifetime (Ref. 3); and nearly half of American adults have high blood pressure, which is linked to leading causes of death for Americans: heart disease and stroke (Refs. 4 and 5). While these diseases can result from a mix of risk factors, such as genetic, biological, behavioral, socioeconomic, and environmental factors, unhealthy dietary patterns increase the risk of developing chronic diseases (Ref. 6). Diet-related chronic diseases are experienced disproportionately by certain racial and ethnic populations and those with lower socioeconomic status (Refs. 7 to 12).

The *Dietary Guidelines for Americans, 2020–2025* (*Dietary Guidelines, 2020–2025*) recommends, among other things, that Americans limit their intake of saturated fat, sodium, and added sugars to achieve healthy dietary patterns (Ref. 6). Under the National Nutrition Monitoring and Related Research Act of 1990 (Pub. L. 101–445, 104 Stat. 1034), the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (HHS) must publish the Dietary Guidelines for Americans

(Dietary Guidelines) at least every 5 years and must base them on the preponderance of the current scientific and medical knowledge. Development of the Dietary Guidelines entails a rigorous process and includes appointment of a federal advisory committee of external scientific experts, review of the scientific evidence by the committee, public meetings, issuance of a scientific report by the advisory committee, and a public comment process (Ref. 13). With those requirements and practices in place, the *Dietary Guidelines, 2020–2025* concludes that healthy dietary patterns are based on, among other things, “consuming foods and beverages in their nutrient-dense forms—forms with the least amounts of added sugars, saturated fat, and sodium” (Ref. 6).

FDA, as part of a whole-of-government approach, broadly seeks to help reduce the burden of diet-related chronic diseases. We are committed to accomplishing this goal by, in part, prioritizing nutrition initiatives that can help improve dietary patterns in the United States. Americans’ choice of foods is influenced by, among other things, their knowledge about and understanding of the foods available to them. As consumers make their food purchases and daily food choices, food labeling provides them with valuable information about nutrients and how a particular food fits into their daily diet. Congress recognized this and passed the NLEA, which gave the Secretary of HHS, and by delegation, FDA, authority to require certain nutrition information to be conveyed in a manner that allows the public to readily observe and comprehend such information and to

understand its relative significance in the context of a total daily diet (21 U.S.C. 343 note).

The NLEA, which added section 403(q) of the FD&C Act, specifies certain nutrients to be declared in nutrition labeling, including saturated fat and sodium, and authorizes FDA to require the declaration of other nutrients if we determine that the declaration will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.

We have established various requirements under the NLEA related to nutrition information on food labels, such as the declaration of nutrients (including saturated fat and sodium), the format for nutrition labeling (including the Nutrition Facts label), reference values for use in declaring a food’s nutrient content, and allowances for specified products to be exempt from nutrition labeling (§ 101.9 (21 CFR 101.9)). We first issued regulations related to the Nutrition Facts label in 1993 in a final rule entitled “Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label” (58 FR 2079, January 6, 1993) (1993 Nutrition Facts label final rule) and amended them in 1995 (60 FR 67164, December 28, 1995) and in 2003 (68 FR 41434, July 11, 2003). In 2016, we again amended our regulations related to the Nutrition Facts label in a final rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742, May 27, 2016) (2016 Nutrition Facts label final rule) to, among other things, require the declaration of added sugars (codified at

§ 101.9(c)(6)(iii)). We took this action, in part, because of scientific evidence demonstrating a strong association between a healthy dietary pattern low in sugar-sweetened foods and a reduced risk of cardiovascular disease, evidence showing it is difficult to meet nutrient needs within calorie limits when added sugars consumption is high, and consumption data showing that Americans consume too many calories from added sugars (81 FR 33742 at 33759 and 33768 through 33770).

A. Need for the Regulation

In developing this proposed rule, FDA examined the scientific literature on nutrition labeling, including on the Nutrition Facts label. The Nutrition Facts label provides valuable, standardized nutrition information to consumers. Eighty-seven percent of U.S. consumers report ever looking at the Nutrition Facts label, and nearly 80 percent of U.S. consumers use it sometimes or often (Ref. 14). It focuses on numerical information: The quantitative amount per serving of each declared nutrient and the corresponding percent Daily Value (DV), when applicable, tell consumers how much a nutrient in a specified serving of food contributes to a total daily diet.

Using the Nutrition Facts label frequently is associated with healthier dietary patterns (Ref. 15). However, while many consumers use and benefit from the Nutrition Facts label, fewer people who ever look at the Nutrition Facts label look at nutrients to limit (including sodium, saturated fat, and added sugars) in that label (Ref. 14). Use of the Nutrition Facts label use also differs by sex, race/ethnicity, education level, and household income. Specifically, regular use of the Nutrition Facts label is lower among men, those with lower education levels, and those with lower incomes (Refs. 15 to 17). Additional nutrition labeling that is interpretive and prominently displayed on the front of food packaging could help improve consumer awareness of nutrients to limit by providing a more accessible description of certain information contained in the Nutrition Facts label.

The scientific literature on nutrition labeling also demonstrates that some consumers struggle to understand the numerical values used to represent the nutrient content of the food or use the information in the labeling to make their food selections (Refs. 18 and 19). Additionally, information FDA has collected shows that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative

significance of the nutrients in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages (Refs. 20 and 21). Based on this data and other information referenced in this document, we have tentatively determined that an interpretive FOP nutrition label is needed to help consumers readily observe and comprehend information about certain nutritional attributes of a food at the point of decision-making (*i.e.*, when a consumer is deciding whether to buy, use, or eat the food) that will assist them in maintaining healthy dietary practices.

B. Regulatory and Research History

FDA has considered the possible use of FOP nutrition labeling under its NLEA and FD&C Act authorities since at least 2007. In the **Federal Register** of July 20, 2007 (72 FR 39815), we issued a notice of public hearing and request for comment about symbols then in use to communicate nutrition information on food labels. In the **Federal Register** of December 1, 2009 (74 FR 62786), we announced that we had submitted two experimental studies for Office of Management and Budget (OMB) review and clearance under the Paperwork Reduction Act of 1995, with the intent to quantitatively assess consumer reactions to various FOP nutrition labeling schemes. We discussed how we completed a focus group study in April 2008 to obtain comments and information about many consumer issues related to FOP nutrition labeling schemes (*id.*). We noted that the information available to us left gaps in our understanding of the impacts of FOP nutrition labeling schemes on U.S. consumers and commented that there was a lack of publicly available quantitative consumer research on the relative effectiveness of existing and alternative nutrition labeling schemes (*id.*).

In a **Federal Register** notice entitled “Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information” (75 FR 22602, April 29, 2010), we established a docket to ask questions and obtain data and other information about ways to enhance the usefulness of point-of-purchase nutrition information, such as through FOP nutrition labeling. We stated that we were working with interested parties to develop a voluntary FOP nutrition label that was driven by sound nutrition criteria, consumer research, and design expertise (*id.* at 22603). In 2011, we issued a letter (Ref. 22) to the Grocery Manufacturers

Association (now the Consumer Brands Association) and the Food Marketing Institute (now the Food Industry Association) announcing our intent to exercise enforcement discretion with respect to certain FDA nutrition labeling regulations so that the associations could introduce and use their Facts Up Front (FUF) FOP nutrition labeling program (Ref. 23). We recognized in the letter that the standardized, non-selective presentation of calories, saturated fat, sodium, and total sugar content on a company’s entire product line, if widely adopted by the food industry in a uniform manner, could contribute to FDA’s public health goals by fostering awareness of the nutrient content of foods in the marketplace and helping consumers in making quick, informed, and healthy food choices (Ref. 22).

Congress has also demonstrated its interest in FOP nutrition labeling. In 2009, Congress directed the Centers for Disease Control and Prevention to commission a study by the Institute of Medicine (IOM) (now the National Academies of Sciences, Engineering, and Medicine (NASEM)) to examine and provide recommendations regarding FOP nutrition symbols (Refs. 24 and 25). In 2010, the IOM released a Phase I report (Ref. 26), which found, among other things, that FOP systems had been established internationally as far back as 1989, may have the greatest potential benefit if the nutrition components included are limited to those most closely related to prominent public health conditions, and that research was needed to determine the most effective way of presenting nutrition ratings to consumers so they could make food choices that contribute to a healthy diet. In 2012, the IOM released a Phase II report (Ref. 27), which addressed the potential benefits of a single, standardized front-label food guidance system regulated by FDA, assessed which systems are most effective with consumer audiences, considered which systems best promote health, and recommended ways to maximize the use of such systems. The IOM concluded that a single, standardized system that is easily understood by most age groups and appears on all products would be the best option (*id.*).

Further, in 2011, we commissioned a literature review (Ref. 28) to look at scientific studies, including, *e.g.*, experimental and real-world studies, on FOP and Shelf Label Nutrition Systems (*i.e.*, tags set on grocery store shelves rather than directly on food packaging) and learn which types of systems were most effective at informing consumers about the relative healthfulness of foods.

This literature review found that summary systems incorporating text and color worked better than those using only numeric information in attracting consumer attention and informing them about the relative healthfulness of foods (id.).

In 2016, FDA commissioned an update to our previous literature review (Ref. 29), which captured more recent scientific literature on FOP nutrition labeling from 2010 to August 2016. Like previous reviews, the update reported that, among other things, consumers, no matter their nutrition knowledge, preferred visually simple labels that were quick and easy to read over those that have more complex numerical information.

The White House released a National Strategy (Ref. 30) at the September 2022 Conference on Hunger, Nutrition, and Health that outlined the goal of ending hunger and increasing healthy eating and physical activity by 2030, so that fewer Americans experience diet-related diseases such as type 2 diabetes, hypertension, and certain cancers. The strategy highlighted several FDA initiatives to help empower consumers with information and help create a healthier food supply. The National Strategy included FDA's work to, among other things, conduct research on and propose a standardized FOP system for food packages to help consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern.

C. Citizen Petition

On August 5, 2022, the Center for Science in the Public Interest, the Association of SNAP Nutrition Education Administrators, and the Association of State Public Health Nutritionists submitted a citizen petition asking that we amend our regulations to require an easy-to-understand, standardized system of nutrition labeling on the principal display panel of foods (Citizen Petition from Peter Lurie, MD, MPH, Executive Director and President, and Eva Greenthal, Senior Science Policy Associate, Center for Science in the Public Interest, Amy Branham, Immediate Past Co-chair, ASNNA Leadership Team, Association of SNAP Nutrition Education Administrators, and Jamie Stang, Ph.D., MPH, RDN, President, Association of State Public Health Nutritionists, to Dockets Management Staff, Food and Drug Administration, dated August 5, 2022, Docket No. FDA-2022-P-1832 (petition) at page 1). The petition requested that such a system be

mandatory, nutrient-specific, inclusive of calories, and interpretive with respect to the levels of added sugars, sodium, and saturated fat per serving (id.).

The petition claimed that experimental and real-world evidence shows that policies that aim to give consumers information about the healthfulness of foods that is clear, quick, and easy to access and understand, such as interpretive FOP nutrition labeling, can improve consumer understanding and encourage healthier diets (id. at page 4). The petition provided various examples of FOP systems that would meet its criteria. We have considered this citizen petition in proposing this rule.

D. Updated FDA Literature Review and New Research Overview

We have seen rising global interest in FOP nutrition labeling schemes in recent years, and many countries have implemented, or are implementing, their own versions amid growing concern about the impact of diet-related chronic diseases, which can include cardiovascular disease, diabetes, and certain forms of cancer (Refs. 20 and 31). As of 2024, countries in North America, South America, Asia, and Africa have implemented, or are implementing, mandatory FOP nutrition label schemes, while several other countries in Africa, Europe, Asia, and Oceania have voluntary schemes (Refs. 32 to 34). The schemes in these countries represent a variety of types, such as warning-type schemes (e.g., where a triangle and exclamation point on the FOP call attention to nutrients above a certain threshold in a serving size) and nutrient summary schemes (e.g., where a letter grade is determined and displayed to represent the healthfulness of a food's nutrient profile), among other types of schemes. We examined these various schemes in the literature review we conducted, which informed our consumer research studies. We describe our literature review and consumer research in the sections that follow.

1. Literature Review

To inform our proposed Nutrition Info box, we first conducted a systematic review of the scientific literature on FOP nutrition labels, the most recent version of which we made public in April 2023 (Ref. 20). Results of the scientific literature review showed that FOP nutrition labels have been extensively studied and some large-scale literature reviews on FOP nutrition labels have been conducted. As mentioned elsewhere in this document, the IOM conducted a two-

phase literature review on FOP nutrition labels, concluding that such FOP nutrition labeling schemes benefit consumers and that consumers prefer simple, interpretive schemes, which are also rated most helpful to consumers (Refs. 26 and 27). The body of research after the IOM reviews has been consistent with the IOM findings. Specifically, certain overarching themes emerged from our updated literature review, including that an FOP nutrition label can help consumers identify and select healthy foods, consumers generally prefer simple labels, and government endorsement of logos may be related to greater confidence in the label (Ref. 20). Moreover, recent literature on FOP nutrition labeling schemes suggests that familiarity with these schemes will make them even more useful as time passes, and that these schemes are useful across all demographics and levels of nutrition knowledge, can help consumers understand the nutrition quality of food, and can positively impact consumers' intention to purchase healthful foods (id.). The scientific literature on consumers' use of FOP nutrition labels has strongly and consistently found that FOP nutrition labels attract consumer attention, and any FOP nutrition label communicates something more about the product's nutrient content to consumers than no FOP nutrition label (id.). FDA began its most recent round of consumer research exploration of FOP nutrition labeling schemes using the findings from the literature review (id.) and continued to monitor the literature throughout the research process.

2. First Focus Group Testing

In 2022, FDA conducted its first set of focus groups (OMB control number 0910-0497, "Front-of-Pack Focus Groups") to test FOP concepts and draft FOP labels, some of which we had included in the 2008 focus group testing (see Refs. 32 and 33; see also https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=253321). We tested variations of four FOP nutrition labeling schemes in these focus groups, which were composed of U.S. adult food shoppers whose race/ethnicity, age, sex, and education reflected U.S. population demographics (Ref. 35). The schemes were based on those currently found in the U.S. and international marketplace: (1) Guideline Daily Amount (GDA); (2) Nutrition Tips; (3) Nutrition Tips—High In; and (4) High In (id.). The GDA scheme listed calories, quantitative amount of nutrients (sometimes including both nutrients to limit (those

that may be associated with adverse health effects and that Americans generally consume too much of—*e.g.*, saturated fat, sodium, added sugars) and nutrients to get enough of (those that Americans generally do not get the recommended amount of—*e.g.*, fiber, calcium)), and the adult proportion recommended for daily consumption represented by a serving of the food in both numerical (*i.e.*, percent DV) and interpretive (*i.e.*, “Low,” “Med,” and “High”) form. This scheme resembled the voluntary FUF scheme developed by the U.S. food industry. The Nutrition Tips scheme mimicked the design of the Nutrition Facts label and included low, medium, and high interpretive descriptions about nutrient levels for saturated fat, sodium, and added sugars (and, in certain test schemes, fiber and calcium). The Nutrition Tips—High In scheme also mimicked the Nutrition Facts label design, but it only listed a nutrient, its interpretive description, and corresponding percent DV when a serving of the product was “high in” saturated fat, sodium, or added sugars. The High In scheme showed the nutrient(s) (and, in certain test schemes, the percent DV) in the product that, per serving, were considered high. In total, we tested 41 variations of these schemes—14 GDA schemes, 12 Nutrition Tips schemes, 9 Nutrition Tips—High In schemes, and 6 High In schemes (Ref. 36). We used these varied schemes to learn more about consumer reactions to the elements depicted (*e.g.*, use of color, use of interpretive words, use of numbers) and to help us understand which FOP nutrition labeling schemes may be most useful to consumers.

Within the GDA category, we tested schemes that included both nutrients to limit (*i.e.*, saturated fat, sodium, and added sugars) and nutrients to get enough of (*i.e.*, fiber and calcium), schemes that used colors beyond black and white (*i.e.*, red, yellow, and green), schemes that included interpretive descriptions (*i.e.*, low, medium, and high) of nutrient levels, schemes that included quantitative nutrient level information (*e.g.*, how much a nutrient in a single serving of food contributes to your daily diet (*i.e.*, percent DV), quantitative declaration of grams (g) or milligrams (mg) of a nutrient), and schemes that included descriptive terms (*i.e.*, “avoid too much” or “get enough”). In the Nutrition Tips category, we tested schemes that included both nutrients to limit and nutrients to get enough of, schemes that used either black and white colors only or colors beyond black and white (*i.e.*,

red, yellow, and green), schemes that included and excluded interpretive descriptions regarding nutrient levels, schemes that included and excluded quantitative nutrient level information (*i.e.*, percent DV), and schemes that included and excluded an “*FDA.gov*” statement in the FOP nutrition label. In the Nutrition Tips—High In category, we tested schemes that included only nutrients to limit, different color variations (*i.e.*, black on white compared to white on black), and the use of an abbreviated heading for “% Daily Value.” In the High In category, we tested schemes that included only nutrients to limit and schemes that included and excluded quantitative percent DV information.

These focus groups provided FDA with qualitative feedback and insight into the varying ways that consumers react to and comprehend FOP nutrition information and helped us understand which schemes might be most helpful for U.S. consumers to quickly and easily identify how foods can be part of a healthy diet (Ref. 37). Among other things, participants reported they believed that products bearing “High In” labels without quantitative percent DV information were not healthy (*id.*). Participants were also confused by the colors red, yellow, and green when schemes contained both nutrients to limit and nutrients to get enough of (*e.g.*, they had trouble interpreting the scheme when red indicated a high amount of a nutrient to limit *and* a low amount of a nutrient to get enough of) (*id.*). These focus group participants also preferred differing amounts of information in the FOP schemes we tested and reacted positively to neutrally about the inclusion of “*FDA.gov*” in the scheme (*id.*). For example, when “*FDA.gov*” appeared in a scheme, some participants thought it made the scheme more credible or trustworthy and understood it to mean that the information on the FOP nutrition label was not marketing, but rather information provided by a government source, while others reported they would not notice the FDA attribution in a label (*id.*). We considered this information, as well as the literature review, in identifying FOP scheme types for quantitative testing.

3. Experimental Study

We used our learnings from the focus group testing and the information from the literature reviews to help inform the scheme types we chose to test in the experimental study (OMB Control Number 0910–0920, “Quantitative Research on Front of Package Labeling on Packaged Foods”) to further explore

consumer responses to various FOP nutrition labeling schemes. In the experimental study, we tested a smaller subset of FOP nutrition labeling schemes from the focus group testing, with additional variations informed by, among other things, focus group results. The study was a controlled, randomized experiment, using a 15-minute web-based questionnaire to collect information from 9,200 U.S. adult members of an online consumer panel maintained by a contractor (Ref. 38). The sample reflected U.S. Census data on sex, education, age, and race/ethnicity, in a balanced manner (*id.*). A measure of nutrition literacy was also used to balance the sample to ensure a variety of nutrition literacy levels for each condition (*id.*). The “Quantitative Research on Front of Package Labeling on Packaged Foods, Final Study Report” has been peer reviewed by independent external experts. Taking into consideration comments from this peer review, we revised the final report, which is available in the docket for this proposed rule (Ref. 38). The findings from the experimental study informed the development of this proposed rule.

We tested three FOP scheme categories with various features (*e.g.*, one scheme category, shown both with and without percent DV), for a total of eight FOP schemes, in our experimental study (*id.*). Each scheme displayed information about the three nutrients of interest (*i.e.*, saturated fat, sodium, and added sugars) in the three scheme categories: (1) GDA; (2) Nutrition Info (formerly “Nutrition Tips” but renamed in the experimental study to better align with the Nutrition Facts label and to underscore that the FOP nutrition label contains fact-based disclosures, including additional nutrient content interpretation); and (3) High In (*id.*). The “Low,” “Med,” and “High” interpretive descriptions included in the study for the three nutrients were based on our longstanding general approach for interpreting the percent DV of a nutrient (*i.e.*, 5% DV or less for “Low,” 20% DV or more for “High”) (see section V.B.3 of this document for further discussion).

The study guided participants through two independent tasks (*id.*). In the first task, participants viewed three different nutrient profiles (healthiest, middle, and least healthy, which for study purposes was based on saturated fat, sodium, and added sugars levels) of a single FOP nutrition scheme and were asked to select the most and least healthy nutrient profile, based only on the levels of saturated fat, sodium, and added sugars displayed (*id.*). If participants wanted additional nutrition information when reviewing the

nutrient profiles, instructions indicated they could click anywhere on the profiles for more detail. By doing so, the corresponding Nutrition Facts label was displayed (we note, however, that our data showed that participants rarely did this (id.)). The nutrient profiles were similarly based on our longstanding general approach for interpreting the percent DV of a nutrient as either “low” or “high” (88 FR 39257) (see section V.B.3 of this document for further discussion). Each participant viewed a total of three randomly assigned FOP nutrition schemes (Ref. 38). In the second task, participants viewed an FOP nutrition scheme that varied by nutrient profile on one of three mock food product labels (cereal, frozen meal, or canned soup). Participants answered questions about the product and the FOP nutrition scheme, including questions about perceptions of healthfulness and nutrient content, and also answered questions about their attitudes toward the scheme (id.).

a. Nutrition Info. Similar to the “Nutrition Tips” design tested in the first focus groups, the Nutrition Info scheme mimicked the design of the Nutrition Facts label and provided interpretive nutrition information by identifying the level of the three nutrients per serving as “Low,” “Med,” or “High.” The nutrient information was displayed vertically, using contrasting colors. We tested versions that:

- Included and excluded quantitative percent DV amounts;
- Used either black and white colors only or used black, white, green, yellow, and red, with the latter three colors representing low, medium, and high, respectively; and
- Included and excluded a magnifying glass icon.

The Nutrition Info schemes performed best overall in helping consumers identify healthier nutrient profiles (id.). Specifically, the Nutrition Info schemes produced more correct answers regarding the healthfulness of the product shown than the other schemes tested, and participants were generally able to correctly identify the level of saturated fat, sodium, and added sugars in products (id.). Participants viewing the Nutrition Info schemes also spent significantly less time evaluating the nutrient profile of a product than those viewing the other schemes tested (*i.e.*,

they felt confident enough to answer questions in a shorter amount of time) (id.). In the various Nutrition Info schemes described elsewhere in this document that were tested against each other, none performed better than the others across all measures, but the versions that were black and white with percent DV performed best in most instances (id.).

b. High In. The High In scheme only displayed any of the three nutrients to limit that fell into the “High” description according to our longstanding general approach for interpreting a nutrient’s percent DV per serving of a product. For example, if a test product was medium in saturated fat, high in sodium, and low in added sugars per the established criteria, the High In scheme for that product would only include “Sodium,” and, in some instances, additional information about the sodium content. Specifically, we tested High In schemes both with and without a quantitative percent DV.

While the High In schemes seemed to emphasize to participants higher levels of nutrients to limit, they performed the worst among the schemes tested when participants were asked to identify a product’s healthfulness (id.). Participants viewing the High In schemes were significantly less likely to correctly identify the healthiest and least healthy nutrient profiles and were more likely to rank the products as less healthy than those who viewed the GDA and Nutrition Info schemes (id.). Participants viewing the High In schemes also spent significantly more time evaluating the information provided before answering questions about the healthiest and least healthy nutrient profiles (*i.e.*, they were not as confident in providing an answer in the same amount of time as compared to their responses when using other schemes) (id.). Although very few participants overall clicked to see the Nutrition Facts label when responding to the study questions, those viewing the High In schemes were significantly more likely to do so than those viewing either the GDA or the Nutrition Info schemes, suggesting that participants needed or wanted additional nutrition information before providing a response (id.). Most of the ratings on the attitude and perception questions were significantly lower for the High In

schemes than they were for the GDA and Nutrition Info schemes (id.).

c. Guideline daily amounts. The GDA scheme we tested was a set of icons placed horizontally that displayed nutrition information per serving. This scheme was quantitative-only and did not include any interpretive descriptions, such as whether nutrient levels were low, medium, or high. Each icon displayed the number of grams or milligrams of a nutrient in its center and the nutrients’ corresponding percent DV at the bottom.

While participants had a positive reaction to and perception of the GDA scheme (*e.g.*, liking its look), it tested lower than the other schemes on several important factors we measured. In contrast to participants’ reactions to the Nutrition Info and High In schemes, they were significantly less likely to correctly identify the level of saturated fat, sodium, and added sugars when viewing the GDA scheme (id.). Additionally, participants viewing the GDA scheme spent more time evaluating the information provided before answering questions about the healthiest and least healthy nutrient profile as compared to the Nutrition Info schemes (id.).

4. Second Focus Group Testing

In Fall 2023, we conducted a second set of focus groups (OMB control number 0910–0497, “Front-of-Package Nutrition Labeling Focus Groups 2”) as a follow-on to the experimental study to gather additional input on our assumption that consumers would react to FOP nutrition labeling on beverage products and non-beverage products in the same way (Ref. 39). Almost all participants reported that they viewed the FOP nutrition information on beverage and non-beverage products similarly (Ref. 21).

5. Summary of FDA’s Research and How It Relates to Our Current Proposal

We are proposing the Nutrition Info box, which would be a mandatory, compact, standardized FOP nutrition label that closely aligns with the Nutrition Info scheme tested in our quantitative research. An example Nutrition Info box that reflects all proposed requirements is as follows:

Nutrition Info		
Per serving		% Daily
5 cookies		Value
Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	10%	Med
FDA.gov		

This Nutrition Info box would address our public health goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify, at the point of decision-making, how foods can be part of a healthy diet—including by allowing them to compare nutrition information across foods.

Including interpretive information on the label or labeling of a food is expected to provide a more accessible description of the numerical information contained in the Nutrition Facts label, thereby helping to address the differences in use that we see with the Nutrition Facts label (Refs. 15 to 17). For example, our experimental study, which included a diverse sample of participants that varied by age, sex, geography, race/ethnicity, and education, showed that all groups tested can use interpretive FOP nutrition information equally well (Ref. 38), and the scientific literature indicates that interpretive FOP nutrition information is helpful for all consumers (Ref. 20). Moreover, in our consumer research, participants reported that using interpretive descriptions, such as “Low,” “Med,” and “High,” put the percent DV of a nutrient into context by helping consumers understand whether that number contributes a little or a lot of that nutrient to the daily diet (Ref. 21). Additionally, the scientific literature shows that making this information available on the front of food packages, so it is immediately visible at the point of decision-making, captures consumers’ attention, which could further help address these differences (Ref. 20). Thus, interpretive FOP nutrition labeling, such as the Nutrition Info box proposed here, would supplement the Nutrition Facts label by providing additional context that consumers could use to help them quickly and easily identify how foods can be part of a healthy diet.

IV. Legal Authority

We are proposing to require FOP nutrition labeling consisting of an informational FOP nutrition label that includes interpretive content regarding the levels of certain nutrients to limit, consistent with our general food labeling and nutrition labeling authorities in the NLEA and the FD&C Act. Specifically, this rule proposes a mandatory label element on the principal display panel that details and interprets—using low, medium, and high descriptions—the percent DV for saturated fat, sodium, and added sugars in a serving of food. This rule also proposes updates to the low sodium and low saturated fat nutrient content claims.

A. Statutory Framework

Congress authorized FDA to require that certain information be included on food labels or labeling and that the information presented assists consumers in maintaining healthy dietary practices. The NLEA added section 403(q) to the FD&C Act, which specifies, in part and with certain exceptions, that food is deemed misbranded unless its label or labeling bears nutrition information regarding certain nutrients. The statute lists certain information that must be included in food labeling and authorizes the Secretary, and by delegation, FDA to specify additional requirements by regulation. Under section 403(q)(1) of the FD&C Act, FDA may issue regulations to require that any required nutrition information be highlighted with larger type, bold type, or contrasting color after determining that such highlighting will help consumers in maintaining healthy dietary practices. Further, sections 403(q)(2)(A) and 403(q)(2)(B) of the FD&C Act provide a process for adding nutrition information to or removing statutorily required nutrition information from the label if FDA determines that such actions would help consumers maintain healthy dietary practices. In addition, section

403(f) of the FD&C Act specifies, in part, that a food is misbranded if any information required under the authority of the FD&C Act is not prominent on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. These provisions demonstrate that Congress intended that nutrition information required to be on the label be presented in a way that helps consumers use that information to maintain healthy dietary practices. To that end, Congress gave FDA authority to determine what information is required and how it is presented to achieve this aim.

Additionally, the NLEA specifically directs FDA to require nutrition information be presented in a way that makes it observable, understandable, and useful to consumers. Under the NLEA, FDA must require the information to be disclosed on the label in a way that enables consumers to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (NLEA § 2(b)(1)(A), Pub. L. 101–535, 104 Stat. 2353, 2357; 21 U.S.C. 343 note). This provision gives us the authority to require that interpretive information about the relative amount of certain nutrients required to be included in the Nutrition Facts label be displayed in a readily observable and understandable format so that consumers can quickly and easily determine how a food fits into their daily diet, as we are proposing in this rule. Additionally, the NLEA does not specify where on the label the nutrition information must appear to enable the public to readily observe the information, and, for decades, industry has been able to place the required Nutrition Facts labels on different panels (e.g., principal display panel, information panel) and in various locations on different products throughout the food marketplace.

In enacting the NLEA, Congress “expressly delegate[d]” the authority to the Secretary (subsequently delegated to FDA) “to prescribe rules to ‘fill up the details’ of a statutory scheme” (*Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024), throughout section 403(q) of the FD&C Act, and in 21 U.S.C. 343 note). As most relevant here, section 403(q)(1) of the FD&C Act provides that “if [FDA] determines” that certain highlighting “will assist consumers in maintaining healthy dietary practices,” FDA “may by regulation require” the required nutrition information “to be highlighted” with “larger type, bold type, or contrasting color.” Section 403(q)(2)(A) of the FD&C Act provides that “if [FDA] determines” that information about an additional nutrient “will assist consumers in maintaining healthy dietary practices,” FDA “may by regulation require that information relating to such additional nutrient be included” in the food label. Section 403(q)(2)(B) of the FD&C Act provides that “if [FDA] determines” that information about a nutrient is “not necessary to assist consumers in maintaining healthy dietary practices,” “[FDA] may by regulation” remove the requirement to include such information. In 21 U.S.C. 343 note, Congress directed FDA to issue regulations “to implement section 403(q)” of the FD&C Act and specifically to “require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” Therefore, the best reading of section 403(q) of the FD&C Act is that Congress delegated discretionary authority to FDA to decide, as appropriately informed by its technical expertise and within the limits of its statutory authority, how to fill up the details regarding the presentation of nutrition information to assist consumers in comprehending the information and maintaining healthy dietary practices.

The NLEA’s legislative history affirms that Congress contemplated that FDA require labeling information to help consumers understand the nutrient levels in a food in the context of a daily diet. For example, the legislative history explicitly contemplates the use of the terms “low,” “medium,” and “high” to achieve this goal. The House report for the bill states that, in order to present nutrition information in a manner that facilitates the public’s understanding, FDA may choose among a variety of options, for example, including

information about the recommended daily intake on the label or including the use of descriptive terms such as “low,” “medium,” and “high,” or universal symbols to indicate desirable or undesirable levels of particular nutrients (Ref. 40). According to the report, while the bill would not (and the enacted provision did not) mandate that FDA adopt any particular approach, it would (and does) require FDA to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information (id.). This report language further affirms Congressional intent that FDA must issue regulations implementing the NLEA that would help consumers place the amounts of particular nutrients in a context that would help them build their daily diets (see NLEA § 2(b)(1)(A), Pub. L. 101–535, 104 Stat. 2353, 2357; 21 U.S.C. 343 note).

The NLEA also created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA’s authorizing regulations (section 403(r)(1)(A) and (r)(2)(A) of the FD&C Act).

Additional authorities for this rulemaking can be found in section 701(a) of the FD&C Act regarding efficient enforcement of the FD&C Act, as well as in sections 403(a)(1) and 201(n) of the FD&C Act regarding our general food labeling authority.

B. Current Proposal

Since the Nutrition Facts label was last updated in May 2016, FDA has tentatively determined that additional, interpretive nutrition information on the front of food packages—to provide context for certain nutrient declarations—is necessary to help consumers more easily observe and better understand and use this information when building their diets.

As mentioned elsewhere in this document, nearly 80 percent of U.S. food shoppers use the Nutrition Facts label sometimes or often (Ref. 14), and it is a valuable tool to help consumers maintain healthy dietary practices. However, the information, including scientific literature on nutrition

labeling, that FDA has received on the Nutrition Facts label after decades of use has demonstrated that certain consumers do not look at the Nutrition Facts label (Refs. 15 to 17), and some struggle to understand the numerical values used to represent the nutrient content of the food or use the information presented there to make their food selections (Refs. 18 and 19). Additionally, information FDA has collected shows that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative significance in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages (Refs. 20 and 21).

Therefore, based on this data and other information referenced in this document, we have tentatively determined that an interpretive FOP nutrition label is needed to ensure that consumers can readily observe and comprehend information about certain nutritional attributes of a food at the point of decision-making that will assist them in maintaining healthy dietary practices. We similarly relied on our authority in section 2(b)(1)(A) of the NLEA to require the declaration of percent DV of a nutrient in a food in the 1993 Nutrition Facts label final rule establishing the Nutrition Facts label, stating that percent DV is needed to help consumers understand the relative significance of nutrition information presented on the label in the context of the total daily diet (58 FR 2206 at 2213, January 6, 1993). We have additionally determined that we have the authority under the NLEA and FD&C Act, as further explained in section IV.C of this document, to specifically require that certain additional interpretive nutrition information be presented on the principal display panel that can help consumers quickly and easily identify how foods can be part of a healthy diet.

As our research study and the broader literature demonstrate, the use of an FOP scheme with interpretive nutrition information allows consumers to make quick and informed decisions about the foods they choose for themselves and their families by making these additional disclosures readily observable and understandable. In our experimental research study, people of different sexes and ages and of all races, ethnicities, education levels, and nutrition knowledge levels were able to understand the nutrients to limit for products bearing the Nutrition Info box that most closely aligns with this

proposal, which includes low, medium, and high interpretive information (displayed as “Low,” “Med,” and “High”), as well as percent DV information, and to use that box to correctly identify products with the healthiest or least healthy nutrition profile based on the displayed nutrients (Ref. 38). Further, this Nutrition Info box performed generally better than other schemes that were tested on both of these measures (id.). Additionally, participants viewing this Nutrition Info box were able to answer questions more quickly about a product’s healthfulness compared with the other schemes tested (id.). Participants also reported that the box would help them easily find nutrition information on a food package and easily compare nutrition information across foods (id.).

The proposed Nutrition Info box would consist of factual disclosures about the nutrient content of a food that provide additional context to the information currently required to be declared in the Nutrition Facts label. The three nutrients that would be required in the Nutrition Info box—saturated fat, sodium, and added sugars—are recommended to be limited by current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025*, to achieve a nutrient-dense diet within calorie limits (Ref. 6). Current nutrition science emphasizes the consumption of healthy dietary patterns. While all foods can be incorporated into a healthy dietary pattern to some extent, current nutrition science highlights nutrient-dense foods as playing an important role in building a healthy dietary pattern, and those foods are, in part, characterized by limited amounts of saturated fat, sodium, and added sugars (id.). Findings from the 2019 Food Safety and Nutrition Survey (FSANS) found that 87 percent of U.S. consumers reported looking at the Nutrition Facts label. However, of those, fewer than half usually looked for saturated fat and added sugars, and slightly more than half usually looked for sodium, demonstrating that there is a gap in how consumers are currently noticing or using the declarations for these important nutrients (Ref. 14). As such, current dietary recommendations based on nutrition science and recent survey findings further support a need to provide consumers with additional, interpretive information about these important nutrients that can help them quickly and easily identify how the levels of these nutrients in a particular food fit in the context of a total daily diet. Further, manufacturers are able to

make claims and provide truthful and non-misleading information about the beneficial nutritional attributes of food products on food labels and labeling including on the principal display panel. Requiring the Nutrition Info box would provide consumers with standardized and factual context about important nutrients on the front of food packages that can be compared across products. To streamline the amount of information provided in, as well as the space we require manufacturers to use for, the proposed Nutrition Info box, we are focusing on the three nutrients to limit to ensure that consumers have this additional context about these three important nutrients on the front of food packages to help inform their food choices.

The descriptions of the level of the nutrients that would be required in the Nutrition Info box (“Low,” “Med,” and “High”) are similarly science-based and reflective of FDA’s long-established use of the nutrition advice regarding how to interpret percent DV declarations on products—that 5 percent or less of a nutrient in a food product is “low” and 20 percent or more of a nutrient is “high” (see section V.B.3 of this document for further discussion). They are further generally consistent with the levels in the “low” and “high” nutrient content claims. See, e.g., §§ 101.62(b)(2) (“low”) and 101.54(b) (“high”), and our discussion of updating the low sodium nutrient content claim to align with current nutrition science in section IV.E of this document. We have tentatively determined that the standardized descriptions of the level of the nutrients that would be required in the Nutrition Info box along with the percent DV would help facilitate consumer understanding of a food’s nutrient profile and help consumers in identifying foods that can help them build a healthy diet. See, e.g., 58 FR 2302 at 2334 (January 6, 1993) (1993 nutrient content claim rule) (stating FDA’s belief that the selection of a food bearing the term “low” should help consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients). This is borne out by our recent research study, which found that, when shown a grouping of three distinct nutrient profiles, the vast majority of study participants were able to correctly identify the healthiest and least healthy nutrient profiles (95 percent and 92 percent, respectively) using the proposed Nutrition Info box, which includes the “Low,” “Med,” and “High” descriptions (Ref. 38).

We also note that previous research we conducted further supports the more

recent findings. In 1992, in arriving at the use of the percent DV on the current Nutrition Facts label, we tested a variety of options, including the use of adjective descriptions (e.g., “low,” “medium,” and “high”) with percent DV (Ref. 41). In the 1993 Nutrition Facts label final rule first establishing the Nutrition Facts label, we stated that the declaration of nutrient amount as percent DV or the placement of adjectival descriptors such as “high” and “low” next to the nutrient amount were both effective ways to help consumers understand the significance of product nutrition information in the context of a total daily diet (58 FR 2079 at 2118). Although we reported in 1993 that adjective formats (i.e., those featuring “low,” “medium,” and “high”) alone led consumers to miss quantitative differences between products when different nutrient levels were described using the same adjective (see, e.g., 58 FR 2079 at 2117), our current research shows that the use of the interpretive low, medium, and high descriptions together with the percent DV in the proposed Nutrition Info box would better inform consumers about where certain foods fall within the ranges of each term than a strictly quantitative label would (Ref. 38).

Further, with regard to the low sodium nutrient content claim and as discussed later in sections V.B.3 and V.G of this document, the low sodium claim may currently be used on the label or in the labeling of a food other than a meal product or main dish if it contains 140 mg or less sodium per reference amount customarily consumed (RACC) (and per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 140 mg or less sodium per 100 g (see § 101.61(b)(4) and (5)). Consistent with our authority in section 403(r) of the FD&C Act, we are proposing to update the low sodium nutrient content claim so that it may be used on the label or in the labeling of a food other than a meal product or main dish if it contains 115 mg or less sodium per RACC (115 mg or less per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 115 mg or less sodium per 100 g. The updated definition for the low sodium nutrient content claim is aligned with the regulation that provides a DRV for sodium of 2,300 mg, which was updated in the 2016 Nutrition Facts label final rule, based on scientific evidence and consensus recommendations (see 81 FR

33742 at 33874 and § 101.9(c)(9)). The proposed updated definition for the low sodium claim (at 115 mg or less sodium per RACC) also generally aligns with the proposed definition for the “Low” interpretive description in the Nutrition Info box (at 5% DV or less).

In addition, as outlined in section V.G, to prevent inconsistency on food labeling that could result in consumer confusion, we are relying on our authority in section 403(r) of the FD&C Act to propose to revise the definitions for the low sodium nutrient content claim and low saturated fat nutrient content claim to require that, in order to bear a low sodium nutrient content claim or low saturated fat nutrient content claim, a food must display “Low” in accordance with proposed § 101.6 for sodium or saturated fat in the Nutrition Info box, respectively. Note that we are not proposing to update the gram amount for the low saturated fat nutrient content claim, as the gram amount for the low saturated fat nutrient content claim (1 g saturated fat) already aligns with the proposed definition for the “Low” interpretive description in the Nutrition Info box (at 5% DV or less) and we have not currently identified another need to update it. See section V.B.3 of this document for a further discussion.

C. Legal Basis for the Proposal

The purpose of the Nutrition Info box and this proposed rule is to implement the congressional mandate set forth by the NLEA that FDA must implement regulations to help consumers readily observe and comprehend the nutrition information pertaining to a particular food in the context of a total daily diet. More specifically, the proposed Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet—which includes the consumption of foods that contain little or no saturated fat, sodium, and added sugars (Ref. 6)—and that allows them to quickly make comparisons of the levels of such nutrients across foods. As contemplated by section 2(b)(1)(A) of the NLEA, the proposed Nutrition Info box, including its interpretive descriptions of certain nutrient levels, would present nutrition information required to be placed on the label or labeling of foods under section 403(q) in a manner that allows consumers to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet (21 U.S.C. 343 note). The presentation of such interpretive information on the principal display

panel is designed to draw attention to and highlight information about certain nutrients that play an important role in the building of healthy dietary patterns, thereby assisting consumers in maintaining healthy dietary practices (see 21 U.S.C. 343(q)). Importantly, we note that the Supreme Court has considered and rejected narrow readings of the FD&C Act, instead embracing broad constructions of the FD&C Act based on the Court’s understanding of its text, congressional intent, and remedial purpose. See, e.g., *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“Congress fully intended that the [FD&C] Act’s coverage be as broad as its literal language indicates.”); *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (“The purposes of [the FD&C Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.”).

As explained in the sections elsewhere in this document, data and other information referenced that FDA has assembled and assessed supports that the proposed Nutrition Info box would be readily observable and comprehensible to consumers; allow them to understand the required information’s relative significance in the context of the total daily diet; and assist them in maintaining healthy dietary practices. As discussed, current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025*, emphasize the role of overall healthy dietary patterns and the consumption of nutrient-dense foods containing little or no saturated fat, sodium, and added sugars. Meanwhile, 2019 FSANS findings demonstrate that, of those who look at the Nutrition Facts label, the majority do not look at saturated fat and added sugars, and slightly more than half look at sodium (Ref. 14). Furthermore, in FDA’s experimental study, the proposed Nutrition Info box performed best among all schemes tested in helping consumers identify healthier nutrient profiles and led them to correctly describe the level of such nutrients (Ref. 38). Additionally, participants spent less time correctly responding to questions about the nutrient profile of a food when viewing the proposed FOP nutrition labeling scheme and reported that the scheme would help them easily find nutrition information on a food and easily compare nutrition information

between foods (id.). Taken together, this data and other referenced information support the inclusion and interpretation of the levels of saturated fat, sodium, and added sugars in the proposed Nutrition Info box and help demonstrate that the box would allow consumers to readily observe and comprehend the information conveyed and assist them in maintaining healthy dietary practices, in line with section 2(b)(1)(A) of the NLEA and section 403(q) of the FD&C Act.

We are also issuing this rulemaking consistent with our authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act, respectively). Sections 403(a)(1) and 201(n) of the FD&C Act represent our general labeling authority and describe when a product label would be misbranded as misleading for failing to include material facts regarding the food. In the context of nutrition labeling, we have considered the declaration of meaningful sources of nutrients to be a material fact (see 55 FR 29487 at 29491 through 29492, July 19, 1990, and 68 FR 41434 at 41438, July 11, 2003). Similarly, here, FDA finds that the relative amounts of these nutrients to limit in food products is material information that consumers must have as they select foods as part of their daily diet. Absent this mandatory, interpretive labeling on the front of food packages to complement the existing nutrition data on the label or labeling of food, data and other referenced information we have gathered show that consumers face challenges in understanding the relative contribution that individual foods make to their total daily intake of these nutrients to limit. Further, under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to “effectuate a congressional objective expressed elsewhere in the [FD&C] Act” (*Association of American Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass’n v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980))).

D. Inapplicability of Nutrient Content Claim Provisions to Proposed § 101.6

Some of the information that would appear in the Nutrition Info box would be a nutrient content claim if a manufacturer chose to voluntarily include it elsewhere on a food label. But we have determined that the proposed information in the Nutrition Info box, when it appears in the Nutrition Info box, is not a nutrient content claim and would not be subject to the requirements for nutrient content claims in section 403(r) of the FD&C Act and

its implementing regulations. Nutrient content claims are voluntary statements used by manufacturers to describe the level of nutrients in a food product. They are permitted by section 403(r) of the FD&C Act and FDA's nutrient content claim regulations. The 1993 nutrient content claim rule stated that the information about the nutrient content of a food be presented in standardized form, using uniform terms defined by FDA, so that consumers will not be misled (58 FR 2302 at 2394). Section 403(r)(1)(A) of the FD&C Act specifies that claims made in the label or labeling of the food that expressly or by implication characterize the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food are only permitted if they are made in accordance with FDA's authorizing regulations. In brief, pursuant to section 403(r) of the FD&C Act and our nutrient content claim regulations, defined nutrient content claims (*e.g.*, "lite," "free," "low," "high") may be voluntarily used only on certain food products that meet the established criteria for such claims, as described at part 101, subpart D. However, section 403(r)(1) of the FD&C Act provides that a statement that appears as part of the nutrition information required or permitted under section 403(q) of the FD&C Act is not a nutrient content claim.

As explained elsewhere in this document, we are proposing this Nutrition Info box in line with our authorities in section 2(b)(1)(A) of the NLEA and section 403(q) of the FD&C Act, and therefore, it is not a nutrient content claim under section 403(r) of the FD&C Act. The proposed Nutrition Info box would include additional contextual information that conveys certain nutrition information required by section 403(q) of the FD&C Act in a manner that the public can readily observe and comprehend. This additional contextual information about the three nutrients to limit would appear on nearly all packaged foods, thereby providing such information to consumers about how they can place these foods into their diets. Similar to the required declaration of percent DV in the Nutrition Facts label, which must

appear on nearly all food packages and allows consumers to understand the required nutrition information's relative significance in the context of a total daily diet, the information included in the proposed Nutrition Info box, including the interpretive descriptions "Low," "Med," and "High," would be required to be displayed on all foods subject to the rule. For these reasons, we find that the proposed required information in the Nutrition Info box would not constitute a nutrient content claim and would not be subject to the requirements for nutrient content claims in section 403(r) of the FD&C Act.

Thus, we have proposed amending § 101.13(c) to specify that the information proposed to be required as part of this Nutrition Info box would not be a nutrient content claim. This is consistent with our determination that the information in the Nutrition Facts label, including percent DV, is not a nutrient content claim. As noted in more detail elsewhere in this document, other voluntary statements, such as "100 calories," that do not appear as part of the nutrition information required or permitted by section 403(q) of the FD&C Act are expressly permitted by § 101.13 as nutrient content claims. We note that any claims about the nutrient levels of a food outside of the Nutrition Facts label and proposed Nutrition Info box would be nutrient content claims, which must meet applicable statutory and regulatory requirements (see section 403(r) of the FD&C Act and the relevant nutrient content claim regulations (for example, those in § 101.13)).

E. Severability

Although we believe that each of the elements of the Nutrition Info box that would be established by this rule, when applied collectively, would best help consumers to identify how foods fit into a healthy diet, each element independently enhances the manner of presentation to increase the likelihood that consumers would be able to readily observe and comprehend the required interpretive nutrition information on the front of food packages. In the event of a stay or invalidation of certain element(s) of the box, the other elements would continue to function sensibly to

advance the statutory objectives. See, *e.g.*, *Belmont Mun. Light Dep't v. FERC*, 38 F.4th 173, 188 (D.C. Cir. 2022) (finding severability of a portion of an administrative action, applying the principle that severability is appropriate where "the agency prefers severability to overturning the entire regulation" and where the remainder of the regulation "could function sensibly without the stricken provision") (citations omitted). For example, if the proposed requirement regarding the location of the Nutrition Info box on the upper third of the principal display panel were invalidated, we have tentatively determined that the substantive elements of the box, such as the requirements to include the interpretive descriptions and percent DV of saturated fat, sodium, and added sugars, would still function sensibly and be needed to provide important context to consumers elsewhere on the principal display panel. Likewise, in the absence of the proposed type style requirement, for example, each of the other features of the Nutrition Info box would continue to function and contribute to consumers readily observing and comprehending the nutrition information provided by the box and assist them in maintaining healthy dietary practices. Overall, it is FDA's intent to preserve each of the rule's aspects to the fullest possible extent, to help advance the important interests described in section IV.A.

V. Description of the Proposed Rule

We propose to add new § 101.6 to part 101, "Food Labeling." The proposed rule would require the inclusion of the Nutrition Info box on the principal display panel of most foods that are required to display the Nutrition Facts label. The Nutrition Info box is intended to complement the Nutrition Facts label and would provide consumers with interpretive information on the front of food packages for three nutrients to limit that would allow consumers to compare the levels of these three important nutrients among foods and quickly and easily identify how foods can be part of a healthy diet.

An example Nutrition Info box that reflects all proposed requirements is as follows:

Nutrition Info		
Per serving	% Daily	
5 cookies	Value	
Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	10%	Med
FDA.gov		

We also propose two overall amendments to certain nutrient content claims: (1) revising § 101.61(b)(4) and (5) to update the limit for the low sodium nutrient content claim to 115 mg per RACC or 100 g, which aligns with current nutrition science; and (2) adding requirements to §§ 101.61 and 101.62 specifying that food subject to this rule must bear “Low” in accordance with proposed § 101.6 for sodium and saturated fat, respectively, in the Nutrition Info box for the food’s labeling to qualify to bear the related low in nutrient content claim, which would avoid within-label inconsistencies with the proposed FOP scheme.

A. Scope/Applicability (Proposed § 101.6(a)(1))

Proposed § 101.6(a)(1) would require that this rule apply to all food covered under § 101.9 (Nutrition labeling of food) that is marketed for people ages 4 and older unless a specific exemption applies. The congressional record for the NLEA indicates that mandatory nutrition labeling was intended to solve problems with voluntary disclosure—the standard at the time—including that a significant percentage of food was sold without any nutrition information (Ref. 40). Section 403(q) of the FD&C Act therefore specifies, in part and with certain exceptions, that a food is misbranded unless its label or labeling bears nutrition information for certain nutrients, and § 101.9 details these requirements. Most foods we regulate (*i.e.*, all foods not specified in § 101.9(j)) must bear a Nutrition Facts label as described in § 101.9 (see § 101.9(a)).

In addition, we relied on our authority in section 2(b)(1)(A) of the NLEA to require the percent DV declaration in the Nutrition Facts label. In the preamble to one of our first regulations related to the Nutrition Facts label, we noted that the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of

a total daily diet, compare the nutritional values of food products, and plan general diets (58 FR 2206 at 2213).

Our research shows that 87 percent of adults living in the United States look at the Nutrition Facts label, and at least 76 percent use the Nutrition Facts label when buying a food for the first time (Ref. 14). However, only 49 percent of adults report looking at the percent DV on the Nutrition Facts label (*id.*). Data also suggest that up to 40 percent of Americans ages 16 and older do not understand the meaning of percent DV (Ref. 42). Accordingly, and consistent with our statutory direction in section 2(b)(1)(A) of the NLEA to require that certain information be conveyed in a manner that consumers can readily observe and comprehend, we are proposing a mandatory labeling scheme that would complement the Nutrition Facts label by providing additional, easy-to-use, interpretive context in the form of descriptive terms for the percent DV of certain nutrients (discussed later in section V.B.4 of this document) on the principal display panel (*e.g.*, the front of the package) of most foods. We discuss exemptions to this requirement later in section V.F of this document.

We propose that the scope of this rule cover foods marketed for the general population. In the 2016 Nutrition Facts label final rule, we updated the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs) (the recommended amounts of nutrients to meet or not to exceed each day, which are often referred to collectively as the Daily Values) for adults and children ages 4 years and older to be consistent with the data on the associations between nutrients and chronic diseases, health related conditions, physiological endpoints, and maintaining a healthy dietary pattern (81 FR 33742). We have traditionally used this age category as representative of the general population for nutrition labeling purposes (*id.*). We note that the DRVs for saturated fat, sodium, and added sugars for pregnant and lactating people are the same as

those for the general population (see § 101.9(c)(9)). Therefore, for purposes of this proposed rule, we consider pregnant and lactating people to be part of the general population.

We are not including foods marketed for children under 4 years old within the scope of this proposed rule. We recognize that infants and children ages 1 to 3 years are vulnerable subpopulations and have specific nutritional needs. The 2016 Nutrition Facts label final rule established mandatory labeling requirements to include specific DRVs for children ages 1 through 3 years (81 FR 33742 at 33927–31, codified at § 101.9(c)(9)). FDA has not established DRVs or percent DVs (*i.e.*, how much a nutrient in a single serving of food contributes to the DRV) for saturated fat, sodium, or added sugars for infants through age 12 months.

Our proposed interpretive descriptions for these nutrients are based on percent DVs. Therefore, for food products marketed for infants through age 12 months (*i.e.*, jars of baby food, teething crackers), we tentatively determine that it currently would not be feasible to provide consumers with additional interpretation—the purpose of the proposed Nutrition Info box—about the relative amounts of saturated fat, sodium, or added sugars in the products.

Additionally, since publication of the 2016 Nutrition Facts label final rule, there have been changes to Federal dietary guidance for children ages 1 to 3 years. The *Dietary Guidelines, 2020–2025* established daily nutrition goals for two subpopulations of children: ages 12 to 23 months and 2 to 3 years. This included goals for sodium for children ages 12 to 23 months and goals for saturated fat, sodium, and added sugars for children ages 2 to 3 years (Ref. 6). These categorizations do not align with current FDA regulations that provide DRVs for saturated fat, sodium, and added sugars for the single category of children ages 1 to 3 years (see

§ 101.9(c)(9)). Additionally, in some cases, the *Dietary Guidelines, 2020–2025* calculated daily nutrition goals using a different methodology than FDA used when establishing DRVs. For example, the *Dietary Guidelines, 2020–2025* established recommendations for daily sodium limits based on the Chronic Disease Risk Reduction level established by NASEM (Ref. 6). However, current FDA regulations include a DRV for sodium for children ages 1 to 3 (see § 101.9(c)(9)) that we derived using the upper limit for sodium established by the IOM for this age group (81 FR 33742 at 33929). The *Dietary Guidelines, 2020–2025* indicate that saturated fat should not be restricted in children younger than 2 years (Ref. 6).

Because we continue to evaluate the information on the nutritional needs of these subpopulations, as well as our DRVs for saturated fat, sodium, and added sugars for children ages 1 to 3 years (given the daily nutrition goals included in the *Dietary Guidelines, 2020–2025*), we are not currently proposing to require FOP nutrition labeling on foods marketed for infants and children ages 1 to 3 years. We invite comment, including data and other information, related to: (1) the nutritional needs of these subpopulations; and (2) the need for or value of interpretive nutrition information that can help consumers quickly and easily identify how foods can be part of a healthy diet for these subpopulations. We expect such feedback could help inform any future FOP policy for foods marketed for infants and children ages 1 to 3 years.

We are also proposing to exempt most dietary supplements from bearing a Nutrition Info box. Dietary supplements labeled in accordance with the special nutrition labeling provisions in § 101.36 are exempt from Nutrition Facts labeling under § 101.9(j)(6) and would therefore be exempt from Nutrition Info box labeling under proposed § 101.6(c)(1), discussed elsewhere in this document. Dietary supplements are products intended for ingestion, that, among other requirements, contain at least one dietary ingredient intended to supplement the diet (21 U.S.C. 321(ff)). Dietary ingredients include vitamins and minerals; herbs and other botanicals; amino acids; dietary substances that are part of the food supply, such as enzymes and live microbials (commonly called “probiotics”); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories (21 U.S.C. 321(ff)(1)). While dietary supplements

are considered foods, they serve a different purpose than conventional foods when it comes to building a healthy dietary pattern; they often provide individual nutrients (e.g., Vitamin C) and are intended to supplement, rather than constitute a core part or foundation of, the diet. Given the distinct role of dietary supplements in the overall diet, we propose to exempt such products from this proposed rule. Many dietary supplements do not contain saturated fat, sodium, and added sugars, and they are not required to have these nutrients declared on their nutrition label unless the supplement contains quantitative amounts by weight that exceed the amount that can be declared as zero (see 21 CFR 101.36(b)(2)). However, we are aware that some dietary supplements may contain what this proposed rule would describe as “High” levels of saturated fat, sodium, or added sugars per serving. We therefore invite comment on our proposed exemption of dietary supplements from the requirements of this rule.

B. Content (Proposed § 101.6(a)(2))

1. Headings and Subheadings (Proposed § 101.6(a)(2)(i) and (ii))

Proposed § 101.6(a)(2)(i) would require using “Nutrition Info” as the heading, or title, for the Nutrition Info box. This title describes what the box would convey and should be familiar in appearance to the “Nutrition Facts” title of the Nutrition Facts label (see § 101.9(d)(2)). We are proposing “Info” rather than “Information” to keep the title shorter and, therefore, the box smaller. This title reflects our intent to provide, in a convenient format, interpretive nutrition information to consumers that can help them quickly and easily identify how foods can be part of a healthy diet. The title would be displayed across the same distance of the box as the “Nutrition Info” header to orient the consumer and make it clear that the nutrition information that follows is part of this Nutrition Info box.

For the Nutrition Info box to be useful, consumers need to understand what nutrition information is being conveyed. Proposed § 101.6(a)(2)(ii)(A) would require using the subheading “Per serving” to help consumers understand that the Nutrition Info box, like the Nutrition Facts label, provides information about one serving of the food. We also propose including a statement of the serving size, expressed in household measures, alongside the “Per serving” subheading (e.g., “Per serving (whole package)” or “Per serving (½ cup)”) to further help

consumers understand what one serving is. The inclusion of both “Per serving” and the serving size expressed in household measures would be consistent with the information required in the Nutrition Facts label (see § 101.9(b)) and would help consumers understand whether the product is “Low,” “Med,” or “High” in the three nutrients disclosed for a specific amount of the product. Further, listing “Per serving” with a statement of the serving size expressed in household measures would help improve awareness that the information presented in the Nutrition Info box does not refer to the contents of the entire package when the package contains multiple servings.

While the Nutrition Facts label includes a statement of the serving’s gram amount (see § 101.9(b)(7)), the proposed Nutrition Info box would include only the serving’s household measure. Section 403(q)(1)(A)(i) of the FD&C Act specifies that a food is misbranded unless its nutrition labeling bears the serving size, which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. In our proposed rule to implement this and other labeling requirements, entitled “Food Labeling; Serving Sizes” (56 FR 60394, November 27, 1991), we proposed requiring that manufacturers provide the equivalent metric quantity, in parentheses, after the common household measure (e.g., 1 cup (28 g)), on what would become the Nutrition Facts label (id. at 60410). We finalized that requirement in the 1993 Nutrition Facts label final rule and clarified that the gram declaration was for compliance purposes (58 FR 2079 at 2163) (codified at § 101.9(g)(7) (“Compliance will be based on the metric measure specified in the label statement of serving size.”)).

This Nutrition Info box would reflect the serving size, in common household measures, declared in the Nutrition Facts label, and only the Nutrition Facts label would also declare the serving size’s metric measure. The inclusion of a metric measure would unnecessarily increase the Nutrition Info box’s size, and inclusion of a second statement of serving size measurement could increase the box’s complexity. Therefore, we are not proposing to include a second statement of the serving size’s metric measure, as its inclusion would not align with our goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet.

Proposed § 101.6(a)(2)(ii)(B) would require including the subheading “% Daily Value” in the Nutrition Info box. This heading would appear above the declaration of the quantitative percent DV and the interpretive “Low,” “Med,” and “High” descriptions for the three nutrients included. We propose using the “%” symbol instead of the word “percent” due to spacing considerations and for consistency with the Nutrition Facts label (see § 101.9(d)(6)).

2. Nutrients to Limit (Proposed § 101.6(a)(2)(iii))

Proposed § 101.6(a)(2)(iii) would require that the Nutrition Info box include information on saturated fat, sodium, and added sugars. We propose that saturated fat, sodium, and added sugars be the only nutrients in the Nutrition Info box, given their significance in building healthy dietary patterns, the scientific research on FOP nutrition labeling, and the current food labeling landscape, in which consumers report being familiar with a wide variety of industry claims (Ref. 14). This Nutrition Info box would be a continuation of our efforts to help consumers by providing information that can help them improve their dietary patterns by providing them with interpretive nutrition information presented on the front of food packages in a consistent, uniform way about the amounts of the three nutrients in covered products so they can quickly and easily understand their relative significance in the context of a total daily diet.

In the 2016 Nutrition Facts label final rule, we noted that nutrition science supports limiting intake of saturated fat, sodium, and added sugars (see 81 FR 33847). Similarly, the *Dietary Guidelines, 2020–2025* includes recommendations to choose nutrient-dense foods across and within food groups while limiting foods (including beverages) higher in saturated fat, sodium, and added sugars as a key strategy in emphasizing healthy overall dietary patterns (Ref. 6). For instance, research shows that people with diets characterized, in part, by lower intake of saturated fat, sodium, and added sugars were at 13 to 27 percent decreased risk for dying from any cause, cancer, or cardiovascular disease (Ref. 43). Still, most Americans exceed the recommended intake limits for saturated fat, sodium, and added sugars (Ref. 6).

FDA has been prioritizing nutrition initiatives that can help improve dietary patterns as part of a broader effort to help reduce the burden of diet-related chronic diseases in the United States and advance health equity, as diet-

related chronic diseases are experienced disproportionately by certain racial and ethnic populations and those with lower socioeconomic status. Our initiatives include those that support consumer understanding of nutrients to limit in the diet. For example, on December 27, 2024, FDA published a rule amending the “healthy” implied nutrient content claim (89 FR 106064). The framework for the updated “healthy” definition includes criteria for nutrients to limit. We state in the rule that these criteria are consistent with current nutrition science and the *Dietary Guidelines, 2020–2025* recommendations to limit intake of saturated fat, sodium, and added sugars, and help ensure that foods bearing the “healthy” claim do not contain excess amounts of these nutrients, which can, among other things, increase the risk of chronic disease (id. at 106091, 106093, 106104, and 106110). Additionally, in 2021, FDA published short-term (2.5-year) voluntary sodium reduction targets for the food industry, as part of a gradual, iterative approach to help reduce sodium in the food supply and support reducing sodium intakes over time (see 86 FR 57156, October 14, 2021). We published draft Phase II (3-year) goals in 2024 (see 89 FR 66727, August 16, 2024).

Regarding the scientific research on FOP nutrition labeling, our research found, and the scientific literature we considered confirms, that simpler schemes are easier for consumers to understand and that consumers often have access to information about nutrients to get enough of on the front of food packages. The *Dietary Guidelines, 2020–2025* names five nutrients of public health concern (i.e., nutrients to get enough of) (dietary fiber, vitamin D, calcium, iron, and potassium (Ref. 6)) as well as the three nutrients to limit, and the scientific research and literature on FOP nutrition labeling indicate that the inclusion of nutrients to get enough of with nutrients to limit may not lead to simple schemes that help consumers. For example, we tested FOP nutrition labeling schemes that included fiber and calcium, along with saturated fat, sodium, and added sugars, in our first focus groups (Ref. 36), given that these nutrients to get enough of may be included in certain industry-based, voluntary FOP initiatives in the United States (Ref. 20) and in certain international schemes (Ref. 32). The feedback we collected through our first focus group research indicated that participants were confused by the inclusion of both nutrients to limit and nutrients to get enough of in the same

FOP scheme (Ref. 44). This focus group testing helped inform our experimental study, which included schemes with only the three nutrients to limit.

Regarding the current food labeling landscape, we note that manufacturers have many ways to communicate information on the front of a food package about nutrients to get enough of. Use of nutrient content claims can inform consumers interested in intake of specific nutrients. Health claims (i.e., claims that have been reviewed by FDA and are authorized on food products to state that a food or food component may reduce the risk of a disease or a health-related condition) can also highlight the content of specific nutrients in a food and their relation to the risk of various diseases. Other claims can highlight nutrients and provide context to their role in the normal structure or function of the body. In addition to these claims, manufacturers may voluntarily include truthful and non-misleading information about their products on food labels or labeling.

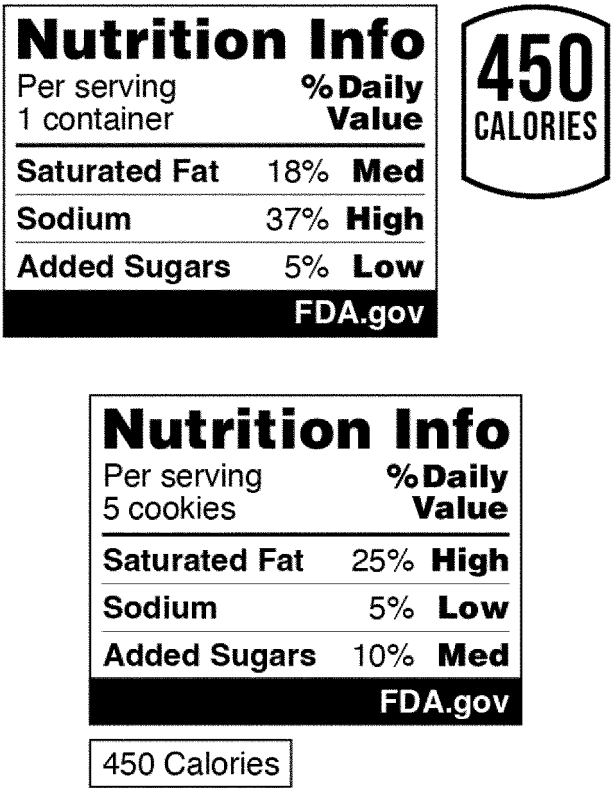
As discussed elsewhere in this document, the proposal would provide consumers with a quick- and easy-to-use scheme immediately visible on the label or labeling that would state relative amounts of the three disclosed nutrients. We tentatively conclude that a scheme that focuses only on certain nutrients to limit would provide consumers with important information to help them build and maintain healthy dietary practices without including additional information that could lessen the effectiveness of a nutrition label designed for quick, easy use. This would also make the scheme simpler, which research shows consumers prefer (Refs. 20 and 27).

We also considered whether to include or allow a calorie disclosure in the proposed Nutrition Info box. We are aware that some interested parties would prefer the inclusion of a quantitative calorie statement in the Nutrition Info box. However, a quantitative calorie statement would not provide consumers with new, interpretive information. Regarding an interpretive description of calories, our regulations, at § 101.9(c)(9), specify the DRVs for, among other things, saturated fat, sodium, and added sugars. While these DRVs are based on the reference caloric intake of 2,000 calories, which we use for general nutrition advice, we note that there is no DRV, and therefore no percent DV, for calories. In the 2014 proposed rule to update the Nutrition Facts label, we explained that setting a DRV for calories would necessitate determining a quantitative intake recommendation for calories, but also

noted that there is no appropriate quantitative intake recommendation for calories and that we were not aware of any other data or information on which a DRV for calories could be determined (79 FR 11880 at 11892–93). We maintained this position in the 2016 Nutrition Facts label final rule. We noted that quantitative intake recommendations for calories are called estimated energy requirements (EERs), and they are based on healthy individuals of defined age, sex, weight, height, and level of physical activity (81 FR 33742 at 33782). We explained that it would be difficult to combine the EERs into a single reference calorie level

applicable to the general population because calorie needs vary based on many factors (id.). Therefore, we did not establish a DV for calories and have continued to use the reference caloric intake of 2,000 calories for general nutrition advice (id.). We are aware of no new data or other information published after the 2016 Nutrition Facts label final rule that changes our determination. Therefore, we tentatively conclude that it would not be appropriate to provide consumers with an interpretation of the quantitative calorie information currently required on the Nutrition Facts label.

We acknowledge that some food manufacturers are voluntarily providing calorie information on the front of food labels, including to help vending machine operators comply with FDA’s calorie labeling requirements for articles of food sold from certain vending machines (see § 101.8(c)(2)(ii)), and have an interest in continuing this practice. Our existing regulations allow manufacturers to voluntarily include such a statement on the principal display panel (see § 101.13(i)(3)). Our proposal would not change that. Examples of what such labeling might look like are as follows:



We invite comment on the inclusion of a mandatory or voluntary quantitative statement of calories in the Nutrition Info box. We also invite comment on any ways we could consider inclusion of an interpretation of quantitative calorie information in the Nutrition Info box, including any new data or other information on which to base such an interpretation.

3. “Low,” “Medium,” and “High” Interpretive Descriptions (Proposed § 101.6(a)(2)(iv))

Proposed § 101.6(a)(2)(iv) would require low, medium, and high (“Low,” “Med,” and “High”) descriptions for each nutrient to limit in the Nutrition

Info box. These descriptions would interpret the percent DV of saturated fat, sodium, and added sugars per product serving. We propose a range of 5% DV or less for “Low”; 6% to 19% DV for “Med”; and 20% DV or more for “High.” Because the percent DV declarations will have already been calculated and appropriately rounded for the Nutrition Facts label according to § 101.9(c)(9) and (d)(7)(ii), we do not address calculation or rounding considerations in this proposed rule.

In proposing ranges for the low, medium, and high interpretive descriptions, we considered the regulatory history related to establishment of the percent DV and

such descriptions; our longstanding consumer education activities designed to help consumers understand the percent DV in the context of the total daily diet; the nutrition education initiatives of other groups; and our existing regulatory definitions for nutrient content claims, including definitions established for “low” and “high” claims. The ranges we propose for determining interpretive descriptions for saturated fat, sodium, and added sugars—in particular, the designation of 5% DV or less to be “Low” and 20% DV or more to be “High”—align with our longstanding general approach for interpreting the percent DV.

First, percent DV declarations use a common numeric reference standard (*i.e.*, 0 through 100), and interpretive descriptions help to put those numeric values into the context of a total daily diet using easily understood terms (*e.g.*, “Low,” “Med,” “High”). As discussed elsewhere in this document, the NLEA’s legislative history explicitly mentions using the terms “low,” “medium,” and “high” to help consumers place the nutrient levels in a food into the context of a daily diet (Ref. 40). As early as 1993, we considered the addition of interpretive descriptions to the Nutrition Facts label next to the percent DV to help consumers understand a food’s nutrient profile and identify foods that could fit into healthy dietary patterns (see, *e.g.*, 58 FR 2079 at 2118). While we concluded in the 1993 Nutrition Facts label final rule that both percent DV and interpretive descriptions next to the nutrient amount information were effective in helping consumers understand the significance of nutrition information in the context of a total daily diet, we ultimately finalized contextualizing nutrient amount information as percent DV (58 FR 2079 at 2118 and 2125), stating our belief that consumers would be able to use percent DV declarations more effectively than any other format we tested. However, recent data show that up to 40 percent of American consumers misinterpret or do not understand the meaning of percent DV (Ref. 42). Additionally, our recent research found that, when shown a grouping of three distinct nutrient profiles, the vast majority of participants were able to correctly identify the healthiest and least healthy nutrient profiles (95 percent and 92 percent, respectively) using the Nutrition Info scheme, which included low, medium, and high descriptions and percent DVs (Ref. 38).

Second, for many decades, FDA has publicized a general framework designed to help consumers interpret nutrient levels in a product. This framework (5/20 principle) has informed consumers that 5% DV or less of a nutrient per serving is considered low and 20% DV or more of a nutrient per serving is considered high (Refs. 45 and 46). In 2011, as part of a “Food Label and You” campaign, we released several videos to promote consumer awareness and understanding of the 5/20 principle for interpreting percent DV on a food label (Ref. 47). We continued publicizing this general framework on our website as a component of our consumer education campaign, “The New Nutrition Facts Label: What’s in it

for You,” after the 2016 Nutrition Facts label final rule published (*id.*).

Third, diverse groups, including health agencies, academic institutions, medical and public health groups, and media outlets, have also relied on the 5/20 principle for decades. For example, the American Heart Association, American Diabetes Association, Mayo Clinic, Johns Hopkins University, The Ohio State University, National Institute on Aging, International Food Information Council, Public Broadcasting Service, New York Times, and Business Insider provide this advice in education initiatives designed to help consumers understand and interpret information on food labels (*id.*). Food retailers and industry groups have also adopted this general approach in public-facing materials when discussing nutrition information on the food label (*id.*). As such, the designation of 5% DV or less to be “Low” and 20% DV or more to be “High” for the nutrients required to be listed in the Nutrition Info box aligns with widely adopted and used definitions for low and high in nutrition-related consumer education initiatives.

Fourth, the NLEA and FD&C Act permit claims on a food label that are authorized by FDA regulations and characterize the level of a nutrient in a food (*i.e.*, nutrient content claims). Nutrient content claims can be voluntarily used by manufacturers to describe the level of a nutrient in a food using terms such as “low” and “high,” and most are applicable only to nutrients that have an established DV. When we first established the regulatory definitions for nutrient content claims, we stated that our objectives included consistency among definitions, claims that aligned with public health goals, and claims that consumers could use to maintain healthy dietary practices (58 FR 2302 at 2319).

FDA has nutrient content claims regulations for low saturated fat (§ 101.62(c)(2) and (3)) and low sodium (§ 101.61(b)(4) and (5)). These regulations provide criteria for “low” and its specified equivalent terms. Our regulatory definitions for “low” claims provide absolute amounts (*i.e.*, grams, milligrams); however, we have long applied the general principle that 5% DV or less is considered “low” in consumer education (Refs. 45 to 47), and the relevant gram amounts are generally consistent with that principle, as discussed further here.

In 1993, we established a DRV of 20 g for saturated fat, which was based on the 1990 Dietary Guidelines recommendation that consumption of saturated fat should be less than 10

percent of calories (58 FR 2206 at 2217). In the 1993 nutrient content claim final rule, we noted that using an average level of 1 g in 16 to 20 servings of food per day would supply 16 to 20 g of saturated fat daily, which is within the DRV of 20 g (58 FR 2302 at 2338 through 2340). In addition to this 1 g or less per RACC criterion, we also established a second criterion for low saturated fat of 15 percent or less of calories from saturated fat for individual foods and 10 percent or less of calories from saturated fat for meals and main dishes. This second criterion was established to limit “low” claims on foods with small serving sizes because these foods do not contain especially low levels of saturated fat (58 FR 2338 at 2339). Our analysis highlighted that saturated fat was present in more than half of 18 United States Department of Agriculture-defined food categories (58 FR 2302 at 2338). We also noted that very little saturated fat was found in most fruit, vegetables, and grains. In the 2016 Nutrition Facts label final rule, we retained the DRV of 20 g for saturated fat because consensus reports continued to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of cardiovascular disease (81 FR 33786). The low saturated fat claim of 1 g or less per RACC is 5% DV or less.

We established the nutrient content claim for low sodium in a final rule entitled “Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content” (49 FR 15510, April 18, 1984) (1984 final rule). In the proposed rule entitled “Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content” (47 FR 26580, June 18, 1982), we estimated that the consumption of 20 low-sodium foods would contribute about 2,800 mg of sodium per day (using 20 servings per day as a reasonable average number of servings for adults and 140 mg of sodium per serving—considered to be low in sodium), which at the time fell into the National Academy of Sciences (now NASEM) and National Research Council’s range for a mildly restricted sodium diet (*id.* at 26581 through 26585) (we proposed using the term “moderately low sodium” for this nutrient content claim but finalized the term “low sodium” to characterize nutrient content claims for foods containing 140 mg or less of sodium per serving—see 49 FR 15510 at 15519). Assuming 20 servings per day, 140 mg sodium per serving equaled 5 percent of 2,800 mg sodium per day for a mildly

restricted sodium diet. In the 1984 final rule, we concluded that a significant proportion of the food supply would be eligible to bear the low sodium claim (49 FR 15510). We noted that foods that could be labeled “low sodium” included some hot and cold cereals, many cuts of fresh meat and poultry, some fish, frozen vegetables, and some desserts and snacks such as cookies, cakes, and candy (id.).

In the 1993 Nutrition Facts label final rule, we established a DRV for sodium of 2,400 mg per day (58 FR 2206 at 2217). However, in the 1993 nutrient content claim final rule, we retained the definition for the low sodium claim as 140 mg or less sodium, highlighting that comments related to the rulemaking and at public hearings did not indicate a need for change and supported the existing criteria (58 FR 2302 at 2335 through 2336). We also established weight-based criteria for low claims for products with small serving sizes—RACCs of 30 g or less or 2 tablespoons or less—stating that this would prevent misleading claims on certain nutrient-dense foods (we stated in the proposed rule entitled “Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms” (56 FR 60421, November 27, 1991) (one of two proposed rules underlying the 1993 nutrient content claim final rule) that (1) without the weight-based criterion, low claims would be allowed on certain foods that are nutrient dense on a weight basis yet still qualify for a low claim because of their small serving size, and (2) that nutrient-dense foods with small serving sizes could be consumed frequently throughout the day and ultimately make substantial contributions to the diet despite their low claims (id. at 60430)). We also established a weight-based criterion for meal products and main dishes in the 1993 nutrient content claim final rule, stating that providing for the level of a nutrient per 100 g of food is generally sufficient to prevent misleading claims on meal-type products (58 FR 2302 at 2315 through 2320 and 2379 through 2381).

In the 2016 Nutrition Facts label final rule, we updated the DRV for sodium from 2,400 mg to 2,300 mg based on consensus recommendations to reduce sodium intake because there is a direct relationship between sodium intake and increased blood pressure (81 FR 33742 at 33875 through 33880). With these updates, the low sodium threshold of 140 mg or less per serving equals 6% DV or less for low sodium nutrient content claims.

Given the updated 2,300 mg DRV for sodium in the 2016 Nutrition Facts label

final rule, and in line with FDA’s ongoing efforts to support reducing sodium intake in the United States (<https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction>, accessed June 13, 2024), we propose to update the low sodium nutrient content claim limit to 115 mg sodium (20 servings at 115 mg equals 2,300 mg). With this update, the low sodium nutrient content claim could be used on the label or in the labeling of a food other than a meal product or main dish if it contains 115 mg or less sodium per RACC (115 mg or less per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 115 mg or less sodium per 100 g. This updated definition for the low sodium nutrient content claim would generally align with the 5% DV or less range that we are proposing for “Low” for sodium in the proposed Nutrition Info box. Additionally, the revised definition would apply to foods that are not subject to the proposed requirement to display a Nutrition Info box.

We are aware of limited exceptions to this alignment. For example, foods with RACCs greater than 30 g that have 116 mg to 125 mg sodium per serving (e.g., certain reduced sodium canned vegetables) would fall under the “Low” categorization for sodium in the proposed Nutrition Info box but would not qualify to bear a low sodium nutrient content claim. Additionally, meal products or main dishes that contain 115 mg or less sodium per 100 g might fall into the “Med” categorization for sodium in the proposed Nutrition Info box and therefore would not be able to bear a low sodium nutrient content claim. However, in most cases, the updated definition for the low sodium nutrient content claim (115 mg sodium or less) would align with the 5% DV or less that we are proposing for “Low” for sodium in the proposed Nutrition Info box. We also note that, in all cases in which the Nutrition Info box would be required, labeling would be consistent, as we are proposing an update to the low sodium nutrient content claim that would require consistency between the Nutrition Info box and use of a low sodium nutrient content claim (see section V.G of this document).

While FDA has nutrient content claim regulations for low sodium and low saturated fat, we do not have a nutrient content claim regulation for low added sugars. However, the *Dietary Guidelines for Americans, 2020–2025* recommends limiting intake of added sugars to less than 10 percent of calories per day, or

50 g for a 2,000 calorie per day diet (which we use for general nutrition advice) (Ref. 6). In the 2016 Nutrition Facts label final rule, we established a DRV for added sugars of 50 g (see 81 FR 33742 at 33982, codified at § 101.9(c)(9)). As we stated in that final rule, small amounts of added sugars found in many different foods and ingredients can add up throughout the day and can contribute empty calories in the diet at levels that exceed what would otherwise be reasonable within recommended calorie limits (id. at 33813). With this information in mind, and consistent with our longstanding advice regarding how to interpret the percent DV, we propose using 5% DV or less as the range for “Low” for added sugars to provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, which includes limiting their overall intake of added sugars.

Applying a range of 20% DV or more for “High” is consistent with our nutrient content claim regulations (§ 101.54(b)(1)) for nutrients having either an RDI established in § 101.9(c)(8)(iv) or a DRV established in § 101.9(c)(9). While we are not aware that industry uses the claim for nutrients to limit, a “high” nutrient content claim for saturated fat, sodium, and added sugars is permitted under our existing regulations (see § 101.54). Moreover, under our general requirements for health claims, we use 20% DV to derive disqualifying levels (i.e., the levels of these nutrients above which the label or labeling of a food may not bear a related health claim) for saturated fat and sodium (§ 101.14(a)(4)) (58 FR 2478 at 2494). Twenty percent DV is also used to establish the disclosure levels for, among other nutrients, saturated fat and sodium when a food bears a nutrient content claim about one of the other enumerated nutrients under § 101.13(h)(1) (58 FR 2302 at 2308). For example, if a food displays a low sodium nutrient content claim and also has 4 g saturated fat (i.e., 20% DV saturated fat), the food would be required to display a disclosure such as “See nutrition information for saturated fat content.”

FDA does not have a regulation for a nutrient content claim of “medium” for any nutrient. However, we are proposing a range of 6% to 19% DV for “Med” for purposes of the Nutrition Info box. This range falls between the proposed low and high ranges for saturated fat, sodium, and added sugars and provides a categorization for such nutrients that are too high to fall into “Low” but too low to fall into “High.”

The adjective “medium” is defined as, for example, “being in the middle between an upper and lower amount, size, degree, or value” (Ref. 48) and “intermediate in quantity, quality, position, size, or degree” (Ref. 49). The common meaning of the adjective “medium,” then, aligns with the meaning of the interpretive description “Med” we are proposing. Additionally, many participants in our experimental study recognized that 15% DV of a nutrient fell somewhere in between “High” and “Low” (Ref. 38), and we provided no form of consumer education before they responded.

We recognize that some other countries use more than one value to establish their categorizations and provide different categorizations based on product type. For example, foods with smaller serving sizes, such as peanut butter, might fall under the “High” categorization at a lower percent DV than most other foods, while foods with larger serving sizes, such as prepackaged main dishes, might fall under the “High” categorization at a higher percent DV. We have established a similar tiered approach for certain nutrient content claims that would meet a “low” criterion for amount per serving but still, on a weight basis, contain a substantial amount of the nutrient. For example, to use the “low fat” claim, we require foods with small RACCs of less than 30 g or 2 tablespoons or less to be calculated at a 50 g basis (§ 101.62(b)(2)(i)(B)). Without this weight-based criterion, a dessert topping that contains 2 g fat per serving would meet the definition of “low fat” but contain as much as 25 g fat per 100 g of food. We invite comment on this serving size issue and welcome data and other information on possible different approaches.

Additionally, we request data and other information on any alternative criteria for the proposed interpretive “Low,” “Med,” and “High” descriptions that could support our goals of providing consumers with interpretive information for the levels of the three nutrients to limit in the Nutrition Info box that can help them quickly and easily identify how foods can be part of a healthy diet. We also invite comment on use of the “Low” categorization for products that declare 0% DV for any of these three nutrients, rather than a fourth categorization, such as “Zero” or “Free,” to indicate that the product is not simply “Low” for that nutrient but contributes zero percent to the DV.

In FDA’s experimental study, we tested variations of the Nutrition Info box that included the colors green, yellow, and red to help communicate to

consumers that a product was low, medium, or high, respectively, in the listed nutrients to limit. While there is some information in our literature review suggesting that color coding with text can lead to improved understanding of nutrition information, our experimental study found that colors neither significantly increased the utility of the Nutrition Info box for U.S. consumers nor increased understanding of the interpretive information provided in a statistically significant way (Ref. 38). Additionally, we have heard concerns from interested parties about potential difficulty with using color coding for consumers with red-green color blindness (which is the most common form (Ref. 50)) and that mandating colors would substantially increase the cost of complying with the rule. Given these factors, the importance of maintaining consistency for consumers, and to facilitate comparisons between products, our proposal would not require or allow such colors.

4. Inclusion of Percent Daily Value (Proposed § 101.6(a)(2)(v))

Proposed § 101.6(a)(2)(v) would require that the Nutrition Info box include the corresponding quantitative percent DV for people ages 4 and older for each nutrient listed, which will have already been calculated for the Nutrition Facts label according to § 101.9(c)(9) and (d)(7)(ii). We propose that these values be placed in a column underneath the “% Daily Value” subheading and to the left of the interpretive descriptions (see section V.B.3 of this document). As we stated in the 2016 Nutrition Facts label final rule, a percent DV declaration helps consumers understand the nutrient information on the product label in the context of the total diet (81 FR 33742 at 33748). Including the quantitative percent DV in the Nutrition Info box for each nutrient would therefore allow consumers to quickly compare the nutrient levels between products, particularly if the products have the same interpretive description (e.g., comparing two products that are “High” in added sugars, where one contains 30% DV and the other contains 60% DV). As noted elsewhere in this document, we reported in 1993 that adjective formats (*i.e.*, those featuring “low,” “medium,” and “high”) alone led consumers to miss quantitative differences between products when different nutrient levels were described using the same adjective (see, e.g., 58 FR 2079 at 2117). However, our current research shows that quantitative percent DV together with interpretive

descriptions in the Nutrition Info box may help consumers better understand why a serving of food has the interpretive description it does and would better inform consumers about where certain foods fall within the ranges of each term than a strictly interpretive label would (Ref. 38). In addition, we believe that including percent DV along with the interpretive descriptions in the Nutrition Info box could result in additional consumers understanding the meaning of percent DV when it is displayed on food labels, including in the Nutrition Facts label.

Moreover, including the quantitative percent DV in addition to the “Low,” “Med,” and “High” descriptions may help consumers better understand why a serving of a food has the interpretive descriptions it does. In our second set of focus groups, many participants said they liked seeing the percent DV next to the interpretive description because it provided some context for the interpretation (Ref. 33). In addition, of the Nutrition Info schemes we tested in our experimental study, those that included percent DV declarations performed better in measures assessing ease of use and understanding (Ref. 38). Therefore, we are proposing to require both percent DV and interpretive descriptions for the nutrients to limit in the Nutrition Info box to help consumers quickly and easily identify how foods can be part of a healthy diet.

5. Inclusion of an Attribution Banner (Proposed § 101.6(a)(2)(vi))

Proposed § 101.6(a)(2)(vi) would require the inclusion of a banner at the bottom of the Nutrition Info box that includes an “FDA.gov” attribution statement. Several studies on FOP nutrition labeling found that inclusion of an attribution for the FOP nutrition label increases consumers’ trust in and the credibility of the information. For example, in their experimental study to test variations of a “High In” FOP nutrition label, Canadian researchers found that the presence of a Health Canada attribution resulted in higher trust in and credibility of the FOP nutrition symbol (Ref. 51). Almost all participants who saw the FOP nutrition symbol with the Health Canada attribution found it helpful to include because it engendered trust in the FOP nutrition symbol, drew their attention to the FOP nutrition symbol, and made the FOP nutrition symbol look more official (*id.*). Other studies found that government attribution or endorsement by health organizations increased the believability and credibility of the label (Refs. 52 to 54). In our first set of focus groups, participants expressed mixed

reactions to the inclusion of an attribution statement (Ref. 37). However, most participants viewed “*FDA.gov*” as making the scheme credible and trustworthy (Ref. 44). Informed by the literature findings, as well as this feedback, we propose to include the attribution statement “*FDA.gov*” in the Nutrition Info box to indicate that the proposed Nutrition Info box appears as required by FDA and to signal to consumers where they can find additional information regarding the Nutrition Info box, nutrition information, and our nutrition labeling requirements.

C. Format (Proposed § 101.6(a)(3))

Proposed § 101.6(a)(3) would require nutrition information to be presented on food labels or labeling in a specific format for the standard Nutrition Info box (we discuss our proposal to allow an alternative intermediate-package Nutrition Info box in section V.E.7 of this document). The proposed Nutrition Info box’s format elements include type style (*i.e.*, a single font); size (*i.e.*, point); color; justification (*i.e.*, left, right, or centered); and use of boldface and hairlines.

We considered many factors when designing the proposed Nutrition Info box’s format, including findings from consumer research and literature reviews (Refs. 20, 21, 26, 27, 37, 38, and 44); places where we expect people would use the Nutrition Info box (*i.e.*, at the point of decision-making); and the diversity of the intended audience (*e.g.*, level of nutrition knowledge, time available to make a purchase or consumption decision). Studies consistently confirm that simple formats are easier to comprehend and require less consumer effort than complex formats (Refs. 28 and 55). In our view, a simple format is one that minimizes clutter and enables the public to readily observe and comprehend the required nutrition information (21 U.S.C. 343 note). Use of a simple format aligns with our goal for FOP nutrition labeling, which is to provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. Thus, our proposed Nutrition Info box is designed to serve as a visual cue to the reader that the information it contains is quickly and easily understandable interpretive nutrition information about the three nutrients to limit.

Additionally, while we are committed to the flexible application of graphic techniques to make the required

nutrition information easy to read and comprehend, we want to ensure that all Nutrition Info boxes, regardless of the products they reflect, look similar so that consumers will immediately recognize them and understand what they are. To accomplish this, our proposed rule would set requirements for certain key graphic elements of the Nutrition Info box. In the interest of uniformity of presentation, FDA strongly recommends that the Nutrition Info box mirrors the examples found throughout proposed § 101.6.

During FDA’s experimental study, we tested variations of the Nutrition Info box that included a magnifying glass icon (see Ref. 34). This icon is used in some international High In FOP schemes (*e.g.*, those in Canada and Brazil), and we tested the icon to help us determine whether a graphic image could increase consumer attention to and understanding of the information in the scheme. We are aware that current FOP nutrition schemes in U.S. and international markets use a variety of shapes and symbols to help draw attention to information included in the FOP nutrition label (Ref. 32). We are not proposing to require a graphic image in the Nutrition Info box because our experimental study did not find that the inclusion of a graphic (*i.e.*, the magnifying glass icon) in this particular scheme yielded statistically significant results (Ref. 38). Because the addition of a graphic image did not meaningfully affect U.S. consumers’ attention to or use of the Nutrition Info box, we tentatively conclude that including a graphic image, such as a magnifying glass icon, could add unnecessary complexity and clutter to the Nutrition Info box, and therefore our proposal would not require or allow the inclusion of a graphic image.

1. Location (Proposed § 101.6(a)(3)(i))

Our existing regulations include various label and labeling requirements regarding placement of information, such as the declaration of net quantity of contents, which generally must appear on the lower 30 percent of the principal display panel (see § 101.7(f)). Proposed § 101.6(a)(3)(i) would require the Nutrition Info box to appear on the upper third of the principal display panel. We reviewed four consumer research studies on FOP nutrition label placement that tested placement on the upper left, upper right, bottom left, and bottom right of the principal display panel (Refs. 51 and 56 to 58). Each study showed that FOP nutrition labels are most effective when placed in the upper left or right of the principal display panel. While study results were mixed

on the best orientation (*i.e.*, left or right placement), the studies found that consumers had improved attention, reaction time, and label understanding when the FOP nutrition label was in the upper left or right of the principal display panel compared to the lower left or right (*id.*).

However, we are aware that foods’ principal display panels often contain other informational and graphic design elements in addition to the information we require and that certain foods come in packages of different shapes. We want to balance our goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet with maintaining flexibility for industry in the design of their principal display panels. Therefore, we propose to require placement of the Nutrition Info box somewhere in the top third of the principal display panel, without specifying the exact location (*e.g.*, upper right corner, ‘x’ inches from any side or design element).

We invite comment, including studies or other research, on the location and specifically on whether to take a flexible approach rather than designating the proposed Nutrition Info box’s exact location.

2. Type Style (Proposed § 101.6(a)(3)(ii))

Proposed § 101.6(a)(3)(ii) would require use of a single, easy-to-read type style in the Nutrition Info box. Information required under the FD&C Act must be prominent, conspicuous, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see section 403(f) of the FD&C Act). We tentatively conclude that a single, easy-to-read type style would be easier for consumers to read and understand, while not proposing to require a specific type style would maintain flexibility for industry. The proposed type style requirement aligns with the Nutrition Facts label’s type style requirements (see § 101.9(d)(1)(ii)(A)). Similarly, we use Helvetica in our example proposed Nutrition Info box (see proposed § 101.6(a)(5))—the same type style we use in our example Nutrition Facts label (Ref. 59)—which is recognized as a very readable type style (Ref. 60).

3. Type Size (Proposed § 101.6(a)(3)(iii))

Proposed § 101.6(a)(3)(iii) would require the use of a minimum type size (at least 8 point) in the Nutrition Info box that is no smaller than the size of the required net quantity of contents declaration specified in § 101.7(h) and

(i). Our existing food labeling regulations for packaged foods, at § 101.7(i), require, among other things, that the declaration of net quantity be in letters and numerals in a type size that is established in relation to the area of the principal display panel of the package. The regulation prescribes the following size specifications for net quantity declarations:

- Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less;
- Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches;
- Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches; and
- Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

If the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, then the lettering sizes are to be increased by one-sixteenth of an inch (§ 101.7(i)).

In our proposed rule entitled “Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size” (83 FR 32221, July 12, 2018) (vending FOP proposed rule), we discussed industry comments noting the existence of several voluntary FOP nutrition labeling programs where nutrition information—in that case, calories—is presented in an FOP type size that ranges from 100 to 150 percent of the size of the net quantity of contents statement on the principal display panel (id. at 32223). We considered those comments when proposing the revised requirement that calorie disclosures on the principal display panel of foods sold from certain vending machines must be at least 150 percent of the size of the net quantity of contents declaration on the front of the package. We also sought comment on an alternative approach of requiring the calorie disclosure to be at least 100 percent of the size of the net quantity of contents statement.

We ultimately finalized our 150 percent proposal (see 84 FR 57603, October 28, 2019) (vending FOP final rule). In the vending FOP final rule, we noted that the area of the principal display panel (calculated in square inches or square centimeters) determines the minimum type size

permitted for the net quantity declaration (as described elsewhere in this section). As such, both the 150 percent requirement we were finalizing and the 100 percent requirement we asked for comment on would be based on the size of the principal display panel (id. at 57606). In other words, the size of both the net quantity of contents declaration and the vending FOP disclosure scale proportionately to the size of the principal display panel. We are proposing the same scaling, based on the net quantity of contents type size, for the minimum type size in the Nutrition Info box. We tentatively conclude that such scaling would help ensure that the Nutrition Info box will be prominent on the label or labeling and its contents readable, while not mandating a size that would occupy an unnecessarily large part of the principal display panel.

In the vending FOP final rule, we also explained that, when a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, visible nutrition information on the front of a package must be large enough, and prominent enough, for prospective purchasers to see and use the information (id. (internal citation omitted)). We stated that the 150 percent type size requirement for FOP calorie disclosures on foods sold from glass-front vending machines, rather than the 100 percent type size alternative approach, will ensure that the declarations are visible, clear, and conspicuous and able to be easily read by a prospective purchaser (id.).

Unlike in the vending machine context, consumers would usually be able to pick up, walk up to, or otherwise closely inspect a food’s Nutrition Info box at a comfortable reading distance. Therefore, we tentatively conclude that mandating a type size no smaller than that which is used in the net quantity of contents declaration—essentially, the alternative we requested comment on in the vending FOP proposed rule—would generally allow consumers to easily read and comprehend the information in the Nutrition Info box.

We are also proposing an absolute minimum type size of 8 point, regardless of the size of the net quantity of contents statement. It is our tentative view that this is the minimum type size necessary to allow for quick and easy readability of the Nutrition Info box and for the Nutrition Info box’s information to be read and understood by the ordinary individual under customary conditions of purchase and use (see

section 403(f) of the FD&C Act). Eight point is the same minimum type size allowed for the information in the Nutrition Facts label (see § 101.9(d)(1)(iii)). We established this minimum type size requirement in the 1993 Nutrition Facts label final rule, noting that we were committed to the flexible application of graphic techniques to achieve an acceptable level of readability for the required nutrition information. However, we noted that minimum standards, including a minimum 8-point type, would ensure that the nutrition information was conveyed so that the public could readily observe and comprehend the information (58 FR 2079 at 2136). We maintained the minimum 8-point type size in the 2016 Nutrition Facts label final rule. Therefore, we propose a minimum 8-point type size for the Nutrition Info box to help ensure readability and to be consistent with the type size requirements in the Nutrition Facts label.

4. Type and Hairline Color (Proposed § 101.6(a)(3)(iv)), Background Color (Proposed § 101.6(a)(3)(v)), and Attribution Banner Color (Proposed § 101.6(a)(3)(xv))

Proposed § 101.6(a)(3)(iv) would require the use of one color (e.g., black) for all type and hairlines in the Nutrition Info box, and proposed § 101.6(a)(3)(v) would require the use of a neutral contrasting background color (e.g., white) to the print in the box. Contrast levels between text and background that exceed 70 percent, which we would expect from the use of a single type color and a neutral contrasting background color, and dark text on light backgrounds provide for optimal legibility (Ref. 61).

For the attribution banner, proposed § 101.6(a)(3)(xv) would require that the background be the same color as used for the rest of the box’s type and hairlines and that the “*FDA.gov*” statement be the same color as used for the rest of the box’s background. We tentatively conclude that the use of an opposite color scheme to the rest of the box would help visually differentiate the attribution banner from the food’s nutrition information. The attribution banner would appear effectively the same on every Nutrition Info box—it would be at the bottom of the box, in an opposite color scheme, and would always contain “*FDA.gov*” right-justified in the banner. That would provide consistency among all Nutrition Info boxes and signal that the Nutrition Info box is an FDA requirement, while

not drawing attention away from the nutrition information above it.

The proposal would allow flexibility for industry to choose background and type colors that meet the requirements in our regulations. However, we believe that some contrasting color combinations might render the proposed Nutrition Info box's text difficult to read. We would consider difficult-to-read type to be unclear, and therefore violative of proposed § 101.6(a)(3)(ii)'s requirement that type be clear and easy to read, which could potentially cause the product to be misbranded under section 403(f) of the FD&C Act. If a particular color combination makes the type unclear, there are other graphic techniques, such as increased type size, bolding, and tracking (the small space between letters) that could be used to overcome this concern.

5. Hairlines (Proposed § 101.6(a)(3)(vi), (vii), and (viii))

Consistent with the Nutrition Facts label design, proposed § 101.6(a)(3)(vi) would require the use of hairlines to delineate the outer box, and proposed paragraphs (vii) and (viii) would require the use of hairlines to distinguish information within the Nutrition Info box. We first introduced the use of hairlines to set the Nutrition Facts label off in a box in the 1993 Nutrition Facts label final rule to preserve a readily identifiable look for the label (see 58 FR 2079 at 2136). Horizontal lines are used throughout the Nutrition Facts label as a key graphic element to divide space, direct the eye, and similarly give the label a unique and identifiable look (id.).

We propose using hairlines in the same way for the Nutrition Info box. Proposed § 101.6(a)(3)(vii) would require the use of a thick, horizontal hairline, centered within the box, and of the same length across the box as the "Nutrition Info" heading to distinguish the heading and subheadings ("Nutrition Info," "Per serving," and "% Daily Value") from the nutrient information that follows them. This horizontal line would divide space and give the box an identifiable look similar to that of the Nutrition Facts label. It would also direct the reader's eye to the nutrition information that follows and help break the information into small chunks, thus making it easier to process and remember the information (Ref. 62). Proposed § 101.6(a)(3)(viii) would require the use of a horizontal hairline, centered within the box, and of the same length across the box as the "Nutrition Info" heading to distinguish each row of nutrient information. The

repeated use of horizontal lines within the box would help with the organization of the Nutrition Info box and consistency with the Nutrition Facts label (Refs. 60 and 61).

6. Bold or Extra Bold Type (Proposed § 101.6(a)(3)(ix), (xi), (xii), and (xiii))

Proposed § 101.6(a)(3)(ix), (xi), and (xiii) would require the use of extra-bold type print and proposed § 101.6(a)(3)(xii) would require the use of bold type print to highlight certain text. In our proposed rule entitled "Food Labeling: Format for Nutrition Label" (57 FR 32058, July 20, 1992), we noted that the graphic presentation of the label had the potential to improve effective communication. We stated that graphic techniques, which included bold typeface to call attention to certain information on the label, go directly to the requirements in section 2(b)(1)(A) of the NLEA that the required nutrition information be presented in a way that enables consumers to readily observe the information (id.). In the 1993 Nutrition Facts final rule, we finalized certain bolding requirements for the Nutrition Facts label, noting that graphic elements such as bolding would, among other things, benefit consumers who have difficulty reading nutrition information on food packages and might otherwise be effectively denied access to that information (58 FR 2079 at 2136). We again used bolding in the 2016 Nutrition Facts label final rule to emphasize the importance of, and draw attention to, certain information (see, e.g., 81 FR 33742 at 33942).

Bold or extra bold type print for certain Nutrition Info box elements would help consumers notice and locate the box and use the information the box contains, according to design principles of highlighting information in bold type (Ref. 62). We propose the use of bold or extra-bold type print for all type in the box other than the "Per serving" subheading, the household measurement declaration, and the quantitative percent DV. An extra-bold "Nutrition Info" heading would call attention to the box itself (see proposed § 101.6(a)(3)(ix)), and an extra-bold "% Daily Value" subheading and the interpretive descriptions underneath the subheading would call attention to the nutrition information the Nutrition Info box would provide (see proposed § 101.6(a)(3)(xi) and (xiii), respectively). Additionally, bold nutrient names would call attention to each nutrient separately (see proposed § 101.6(a)(3)(xii)). In line with our prior rulemakings, we tentatively conclude that the bolding of these elements in the Nutrition Info box would help

consumers readily observe the required nutrition information and assist them in maintaining healthy dietary practices. We note that, in our example proposed Nutrition Info box (see § 101.6(a)(5)), we use both standard bolding (for the nutrient names and "FDA.gov") and the type style Helvetica Black (for the "Nutrition Info" heading, the "% Daily Value" subheading, and the interpretive descriptions), which is an extra-bold version of Helvetica.

7. Text Justification (Proposed § 101.6(a)(3)(ix) through (xv))

Proposed § 101.6(a)(3)(ix) through (xv) would require the use of left, right, and center text justification as a design technique to help consumers read the Nutrition Info box. Proposed § 101.6(a)(3)(x) and (xi) would require left justification for the "Per serving" subheading and the nutrient names, respectively. Proposed § 101.6(a)(3)(xi) and (xiii) would require right justification for the "% Daily Value" subheading and the interpretive descriptions, respectively, and proposed § 101.6(a)(3)(xv) would require right justification for "FDA.gov" in the bottom banner. Proposed § 101.6(a)(3)(vi) would require center justification for the "Nutrition Info" heading. Proposed § 101.6(a)(3)(xiv) would require that the quantitative percent DVs be right-justified with each other, in a column to the left of the interpretive descriptions. This design would create white spaces in the box, which would help isolate elements of the Nutrition Info box and provide information pacing for the reader (Ref. 63). Left-justifying the "Per serving" subheading and right-justifying the "% Daily Value" subheading would create white space that would result in a less cluttered appearance, heightened focus and emphasis, and improved readability (id.). Similarly, left-justifying the nutrient names, right-justifying the interpretive descriptions, and right-justifying the quantitative percent DVs in each of their respective columns in their own, unbroken row would provide a logical flow of information and create a sense of unity and cohesion, which contributes to overall aesthetic and perceived stability (Ref. 62). Right-justifying "FDA.gov" in the banner at the bottom of the Nutrition Info box would similarly provide unity and cohesion (id.).

8. Other Considerations

We considered whether to set off the Nutrition Info box, e.g., by requiring blank space around it. Such a formatting technique could help ensure that the information in the box would be

prominent and conspicuous to consumers. However, we are not proposing to require such a set-off in an effort to provide flexibility for design considerations. Additionally, section 403(f) of the FD&C Act already requires prominence, conspicuousness, readability, and understandability for any information, such as the proposed Nutrition Info box, required under the authority of the FD&C Act. We similarly considered proposing leading, kerning, font weight, tracking, and other typographical requirements, and are not proposing to require any, for the same reasons. While any of these elements might help meet the prominence, conspicuousness, readability, and understandability requirements of section 403(f) of the FD&C Act, we have tentatively concluded that setting specific requirements is not necessary. Throughout this document, we provide examples of Nutrition Info boxes that would comply with the proposed requirements of this rule and also satisfy the requirements of section 403(f) of the FD&C Act. We invite comment on this approach.

D. No Other Information Allowed in the Nutrition Info Box (Proposed § 101.6(a)(4))

Proposed § 101.6(a)(4) would prohibit any information in the Nutrition Info box other than what proposed § 101.6 would require. As we discuss elsewhere in this document, our research has found that too much information can be confusing to consumers. Additionally, our focus with the Nutrition Info box is to provide consumers with standardized, interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet and allow them to compare nutrition information across foods. See section V.B.2 of this document for a discussion about why we would only require—and only allow—information about saturated fat, sodium, and added sugars in the Nutrition Info box.

E. Special Labeling Provisions (Proposed § 101.6(b))

Proposed § 101.6(b) would describe ways to modify or alternatively display the Nutrition Info box for certain labels and labeling. This section of the

preamble also describes additional products for which we considered proposing to establish special labeling provisions but have tentatively concluded must display the Nutrition Info box as required in § 101.6(a)(2) through (4).

1. Packaged Foods That May Use an Aggregate Display in Accordance With § 101.9(d)(13)(i) (Proposed § 101.6(b)(1))

Our regulations, at § 101.9(d)(13)(i) and (h)(2)(ii), allow the use of an aggregate display for the Nutrition Facts label on the outer label of packages of products that contain two or more separately packaged foods that are intended to be eaten individually (e.g., variety packs of cereals or snack foods) or of packages that are used interchangeably for the same type of food (e.g., round ice cream containers). Proposed § 101.6(b)(1) would require packages that may use this aggregate display to display a Nutrition Info box for each different product the package contains or could contain. An example of what such labeling might look like is as follows (see also proposed § 101.6(b)(1)(iii)):

Wheat Squares Sweetened			
Nutrition Info			
Per serving		% Daily	
1 cup		Value	
Saturated Fat	0%	Low	
Sodium	0%	Low	
Added Sugars	22%	High	
FDA.gov			

Corn Flakes Not Sweetened			
Nutrition Info			
Per serving		% Daily	
1 1/2 cup		Value	
Saturated Fat	0%	Low	
Sodium	13%	Med	
Added Sugars	8%	Med	
FDA.gov			

Mixed Grain Flakes Sweetened			
Nutrition Info			
Per serving		% Daily	
1 cup		Value	
Saturated Fat	0%	Low	
Sodium	7%	Med	
Added Sugars	10%	Med	
FDA.gov			

For Nutrition Facts labels, the aggregate display can use less label space than multiple individual Nutrition Facts labels because the “Nutrition Facts” heading, most serving size information, and all declared nutrient, vitamin, and mineral names appear only once. While we are aware that the required display of multiple individual Nutrition Info boxes may occupy more space than an aggregate display, we reiterate that our public health goal with the Nutrition Info box is to provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information, at the point of decision-making, that can help them quickly and easily identify how foods can be part of a healthy diet. Separate, rather than aggregate, Nutrition Info boxes would better help consumers to quickly view this information since consumers would

not need to refer back to nutrient names, among other information, to understand the interpretive information in the box. We are also concerned that an aggregate Nutrition Info box would appear cluttered and unclear, because we designed the proposed box to occupy as little space on the label as possible while still giving consumers information, including the interpretive high, medium, and low categorizations that can help them quickly and easily identify how foods can be part of a healthy diet.

Proposed § 101.6(b)(1)(i) would require the Nutrition Info boxes to appear together in either horizontal or vertical lines. This would mean that all Nutrition Info boxes on packages that may use an aggregate display for the Nutrition Facts label would appear on the label in an unbroken line or set of lines that run either vertically or

horizontally. Grouping the boxes consistently and together on the package, rather than allowing them to appear in different locations on a label or labeling, would help consumers more easily find the boxes and reduce the likelihood that they might not see one of the boxes because it appeared in a different location. While we are proposing to require placement of all boxes in the upper third of the principal display panel, in accordance with and for the same reasons as proposed § 101.6(a)(3)(i), we are not proposing to require any specific location within that upper third to allow flexibility for industry in the design of their labels.

Proposed § 101.6(b)(1)(ii) would require each individual food’s name to appear right-justified at the top of the food’s Nutrition Info box, separated from the “Nutrition Info” header by a horizontal, centered hairline rule.

Inclusion of each individual food’s name at the top of its Nutrition Info box would clarify which individual food’s nutrition information is represented by which Nutrition Info box. Consistent placement of each individual food’s name at the top of its Nutrition Info box on a given package would best help consumers quickly and easily identify the interpretive nutrition information for foods at the point of decision-making because consumers would not need to search for that information. Right-justification of each individual food’s name would provide an alignment cue and create a sense of unity and cohesion, contributing to the box’s overall aesthetic and perceived stability (Ref. 62). Use of a horizontal hairline to separate the individual food’s name from the “Nutrition Info” header would divide space and give the box an identifiable look similar to that of the Nutrition Facts label.

We invite comment, particularly data and other information, on this approach.

2. Packaged Foods That Present Nutrition Facts Labeling for Two or More Population Groups Consistent With § 101.9(e) (Proposed § 101.6(b)(2))

Our regulations, at § 101.9(e), allow the display of multiple sets of nutrition information for multiple groups for which RDIs are established (e.g., both “infants” and “people ages 4 and older”). We call this type of labeling “dual-column labeling” and provide an example at § 101.9(e)(5).

Proposed § 101.6(b)(2) would require the Nutrition Info box for products that present a dual-column Nutrition Facts label for multiple age groups to reflect only the nutrition information for people ages 4 and older. As we described when discussing the scope of this rule (see section V.A of this document), we propose that this rule apply only to the foods covered under

§ 101.9 that are marketed for the general population. Therefore, the Nutrition Info box would only represent nutrition information for this population.

3. Packaged Foods That Present Nutrition Facts Labeling for Both “Per Serving” and “Per Individual Unit” Consistent With § 101.9(b)(2)(i)(D) (Proposed § 101.6(b)(3))

Our regulations, at § 101.9(b)(2)(i)(D), require the display of a dual-column Nutrition Facts label when products are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the applicable RACC. The first column is required to list the quantitative amounts and percent DVs for a serving of the food, and the second column is required to list the quantitative amounts and percent DVs for the entire package (see § 101.9(b)(2)(i)(D)). This is another example of dual-column labeling (see § 101.9(e)(5)).

Proposed § 101.6(b)(3) would require the Nutrition Info box for products that present a dual-column Nutrition Facts label for “per serving” and “per individual unit” nutrition information to reflect only the nutrition information “per serving.” This is consistent with how the standard Nutrition Info box reflects nutrition information “per serving” when the individual unit contains more than one serving. Inclusion of the required “Per serving” subheading with a statement of the serving size expressed in household measure would inform consumers that the package contains more than a single serving.

4. Packaged Foods That Present Nutrition Facts Labeling for Both “As Packaged” and “As Prepared” Forms of the Food Consistent With § 101.9(e) (Proposed § 101.6(b)(4))

Our regulations, at § 101.9(e), allow the display of multiple sets of nutrition

information for, among other things, multiple forms of the same food (e.g., both “as packaged” and “as prepared” for packaged cake mixes) and for common combinations of food as provided for in § 101.9(h)(4) (e.g., both “as packaged” and “with ½ cup of reduced-fat milk” for cereal). This is also an example of dual-column labeling (see § 101.9(e)(5)).

Proposed § 101.6(b)(4) would require that the Nutrition Info box for products that present a dual-column Nutrition Facts label for multiple forms of the same food and for common combinations of food reflect the food “as packaged.” We also propose that a statement clarifying that the box represents “as packaged” nutrition information appear right-justified at the top of the Nutrition Info box and separated from the “Nutrition Info” header by a horizontal, centered hairline rule, similar to aggregate display information as described in section V.E.1 of this document. This would help ensure that consumers know the Nutrition Info box always represents the food as it is at the point of decision-making, without any additional ingredients that would change the percent DV or interpretive descriptions. As with the information for boxes that may use an aggregate display for the Nutrition Facts label, as described in section V.E.1 of this document, right-justification of “as packaged” at the top of the box would provide a sense of unity and cohesion, contributing to the box’s overall aesthetic and perceived stability (Ref. 62). Use of a horizontal hairline to separate “as packaged” from the “Nutrition Info” header would divide space and give the box an identifiable look similar to that of the Nutrition Facts label. An example of what such labeling might look like is as follows (see also proposed § 101.6(b)(4)):

As packaged		
Nutrition Info		
Per serving	% Daily	
1/4 package mix	Value	
Saturated Fat	8%	Med
Sodium	5%	Low
Added Sugars	34%	High
FDA.gov		

Because the proposed Nutrition Info box would appear on the label of most foods—for instance, on both cereal boxes and cartons of milk, or on dry cake mixes and egg cartons—consumers would have the box’s information readily available on the principal display panel of each food that may be combined in whatever way they prefer. Additionally, each Nutrition Info box would reflect unique information (*i.e.*, there would be no overlap or duplication of information), which would help ensure that the Nutrition Info box can help consumers quickly and easily identify how individual foods can be part of a healthy diet.

5. Foods in Packages That Have a Total Surface Area Available To Bear Labeling of 40 or Fewer Square Inches (Proposed § 101.6(b)(5))

Our regulations, at § 101.9(j)(13)(ii)(A), provide that foods in packages that have a total surface area available to bear labeling of 40 or fewer square inches may present the required Nutrition Facts label in a tabular fashion (see § 101.9(j)(13)(ii)(A)(1)) or, if the product’s package shape or size cannot

accommodate a standard or tabular display, in a linear fashion (see § 101.9(j)(13)(ii)(A)(2)). We established this upper limit of 40 square inches of surface area available to bear labeling to define an intermediate-sized package in the 1993 Nutrition Facts label final rule. We noted there that we reviewed comment suggestions, examined the space requirements of the Nutrition Facts label, reviewed data on available label area for a sample of packaged foods, and considered what would make the label readily observable and easily comprehensible to arrive at 40 square inches (58 FR 2079 at 2155). In the 2016 Nutrition Facts label final rule, we declined to increase that number, stating that the promulgation of other space-saving requirements would preclude the necessity of doing so (81 FR 33742 at 33957). We propose to allow similar flexibility for such intermediate packages for the purposes of this rule.

Recognizing the increased need for flexibility for packages with 40 or fewer square inches available to bear labeling, and to help ensure the Nutrition Info

box is readily observable and easily comprehensible, proposed § 101.6(b)(5) would allow foods in packages with a total surface area available to bear labeling of 40 or fewer square inches to use an alternative Nutrition Info box (intermediate-package Nutrition Info box). This box would be smaller than our proposed Nutrition Info box and is designed to balance our public health goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet with the reduced amount of space available to bear labels on intermediate-sized packages relative to larger packages. Consumers have decades of experience with alternate Nutrition Facts label formatting for products that have 40 or fewer square inches of surface area available to bear labeling. Providing flexibility for these intermediate-sized packages to display a modified Nutrition Info box would be consistent with our Nutrition Facts label regulations. An example of an intermediate-package Nutrition Info box is as follows:

Nutrition Info	
Sat. Fat	Med
Sodium	High
Add. Sugar	Low
FDA.gov	

We considered whether to propose allowing the use of the intermediate-package Nutrition Info box only when a package uses the tabular or linear Nutrition Facts label format as specified in § 101.9(j)(13)(ii)(A). In other words, we considered proposing to require the display of a standard Nutrition Info box if an intermediate package did not use the flexibilities provided in § 101.9(j)(13)(ii)(A) and chose instead to display the standard Nutrition Facts label. However, given the labeling space constraints with packages of this size, we think it would be appropriate to extend this flexibility to all products with 40 or fewer square inches available to bear labeling that would be subject to this rule.

Proposed § 101.6(b)(5)(i) would establish the intermediate-package Nutrition Info box, which would omit the “Per serving” and “% Daily Value” subheadings and the quantitative

percent DV declarations. The “Per serving” subheading, including the statement of the serving size expressed in household measures, would be omitted because doing so would reduce the amount of space needed for the intermediate-package Nutrition Info box. Given the smaller package size, our intent is to help ensure the readability of the interpretive information provided in the Nutrition Info box.

We propose that the intermediate-package Nutrition Info box would also not include the quantitative percent DV declarations for the same space and readability considerations as with the “Per Serving” subheading. Without the quantitative percent DV declarations, the “% Daily Value” subheading would be unnecessary, and we therefore also propose to exclude it from the intermediate-package Nutrition Info box. However, as discussed in section V.B.4 of this document, we recognize

that consumers could use the percent DV declarations to, among other things, quickly compare products that have the same interpretive description for a given nutrient. For example, two products may both have “high” added sugars interpretive descriptions, but one may contain 30% DV added sugars, while the other contains 60% DV added sugars. We also recognize that the quantitative percent DV, in addition to the interpretive descriptions, may help consumers better understand why a serving of a food has the interpretive description it does. We invite comment on the exclusion of the quantitative percent DV and on other design factors or choices we could make to balance our public health mission and FOP nutrition labeling goals with the space constraints on intermediate-sized packages.

While we propose certain modifications for the intermediate-package Nutrition Info box, we are

keeping the remaining design elements the same as in the standard Nutrition Info box. This would create consistency between the box types, as well as with the Nutrition Facts label, the design of which underlays our proposed Nutrition Info box formats.

Proposed § 101.6(b)(5)(ii) would require the use of abbreviations for saturated fat (“Sat. Fat”) and added sugars (“Add. Sugar”) to help with potential overcrowding issues in the intermediate-package Nutrition Info box and to help ensure readability. The proposed abbreviation for saturated fat would be consistent with our Nutrition Facts label regulations (see § 101.9(j)(13)(ii)(B)). An abbreviation for added sugars would also help sizing considerations for the intermediate-sized packages, while still providing the information to consumers.

6. Foods Sold From Bulk Containers (Proposed § 101.6(b)(6))

Our existing regulations allow the Nutrition Facts label for foods sold from bulk containers, which do not have a principal display panel, to appear on the labeling of the bulk container plainly in view (§ 101.9(j)(16)), clearly at the point of purchase (§ 101.9(a)(2)), or available in another format consistent with § 101.9(a)(2) (such as in a booklet at the point of purchase). Proposed § 101.6(b)(6) would require that the labeling of foods sold to consumers from bulk containers display the Nutrition Info box plainly in view of the consumer at the point of purchase. This presentation is the best way to ensure that consumers would have immediate access to that information at the point of decision-making—the same way they would have that information on the principal display panel of most packaged foods (see proposed § 101.6(a)(3)(i)). While the Nutrition Facts label may be displayed elsewhere, such as in a booklet, for bulk foods, we tentatively conclude that any such display for the Nutrition Info box would not be consistent with placement on the principal display panel and would not provide consumers with interpretive nutrition information that can help them *quickly and easily* identify how foods can be part of a healthy diet. We invite comment on this approach.

7. Game Meats (Proposed § 101.6(b)(7))

Our regulations, at § 101.9(j)(11), allow the Nutrition Facts label for packaged single-ingredient products that consist of game meat (*i.e.*, animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail,

wild turkey, or ostrich) to present nutrition information either as packaged or as prepared (unless such products make claims that are based on values as packaged and therefore must provide nutrition information on an as packaged basis). Proposed § 101.6(b)(7)(i) would require game meats to display a Nutrition Info box that reflects how the nutrition information is presented under § 101.9. If the Nutrition Facts label for a game meat presents nutrition information as packaged as required under § 101.9(b)(7), then the Nutrition Info box would reflect the nutrition information as packaged. However, if the Nutrition Facts label presents nutrition information as prepared, following the special labeling provision at § 101.9(j)(11), then the Nutrition Info box also would reflect the nutrition information as prepared. We are proposing this because the percent DVs used to determine the interpretive descriptions for each nutrient in the Nutrition Info box are based on a serving’s amount, in grams, of each nutrient. The values may differ between the nutrition information presented as packaged versus as prepared. We tentatively conclude that this approach would ensure that the Nutrition Facts label and the Nutrition Info box provide consistent information.

Our existing regulations, at § 101.9(j)(12), also allow the Nutrition Facts label for game meats not in packages to appear clearly at the point of purchase (§ 101.9(a)(2)) or available in another format consistent with § 101.9(a)(2) (such as in a booklet at the point of purchase) if it does not appear on the label. Proposed § 101.6(b)(7)(ii) would require these game meats to display the Nutrition Info box plainly in view of the consumer at the point of purchase. Similar to our proposed exemption for bulk foods, providing such information clearly in view of the consumer on the labeling of game meat not in packages is the best way to ensure that consumers would have immediate access to that information at the point of decision-making—the same way they would have that information on the principal display panel of most packaged foods (see proposed § 101.6(a)(3)(i)). While the Nutrition Facts label may be displayed elsewhere, such as in a booklet, for game meats not in packages, we tentatively conclude that any such display for the Nutrition Info box would not be consistent with placement on the principal display panel and would not provide consumers with interpretive nutrition information that can help them *quickly and easily*

identify how foods can be part of a healthy diet.

8. Other Products Considered for Special Labeling Provisions

While we are proposing special labeling provisions for some products, we also considered but rejected such proposed provisions for other products. For example, our regulations, at § 101.9(h)(1), allow for foods to display a Nutrition Facts label per serving for each component or as a composite value when separately packaged ingredients (*e.g.*, a salad kit) or assortments of the same type of food (*e.g.*, a package of mixed nuts) are intended to be eaten at the same time (see § 101.9(h)(1)). We considered establishing a special labeling provision for such foods to display either a Nutrition Info box per component or composite value, consistent with the flexibility provided in § 101.9(h)(1). However, such a provision might result in the inconsistent display of Nutrition Info boxes for these products, which would not be consistent with the goal of this proposed rule. For example, consumers would not be able to easily compare a composite Nutrition Info box on one food to multiple Nutrition Info boxes for individual components on another food. Additionally, we tentatively conclude that allowing component Nutrition Info boxes instead of a single, composite box would prevent consumers from quickly and easily identifying how the food can be part of a healthy diet (*e.g.*, the salad kit as a whole). We therefore are not proposing any special labeling provisions for these foods.

F. Exemptions (Proposed § 101.6(c))

Proposed § 101.6(c) would exempt certain foods from the requirement to display a Nutrition Info box. This section of the document also describes additional products we considered proposing to exempt but have tentatively concluded would be subject to the requirements of this rule.

1. Foods Exempt From § 101.9 Under § 101.9(j), Unless Otherwise Stated in This Section (Proposed § 101.6(c)(1))

Our regulations, at § 101.9(j), exempt certain foods, such as raw fruits and vegetables, from bearing a Nutrition Facts label. Proposed § 101.6(c)(1) would similarly exempt those foods from bearing a Nutrition Info box. We are proposing to base the interpretive descriptions of the relative amount of each declared nutrient per serving on the quantitative percent DV, which foods exempt under § 101.9(j) do not have to bear (which, in turn, means that industry would not need to calculate the

percent DVs). Any proposal to change the exemptions in § 101.9(j) would be outside the scope of this rulemaking. Even if it were not, we are not aware of data indicating that we should propose changes to the exemptions.

We note that § 101.9(j) also includes foods subject to special labeling requirements. We propose that only foods *exempt* under § 101.9(j) would be exempt from bearing a Nutrition Info box, unless otherwise specified in this section.

2. Foods in Small Packages That Have a Total Surface Area Available To Bear Labeling of Less Than 12 Square Inches (Proposed § 101.6(c)(2))

Our regulations, at § 101.9(j)(13)(i), provide that foods in small packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from Nutrition Facts labeling, unless nutrition information, such as a claim, is presented on the label. We first proposed this exemption in 1991 (see 56 FR 60366). At that time, we noted our belief that relatively few food packages would qualify as “small” under the proposed exemption, namely candy rolls, breath sweeteners, and a few very small individual-serving size canned foods (*id.* at 60377). We finalized this exemption in the 1993 Nutrition Facts label final rule (58 FR 2079) and kept this exemption in the 2016 Nutrition Facts label final rule (81 FR 33742).

Proposed § 101.6(c)(2) would exempt foods in small packages that have a total surface area available to bear labeling of less than 12 square inches from the requirement to display the Nutrition Info box. While such a small package must bear the appropriately sized Nutrition Facts label if its label includes any other nutrition information, we tentatively conclude that there would not also be enough room to fit a Nutrition Info box on its label that would be legible to consumers without occupying much of the available space to bear labeling. We invite comment, and particularly data and other information, on this approach.

3. Packages Marketed as Gifts That Contain a Variety or Assortment of Foods (Proposed § 101.6(c)(3))

Our regulations, at § 101.9(h)(3), provide special labeling requirements for a package that contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift (gift package). For example, the Nutrition Facts label for foods in such a package may be presented on the label of the outer package or in labeling within or attached to the outer package

(§ 101.9(h)(3)(i)). We defined “outer package” in the 1993 Nutrition Facts final rule to mean the container directly within which component items are packed (58 FR 2079 at 2159), and we maintain that definition here.

Proposed § 101.6(c)(3) would exempt the outer packaging of gift packages from the requirement to display Nutrition Info boxes. Our purpose in proposing the Nutrition Info box is to provide consumers with interpretive nutrition information at the point of decision-making that can help them quickly and easily identify how foods can be part of a healthy diet. We tentatively conclude that the point of decision-making for gift packages is generally after the package is opened, when a consumer is considering which food from the gift package to eat. While we propose that the outer wrapping be exempt, we note that the inner food products would be subject to the requirements in this rule, unless otherwise exempted.

4. Unit Containers in a Multiunit Retail Food Package (Proposed § 101.6(c)(4))

Our regulations, at § 101.9(j)(15), provide that the unit containers in a multiunit retail food package are exempt from Nutrition Facts labeling so long as certain requirements are met (*i.e.*, the multiunit retail food package labeling contains all nutrition information in accordance with § 101.9; the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and each unit container is labeled with the statement “This Unit Not Labeled For Retail Sale” as described in § 101.9(j)(15)(iii)). We first proposed this exemption in the 1990 Nutrition Facts label proposed rule after receiving a comment requesting such an exemption and agreeing that it would be reasonable to exempt unit containers from Nutrition Facts labeling requirements, provided they meet certain requirements (55 FR 29487 at 29505). In the 1993 Nutrition Facts label final rule, we finalized this exemption. We did not discuss or change this exemption when updating the Nutrition Facts label regulations in 2016.

Proposed § 101.6(c)(4) would similarly exempt the unit containers in a multiunit retail food package from FOP nutrition labeling, so long as the unit containers fall under the exemption for Nutrition Facts labeling in accordance with § 101.9(j)(15); and the multiunit retail food package bears the Nutrition Info box in accordance with § 101.6. If those conditions are met, we tentatively conclude that it is unnecessary for the unit containers to

also bear the Nutrition Info box. This is consistent with our similar exemption for the Nutrition Facts label, and it is the Nutrition Info box on the outside of a multiunit retail food package that consumers would use to quickly and easily identify how foods can be part of a healthy diet.

5. Other Products Considered for Exemption

We considered whether to exempt foods that contain insignificant amounts of saturated fat, sodium, and added sugars and use the simplified format of the Nutrition Facts label from the requirement to display the Nutrition Info box. Our regulations, at § 101.9(f), allow for the use of a simplified format for the Nutrition Facts label when a food contains insignificant amounts of, among other things, saturated fat, sodium, and added sugars. We define “insignificant amount” in this context as the amount that allows a declaration of zero in nutrition labeling (§ 101.9(f)(1)). If a food contains insignificant amounts of saturated fat, sodium, and added sugars and uses the simplified Nutrition Facts label format, sodium is the only nutrient that would be required to be declared in the Nutrition Facts label—saturated fat and added sugars would not be declared (see § 101.9(f)(2)). However, a proposed exemption from the requirements of this rule would not be consistent with our goal to provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. An exemption would also make quick comparisons between products more difficult. We tentatively conclude that requiring these foods to bear a Nutrition Info box would provide consumers with interpretive information about the amounts of the three nutrients so they could quickly and easily identify how foods can be part of a healthy diet. Therefore, we are not proposing to exempt foods that use the simplified format of the Nutrition Facts label and that contain insignificant amounts of saturated fat, sodium, and added sugars from the requirement to display the Nutrition Info box.

We also considered whether to exempt products such as electrolyte drinks, glucose products, and nutrition shakes that are required to bear Nutrition Facts labels from the requirement to display a Nutrition Info box. These products are often conventional foods and are marketed and used for a variety of purposes, such as rehydration during or after exercise, providing energy, or general meal

replacement. When these products are conventional foods and are required to bear Nutrition Facts labels, they are often used by healthy individuals and the general population; accordingly, we are not proposing to exempt such products from bearing a Nutrition Info box.

G. Low Sodium and Low Saturated Fat Nutrient Content Claims (Revised §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3))

We are proposing to revise § 101.61(b)(4)(i)(A) and (b)(4)(i)(B) so that a food other than a meal product or main dish product may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per RACC rather than 140 mg or less sodium per RACC; and § 101.61(b)(5)(i) so that meal products and main dish products may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per 100 g rather than 140 mg or less sodium per 100 g. This revision is consistent with the updated DRV for sodium in the 2016 Nutrition Facts label final rule and with FDA's ongoing sodium reduction efforts (see section V.B.3 of this document). It also generally aligns with the 5% DV or less range that we are proposing for "Low" for sodium in the proposed Nutrition Info box.

We are also proposing to amend §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3) to specify that a food subject to this rule must display "Low" in accordance with § 101.6 for sodium or saturated fat in the Nutrition Info box to qualify for a low sodium or low saturated fat nutrient content claim, respectively. A food bearing a low sodium or low saturated fat nutrient content claim but falling into the "Med" or "High" categorization for that nutrient in the Nutrition Info box would lead to inconsistency in the labeling of such food and could result in consumer confusion (see Ref. 64). Therefore, we tentatively conclude that a food subject to this rule must display "Low" in accordance with § 101.6 for the respective nutrient in the Nutrition Info box to qualify for a low sodium or low saturated fat nutrient content claim. In addition to updating the claim to reflect current nutrition science and helping to avoid consumer confusion by aligning with the Nutrition Info box's "Low" description, this amendment would also address products that are not subject to the proposed requirement to display a Nutrition Info box.

We are not proposing to amend the definitions of the low sodium and low saturated fat nutrient content claims to

be "5% DV or less" because our regulations define other "low" nutrient content claims based on g or mg amounts of a nutrient and RACC and weight-based criteria. Proposing to change the units for the amount of sodium and saturated fat from mg or g amounts to a percent DV and proposing to change the additional criteria for nutrient content claims that are based on a per RACC (per 50 g of food if the RACC is small) or a weight-based criteria (e.g., per 100 g of food for meals and main dishes) to a per labeled serving basis for the low sodium and low saturated fat nutrient content claims in this proposed rule would make their definitions inconsistent with the definitions for other "low" nutrient content claims. We invite comment on this approach.

H. Authority Citation

The proposed rule would add the statutory authority 21 U.S.C. 343 note as a regulatory authority for part 101. Specifically, 21 U.S.C. 343 note gives FDA authority to issue regulations that require certain nutrition information to be conveyed in a manner that allows the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

I. Conforming Amendments

The proposed rule would necessitate several conforming changes to our food labeling regulations found in part 101. Because we would establish new requirements for an FOP Nutrition Info box in proposed § 101.6, we are proposing updates to the following sections to cross-reference the new nutrition labeling requirement:

- *Section 101.2:* Information panel of package form food (proposing to add § 101.6 to the list of sections the information in which must appear either on a food's principal display panel or on the information panel, unless otherwise specified by regulation) (see also section V.J of this document, where we propose a technical amendment to the title of this section).

- *Section 101.13:* Nutrient content claims—general principles (proposing that the information required by § 101.6 would not be a nutrient content claim). We recognize that our regulations, at § 101.13(c), provide that information required or permitted in the Nutrition Facts label is not a nutrient content claim and is not subject to the requirements regarding nutrient content claims. However, § 101.13(c) further states that if the information in the Nutrition Facts label appears elsewhere

on the label, it is a nutrient content claim, and any package bearing such a claim must comply with our nutrient content claim requirements. We propose amending § 101.13(c) to specify that the information in the proposed Nutrition Info box would not be a nutrient content claim, like the information in the Nutrition Facts label is not a nutrient content claim. However, we would still consider all other quantitative calorie or nutrient declarations outside of those in proposed amended § 101.13(c) to be nutrient content claims, unless an exception applies under § 101.13. For example, under § 101.13, the label or labeling of a product may contain a statement about the amount of a nutrient without any disclaimer if the statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "150 calories") (see § 101.13(i)(3)).

- *Section 101.15:* Food; prominence of required statements (proposing to exempt the proposed Nutrition Info box from foreign language declarations due to space considerations).

- *Section 101.61:* Nutrient content claims for the sodium content of foods (proposing to add § 101.6 to § 101.61(a)(3) so that a claim about the level of sodium or salt in a food may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).

- *Section 101.62:* Nutrient content claims for fat, fatty acid, and cholesterol content of foods (proposing to add § 101.6 to § 101.62(a)(3) so that a claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).

- *Section 101.65:* Implied nutrient content claims and related label statements (proposing to add § 101.6 to § 101.65(a)(3) so that an implied nutrient content claim may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).

J. Technical Amendments

We propose certain technical amendments in §§ 101.12, 101.13, and 101.15 to make non-substantive edits for purposes of plain language. The Plain Writing Act of 2010 requires that Federal agencies use clear communication that the public can understand and use. Section 1 of Executive Order 13563, "Improving Regulation and Regulatory Review" (76 FR 3821, January 21, 2011)), sets forth

“General principles of regulation,” which include ensuring that regulations are “accessible, consistent, written in plain language, and easy to understand.” To make the requirements of part 101 easier to understand, we are proposing to make editorial changes that do not change the meaning or intent of the language in § 101.2(b), (c)(1)(ii)(B)(1), and (f); § 101.13(n); and § 101.15(c)(2). Specifically, the proposed rule would:

- Revise the title of § 101.2 and paragraph (b) of that section to read “packaged food,” instead of “package form food” or “package of food,” respectively. We propose these changes for consistency with how we refer to these products throughout our nutrition labeling regulations.

- Replace “shall” with “must” in § 101.2(b), (c)(1)(ii)(B)(1), and (f); § 101.13(n); and § 101.15(c)(2). We propose this change to align with the Federal Plain Language Guidelines, which state that Federal Agencies should use “must” and not “shall” to impose requirements, as “shall” is ambiguous and rarely occurs in everyday conversation (Ref. 65).

VI. Proposed Effective/Compliance Dates

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of the final rule’s publication in the **Federal Register**. We propose staggered compliance dates:

- 3 years after the final rule’s effective date for businesses with \$10 million or more in annual food sales; and
- 4 years after the final rule’s effective date for businesses with less than \$10 million in annual food sales.

We recognize that it may take industry time to design and print new labels. A 3-year compliance date for businesses with \$10 million or more in annual food sales and a 4-year compliance date for businesses with less than \$10 million in annual food sales are intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to timely have the proposed information in the Nutrition Info box. We invite comment on these proposed compliance dates.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are “significant” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they “have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” OIRA has determined that this proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that the annual economic impact of this proposed rule is less than 3 percent of annual revenue, we propose to certify that this proposed rule will not 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 estimates of anticipated impacts, 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 \$183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box on the front, or principal display panel, of most foods bearing a Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. The proposed rule would also amend low sodium and low saturated fat nutrient content claim regulations to align with

current nutrition science and avoid within-label inconsistencies. The proposed rule, if finalized, may result in some industry reformulating some products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

We quantify costs to packaged food manufacturers from updating labeling to meet the proposed requirements. Although it is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation as the rule could result in some food manufacturers reformulating some food products. Over 10 years, the total undiscounted cost is \$3.2 billion. Updating labeling to meet the proposed requirements accounts for 32 percent of total costs (\$1 billion) while voluntary reformulation accounts for the other 68 percent of total costs over 10 years (\$2.2 billion). The present value of costs over 10 years would range from \$1.7 billion to \$4.9 billion at a 2 percent discount rate, with a primary estimate of \$3.1 billion. Annualized costs over 10 years would range from \$191 to \$530 million at a 2 percent discount rate, with a primary estimate of \$333 million.

The proposed Nutrition Info box would give consumers additional standardized context about certain nutrients that appear in the Nutrition Facts label and allow them to compare this nutrition information across foods. Benefits of this proposed rule would come from the value consumers receive from the information provided by the FOP label. If some packaged food manufacturers chose to reformulate products to maintain current nutrient content claims or move into a “Low” or “Med” interpretive description, consumers whose nutritional intake changes accordingly would also benefit from a healthier food supply. The proposed rule, if finalized, would provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. We undertake a break-even calculation to describe the magnitude of non-quantified benefits for the benefits to equal or exceed the costs of the regulation.

This is only a summary of our preliminary analysis of the proposed rule. We have developed a 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 (Ref. 66) and at <https://www.fda.gov/about-fda/>

economics-staff/regulatory-impact-analyses-ria.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) 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 proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section below 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. 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:* Food Labeling: Front-of-Package Nutrition Information *Description:* This information collection would support statutory and regulatory requirements that govern food labeling. FDA authorities include the NLEA (21 U.S.C. 343 note (1990)) and sections 403(f) and 403(q) of the

FD&C Act. This information collection also would support sections 701(a), 403(a)(1), and 201(n) of the FD&C Act. The proposed rule, if finalized, would add § 101.6 to require the food industry to disclose certain nutrition information in a compact informational box on the principal display panel of most foods bearing a Nutrition Facts label. The Nutrition Info box would give consumers additional context on the front of most food packages about certain nutrients that appear on the Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. *Description of Respondents:* The respondents to this information collection are manufacturers, packers, and distributors of food products subject to statutory and regulatory food labeling requirements. We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent ²	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs ³
Front of Package Labeling; 101.6	30,413	11	322,378	4	1,289,512	\$143,220,186

¹ There are no operating and maintenance costs associated with this collection of information. ² For purposes of this table, we have rounded up to use whole numbers when calculating the number of disclosures per respondent. All other figures are consistent with the Preliminary Regulatory Impact Analysis. ³ One-time capital cost to relabel.

The estimates in table 2 are consistent with the estimates found in the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 66). In table 21 of the PRIA, we estimate that approximately 30,413 manufacturers will need to add the informational Nutrition Info box to the principal display panel of their food product package. In table 4 of the PRIA, we estimate that approximately 322,326 products will need to be relabeled. For the purpose of this analysis, we used the estimates for the number of manufacturers and disclosures to calculate that each manufacturer will need to relabel about 11 products (322,378 disclosures ÷ 30,413 manufacturers = 10.6). In the existing information collection for Food Labeling Requirements approved under OMB control number 0910–0381, we estimated that an establishment would spend 4 hours per label for labeling requirements for disclosure of nutrition information (21 CFR 101.9). We use the 4-hour estimate for the purpose of this analysis. Each disclosure will take an

estimated 4 hours to complete for an annual third-party disclosure burden of 1,289,512 hours (322,378 disclosures × 4 hours). Based on table 6 of the PRIA, we estimate each product that will be relabeled will cost \$1,333 assuming a 3-year compliance period. That calculates to an annual capital cost of \$143,220,186 (\$1,333 × 107,442 products) over 3 years associated with relabeling with the total capital cost being \$429,660,558. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time capital cost. To ensure that comments on this information collection are received, OMB recommends that written comments be submitted through [reginfo.gov](https://www.reginfo.gov) (see **ADDRESSES**). All comments should be identified with the title of the information collection. 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**. **X. Federalism** We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(3) of the FD&C Act provides that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the FD&C Act. The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local

requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA). If this proposed rule is finalized, the rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act to the extent that these provisions are consistent with section 403(q) of the FD&C Act.

Further, uniformity in FOP nutrition labeling is critical to achieving the goal of this proposed regulation so that consumers are provided with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. If States were able to establish their own FOP nutrition labeling systems with different requirements, consumers would not be able to rely on a single standardized box to compare products and may be confused by conflicting or different information on a separate state FOP nutrition label. Different State or local requirements for FOP nutrition labeling would not be consistent with the NLEA, which directs FDA to require nutrition information be presented in a way that makes it observable, understandable, and useful to consumers and which established section 403A of the FD&C Act with regard to “National Uniform Nutrition Labeling.”

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the minimum level necessary to achieve the objectives of the statute that provided the authority to issue the regulations. The proposed rule, if finalized, would meet the preceding requirement because it would preempt State law narrowly, only to the extent required to achieve uniform national labeling with respect to the requirements related to the contents and design of the FOP Nutrition Info box.

Section 4(d) of Executive Order 13132 states that when an agency foresees the possibility of a conflict between State law and federally protected interests within the agency’s area of regulatory responsibility, the agency must consult with appropriate State and local officials, as practicable, in an effort to avoid such a conflict. Section 4(e) of Executive Order 13132 provides that when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency must provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings. FDA’s Office of Partnerships will invite the States’ participation in this rulemaking by providing notice via email to State

health commissioners, State agriculture commissioners, and State food program directors as well as FDA field personnel of the publication of the proposed rule. The notice will give the States further opportunity for input on the proposed rule, advise the States of FDA’s possible action, and invite State and local governments to provide any comments.

Consequently, we have included § 101.6(d) in the proposed regulatory text stating that a State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this rule. Preemption may also arise regarding other FOP nutrition labeling if a State requirement is found to obstruct the federal purpose articulated in this rule.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, or the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA invites comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

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

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List of Subjects in 21 CFR Part 101

Food labeling, nutrition, reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, FDA proposes to amend part 101 as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 343 note, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Amend § 101.2 by:

- a. Revising paragraph (b);
- b. Revising paragraph (c)(1)(ii)(B)(1);
- c. Adding paragraph (d)(2)(iv); and
- d. Revising paragraph (f).

The revisions and addition read as follows:

§ 101.2 Information panel of packaged food.

* * * * *

(b) All information required to appear on the label of any packaged food under §§ 101.4, 101.5, 101.6, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of this part, and part 105 of this chapter must appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) * * *

(1) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained must bear nutrition labeling if required by § 101.9 and the Nutrition Info box if required by § 101.6; and any vending machine in which it is contained must bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

* * * * *

(d) * * *

(2) * * *

(iv) The Nutrition Info box required by § 101.6 is not required on the lid if this information appears on the container body in accordance with this section.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.6, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of this part, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, *e.g.*, a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, must be submitted under part 10 of this chapter.

■ 3. Add § 101.6 to read as follows:

§ 101.6 Front-of-package Nutrition Info box.

(a) *General provisions*—(1) *Scope*. All food covered under § 101.9 that is marketed for people ages 4 and older must bear the Nutrition Info box described in paragraphs (a)(2) through (4) of this section on its label, unless the product is subject to special labeling provisions under paragraph (b) of this section or exempt under paragraph (c) of this section.

(2) *Content*. The Nutrition Info box must:

(i) Contain the heading “Nutrition Info,” which must be across the top of the Nutrition Info box and in a larger type than all other words in the Nutrition Info box;

(ii) Include two column subheadings under “Nutrition Info”:

(A) “Per serving,” which must be accompanied by a statement of the serving size expressed in household measures as described in § 101.9(b)(5) (*e.g.*, “Per serving (whole package)” or “Per serving (½ cup)"); and

(B) “% Daily Value”;

(iii) Vertically list “Saturated Fat,” “Sodium,” and “Added sugars,” in that order, under the “Per serving” subheading as described in paragraph (a)(2)(ii)(A) of this section;

(iv) Specify, under the “% Daily Value” subheading as described in paragraph (a)(2)(ii)(B) of this section and to the right of the quantitative percent Daily Value (% DV) declaration as described in paragraph (a)(2)(v) of this section, whether the amount of the nutrient per serving, expressed as % DV as established in § 101.9(c)(9) and (d)(7)(ii), is “Low,” “Med,” or “High.” The ranges corresponding to “Low,” “Med,” and “High” are as follows:

(A) Low: 5% DV or less.

(B) Med: 6% to 19% DV.

(C) High: 20% DV or more.

(v) Declare the quantitative % DV for people ages 4 and older, as established in § 101.9(c)(9) and (d)(7)(ii), in its own column immediately under the “% Daily Value” subheading as described in paragraph (a)(2)(ii)(B) of this section and to the left of the “Low,” “Med,” and “High” categorization as described in paragraph (a)(2)(iv) of this section; and

(vi) Include a banner at the bottom with an “FDA.gov” attribution.

(3) *Formatting*. The Nutrition Info box must:

(i) Appear on the upper third of the principal display panel, as defined in § 101.1;

(ii) Use a single, easy-to-read type style;

(iii) Use a minimum type size (at least 8 point) that is no smaller than the size of the required net quantity of contents declaration, as specified in § 101.7(h) and (i);

(iv) Use all black or one color type for text and hairlines;

(v) Use a white or other neutral contrasting background to the print in the box;

(vi) Use hairlines to create the outer box;

(vii) Use a thick, horizontal, centered, hairline rule the same distance across the box as the “Nutrition Info” heading as described in paragraph (a)(2)(i) of this

section to distinguish the heading and subheadings as described in paragraphs (a)(2)(i) and (ii) of this section from the information underneath them;

(viii) Use a horizontal, centered hairline rule the same distance across the box as the “Nutrition Info” heading as described in paragraph (a)(2)(i) of this section to distinguish each row of nutrient information as described in paragraph (a)(2)(iii) of this section;

(ix) Use extra-bold type and center-justify the “Nutrition Info” heading as described in paragraph (a)(2)(i) of this section;

(x) Left-justify the “Per serving” subheading as described in paragraph (a)(2)(ii)(A) of this section;

(xi) Use extra-bold type and right-justify the “% Daily Value” subheading as described in paragraph (a)(2)(ii)(B) of this section;

(xii) Use bold type and left-justify the nutrient names as described in paragraph (a)(2)(iii) of this section;

(xiii) Use extra-bold type and right-justify the “Low,” “Med,” and “High” categorizations as described in paragraph (a)(2)(iv) of this section;

(xiv) Right-justify, within its own column to the left of the “Low,” “Med,” and “High” categorizations as described in paragraph (a)(2)(iv) of this section, the quantitative percent DV declarations as described in paragraph (a)(2)(v) of this section; and

(xv) Use the same color as used for the text and hairlines as specified under paragraph (a)(3)(iv) of this section for the banner background, with “FDA.gov” right-justified, in bold or extra-bold type, and in the same color as used for the rest of the box’s background as described in paragraph (a)(3)(v) of this section.

(4) *No other information allowed in the Nutrition Info box*. No other information may be included in the Nutrition Info box.

(5) *Example*. The following example label illustrates the provisions of paragraphs (a)(2) through (a)(4) of this section.

Figure 1 to Paragraph (a)(5)—Example
Standard Nutrition Info Box

Nutrition Info		
Per serving		% Daily
1 container		Value
Saturated Fat	18%	Med
Sodium	37%	High
Added Sugars	5%	Low
FDA.gov		

(b) *Special labeling provisions.* (1) Packaged foods that may use an aggregate display under § 101.9(d)(13)(i) and (h)(2)(ii) must display a Nutrition Info box as described in paragraph (a) of this section for each different product the package contains or could contain. (i) The Nutrition Info boxes must appear together in either horizontal or

vertical lines and must appear in the upper third of the principal display panel in accordance with § 101.6(a)(3)(i). (ii) The package must specify the name of each food right-justified at the top of each food’s Nutrition Info box, separated from the “Nutrition Info”

header by a horizontal, centered hairline rule. (iii) The following example label illustrates these requirements: **Figure 2 to Paragraph (b)(1)(iii)—Example Nutrition Info Box Modified for Aggregate Display**

Wheat Squares Sweetened		
Nutrition Info		
Per serving		% Daily
1 cup		Value
Saturated Fat	0%	Low
Sodium	0%	Low
Added Sugars	22%	High
FDA.gov		

Corn Flakes Not Sweetened		
Nutrition Info		
Per serving		% Daily
1 1/2 cup		Value
Saturated Fat	0%	Low
Sodium	13%	Med
Added Sugars	8%	Med
FDA.gov		

Mixed Grain Flakes Sweetened		
Nutrition Info		
Per serving		% Daily
1 cup		Value
Saturated Fat	0%	Low
Sodium	7%	Med
Added Sugars	10%	Med
FDA.gov		

(2) Packaged foods that present Nutrition Facts labeling for two or more population groups must display a Nutrition Info box as described in paragraph (a) of this section, or Nutrition Info boxes as described in this paragraph (b)(2), that only reflect(s) the information for people ages 4 and older. (3) Packaged foods that present Nutrition Facts labeling for both “per serving” and “per individual unit” in accordance with § 101.9(b)(2)(i)(D) must

display a Nutrition Info box as described in paragraph (a) of this section that reflects the nutrition information “per serving.” (4) Packaged foods that present Nutrition Facts labeling for both “as packaged” and “as prepared” forms of the food consistent with § 101.9(e) must display a Nutrition Info box as described in paragraph (a) of this section that reflects the nutrition information for the “as packaged” form

and must include a statement right-justified at the top of the box and separated from the “Nutrition Info” header by a horizontal, centered hairline rule to clarify that the box represents “as packaged” nutrition information (e.g., “Represents product “as packaged” ” or “See Nutrition Facts for “As Prepared” information”).

Figure 3 to Paragraph (b)(4)—Example Nutrition Info Box Modified for “As Packaged”

As packaged		
Nutrition Info		
Per serving	% Daily Value	
1/4 package mix		
Saturated Fat	8%	Med
Sodium	5%	Low
Added Sugars	34%	High
FDA.gov		

(5) Foods in packages that have a total surface area available to bear labeling of 40 or fewer square inches may display an alternative (intermediate-package) Nutrition Info box as described in this paragraph.

(i) The intermediate-package Nutrition Info box omits the following content from the Nutrition Info box

described in paragraphs (a)(2) through (4) of this section:

(A) The “Per serving” and “% Daily Value” subheadings; and

(B) The quantitative percent DV declarations.

(ii) The intermediate-package Nutrition Info box uses the abbreviations “Sat. Fat” for “Saturated

Fat” and “Add. Sugar” for “Added Sugars.”

(iii) The following example label illustrates the provisions of paragraphs (b)(6)(i) and (ii) of this section.

Figure 4 to Paragraph (b)(5)(iii)—Example Intermediate-Package Nutrition Info Box

Nutrition Info	
Sat. Fat	Med
Sodium	High
Add. Sugar	Low
FDA.gov	

(6) Foods sold from bulk containers must display a Nutrition Info box as described in paragraph (a) of this section plainly visible to consumers on the bulk container’s labeling at the point of purchase.

(7) Game meats (*i.e.*, animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) must display a Nutrition Info box as described in paragraph (a) of this section:

(i) That reflects how the nutrition information is shown under § 101.9; and

(ii) Is plainly visible to consumers at the point of purchase if the food is unpackaged.

(c) *Exemptions.* The following foods are exempt from the requirements in this section:

(1) Any food exempt from § 101.9 under § 101.9(j), unless otherwise stated in this section;

(2) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches;

(3) Packages marketed as gifts that contain a variety or assortment of foods; and

(4) The unit containers in a multiunit retail food package where:

(i) The unit containers are exempt from Nutrition Facts labeling in accordance with § 101.9(j)(15); and

(ii) The multiunit retail food package label bears the Nutrition Info box in accordance with this section.

(d) *Preemption.* A State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the Nutrition Info box.

■ 4. Amend § 101.13 by revising paragraphs (c), (i) introductory text, and (n) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(c) Information that is required or permitted by § 101.9 or § 101.36 as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, or that is required by § 101.6, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

* * * * *

(i) Except as provided in § 101.6, § 101.9, or § 101.36, as applicable, or in

paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

* * * * *

(n) Nutrition labeling in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable, must be provided for any food for which a nutrient content claim is made.

* * * * *

■ 5. Amend § 101.15 by revising paragraph (c)(2) to read as follows:

§ 101.15 Food; prominence of required statements.

* * * * *

(c) * * *

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label must appear thereon in the foreign language, except for labeling in accordance with § 101.6: *Provided, however*, That individual serving-size packages of foods containing no more than 1½ avoirdupois ounces or no more than 1½ fluid ounces served with meals in restaurants, institutions, and passenger carriers and not intended for sale at retail are exempt from the requirements of this paragraph (c)(2), if the only representation in the foreign language(s) is the name of the food.

* * * * *

■ 6. Amend § 101.61 by:

■ a. Revising paragraphs (a)(3) and (b)(4)(i);

■ b. Redesignating paragraph (b)(4)(ii) as (b)(4)(iii) and revising it;

■ c. Adding new paragraph (b)(4)(ii);

■ d. Revising paragraph (b)(5)(i);

■ e. Redesignating paragraph (b)(5)(ii) as (b)(5)(iii) and revising it; and

■ f. Adding new paragraph (b)(5)(ii).

The revisions and additions read as follows:

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) * * *

(3) The food for which the claim is made is labeled in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable.

(b) * * *

(4) * * *

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 115 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 115 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the “as prepared” form);

(ii) The food must display “Low” in accordance with § 101.6 for sodium in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “fresh spinach, a low sodium food”).

(5) * * *

(i) The product contains 115 mg or less sodium per 100 g;

(ii) The product must display “Low” in accordance with § 101.6 for sodium in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

* * * * *

■ 7. Amend § 101.62 by:

■ a. Revising paragraphs (a)(3) and (c)(2)(i);

■ b. Redesignating paragraph (c)(2)(ii) as paragraph (c)(2)(iii) and revising it;

■ c. Adding new paragraph (c)(2)(ii);

■ d. Revising paragraph (c)(3)(i);

■ e. Redesignating paragraph (c)(3)(ii) as paragraph (c)(3)(iii); and

■ f. Adding new paragraph (c)(3)(ii).

The revisions and additions read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) * * *

(3) The food for which the claim is made is labeled in accordance with

§ 101.6, § 101.9, § 101.10, or § 101.36, as applicable; and

* * * * *

(c) * * *

(2) * * *

(i) The food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids;

(ii) The food must display “Low” in accordance with § 101.6 for saturated fat in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “raspberries, a low saturated fat food”).

(3) * * *

(i) The product contains 1 g or less of saturated fatty acids per 100 g and less than 10 percent of calories from saturated fat;

(ii) The product must display “Low” in accordance with § 101.6 for saturated fat in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

* * * * *

■ 8. Amend § 101.65 by revising paragraph (a)(3) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

(a) * * *

(3) The food or which the claim is made is labeled in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable.

* * * * *

Dated: January 10, 2025.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2025-00778 Filed 1-14-25; 8:45 am]

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FEDERAL REGISTER

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Part XII

The President

Notice of January 14, 2025—Continuation of the National Emergency With Respect to the Situation in the West Bank

Presidential Documents

Title 3—

Notice of January 14, 2025

The President

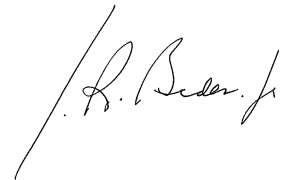
Continuation of the National Emergency With Respect to the Situation in the West Bank

On February 1, 2024, by Executive Order 14115, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the situation in the West Bank.

The situation in the West Bank—in particular high levels of extremist settler violence, forced displacement of people and villages, and property destruction—has reached intolerable levels and constitutes a serious threat to the peace, security, and stability of the West Bank and Gaza, Israel, and the broader Middle East region. These actions undermine the foreign policy objectives of the United States, including the viability of a two-state solution and ensuring Israelis and Palestinians can attain equal measures of security, prosperity, and freedom. They also undermine the security of Israel and have the potential to lead to broader regional destabilization across the Middle East, threatening United States personnel and interests.

The situation in the West Bank continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared in Executive Order 14115 of February 1, 2024, must continue in effect beyond February 1, 2025. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 14115 with respect to the situation in the West Bank.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
January 14, 2025.

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