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Presidential Documents

Title 3—

The President

Proclamation 10678 of November 22, 2023

Thanksgiving Day, 2023

By the President of the United States of America

A Proclamation

As families, loved ones, and friends across the country come together to celebrate Thanksgiving, let us be grateful for all the blessings of this Nation and its limitless possibilities.

Throughout our country's history, this season of reflection and giving thanks comes in good times and tough ones. Before there was a United States of America, the Pilgrims celebrated Thanksgiving in honor of their first successful harvest and the support and generosity of the Wampanoag people who made it possible. Amid the fierce battle for our Nation's independence, General George Washington and his troops celebrated Thanksgiving on the way to Valley Forge. During the Civil War, President Abraham Lincoln proclaimed Thanksgiving a national holiday to honor the blessings of our country, even as he fought to preserve our Union.

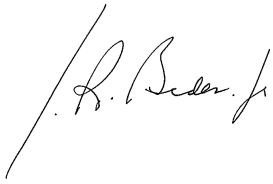
This week, Americans will gather with their loved ones and families, celebrating the love they share and the traditions they built together. To those who are also enduring hard times or grieving the loss of a loved one, know that we are thinking of you.

We are truly a good Nation because we are a good people—the First Lady and I see it every time we travel the country because we meet so many incredible people doing the most extraordinary things. We have met with service members, veterans, and their families, who have selflessly served and sacrificed for our country. We have witnessed the resolve of firefighters, police officers, and first responders, who risk their lives every day to protect us. We have seen the best of our character in the doctors, nurses, scientists, public servants, union workers, and teachers, who ensure everyone is taken care of and no one is left behind. We have seen all the possibilities this Nation holds in the mothers, fathers, and caregivers, who work hard to build a future worthy of their children's greatest dreams, and in young people across the country, who are the most talented, engaged, and educated generation in history.

This Thanksgiving we are grateful for our Nation and the incredible soul of America. May we all remember that we are the United States of America—there is nothing beyond our capacity if we do it together.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim Thursday, November 23, 2023, as a National Day of Thanksgiving. I encourage the people of the United States of America to join together and give thanks for the friends, neighbors, family members, and strangers who have supported each other over the past year in a reflection of goodwill and unity.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-second day of November, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



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Rules and Regulations

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

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FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1240

RIN 2590–AB27

Enterprise Regulatory Capital Framework—Commingled Securities, Multifamily Government Subsidy, Derivatives, and Other Enhancements

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA or the Agency) is adopting a final rule that amends several provisions in the Enterprise Regulatory Capital Framework (ERCF) for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac, and with Fannie Mae, each an Enterprise). The final rule includes modifications related to guarantees on commingled securities, multifamily mortgage exposures secured by government-subsidized properties, and derivatives and cleared transactions, among other items.

DATES: This final rule is effective on April 1, 2024, except for the amendments to §§ 1240.36, 1240.37, and 1240.39, which are effective on January 1, 2026.

FOR FURTHER INFORMATION CONTACT: Andrew Varrieur, Senior Associate Director, Office of Capital Policy, (202) 649–3141, *Andrew.Varrieur@fhfa.gov;* Christopher Vincent, Principal Financial Analyst, Office of Capital Policy, (202) 649–3685, *Christopher.Vincent@fhfa.gov;* or James Jordan, Associate General Counsel, Office of General Counsel, (202) 649–3075, *James.Jordan@fhfa.gov.* These are not toll-free numbers. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

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I. Introduction

On March 13, 2023, FHFA published in the **Federal Register** a notice of proposed rulemaking [1] (proposed rule) seeking comments on amendments to the ERCF [2] that would modify various regulatory capital requirements for the Enterprises. The proposed rule included modifications related to the following items: guarantees on commingled securities, multifamily mortgage exposures secured by properties with a government subsidy, derivatives and cleared transactions, credit scores for single-family mortgage exposures, guarantee assets, mortgage servicing assets (MSAs), time-based calls for credit risk transfer (CRT) exposures, interest-only (IO) mortgage-backed securities (MBS), the single-family countercyclical adjustment, the stability capital buffer, and the compliance date for the advanced approaches.

FHFA proposed these amendments to implement lessons learned through the continued application of the ERCF and to better reflect the risks faced by the Enterprises in operating their businesses. Regulatory capital requirements that properly account for risk will allow the Enterprises to build capital to enhance their safety and soundness and protect U.S. taxpayers against financial losses. FHFA is now adopting in this final rule many of the proposed amendments, with minor modifications as discussed in the relevant sections of this preamble. FHFA currently is not adopting the proposed amendment related to calculating the representative credit score for a single-family mortgage exposure when multiple credit scores are present. The amendments in the final rule will bolster the ERCF as it aims to ensure that each Enterprise operates in a safe and sound manner and is positioned to fulfill its statutory mission to provide stability and ongoing assistance to the secondary mortgage market throughout the economic cycle, in particular during periods of financial stress.

II. Overview of the Final Rule

FHFA continuously monitors the risks faced by the Enterprises and reviews the appropriateness of the ERCF's capital requirements and buffers to mitigate those risks. After carefully considering the comments on the proposed rule, FHFA has determined that the amendments in the final rule will enhance the ERCF, contribute to the Enterprises' safety and soundness, and better enable the Enterprises to fulfill their statutory mission throughout the economic cycle. Specifically, the final rule will:

- Reduce the risk weight and credit conversion factor for guarantees on commingled securities to 5 percent and 50 percent, respectively,
- Introduce a risk multiplier of 0.6 for multifamily mortgage exposures secured by properties with certain government subsidies,
- Replace the current exposure methodology (CEM) with the standardized approach for counterparty credit risk (SA–CCR) as the method for computing exposure and risk-weighted asset amounts for derivatives and cleared transactions,
- Update the credit score assumption to 680 for single-family mortgage exposures originated without a representative credit score,
- Introduce a risk weight of 20 percent for guarantee assets,
- Align the timing of the first application of the single-family countercyclical adjustment with the first property value adjustment, and

[1] 88 FR 15306.
[2] 12 CFR part 1240.

• Delay the compliance date for the advanced approaches to January 1, 2028.

FHFA has also identified several aspects of the ERCF where modifications will clarify and enhance the usefulness of the framework. Therefore, the final rule will also:

• Expand the definition of MSAs to include servicing rights on mortgage loans owned by the Enterprise,

• Explicitly permit eligible time-based call options in the CRT operational criteria, subject to certain restrictions,

• Amend the risk weights for IO MBS to 0 percent, 20 percent, and 100 percent, conditional on whether the security was issued by the Enterprise, the other Enterprise, or a non-Enterprise entity, respectively, and

• Clarify the calculation of the stability capital buffer when an increase and a decrease might be applied concurrently.

III. General Overview of Comments on the Proposed Rule

FHFA received 23 public comment letters on the proposed rule from a variety of interested parties, including private individuals, trade associations, consumer advocacy groups, and financial institutions.[3] In general, and as discussed in greater detail in the relevant sections of this preamble, commenters were supportive of FHFA's proposed amendments to the ERCF.

One commenter recommended that FHFA consider climate-related financial risks in relation to most topics covered in the proposed rule. FHFA recognizes that climate change poses a serious threat to the U.S. housing finance system and the Agency has been actively working to ensure that its regulated entities are accounting for the risks associated with climate change and natural disasters.[4] Outside of this rulemaking, FHFA will continue to evaluate how the ERCF can better account for climate-related financial risks.

In addition to the feedback FHFA received on elements of the proposed rule, FHFA also received comments on many issues that are outside the scope of this rulemaking. In these letters, commenters offered views on important topics such as single-family and multifamily base risk weights, a multifamily countercyclical adjustment, a risk multiplier for multifamily senior housing, defeased loans, early redemption features in senior-subordinated CRT structures, the CRT risk-weight floor, the calculation of the stability capital buffer, the commingling fee, pricing for single-family loans originated by third-parties, the alternative credit score implementation timeline, and the Enterprises' exits from conservatorships. FHFA acknowledges the importance of these topics and will thoroughly consider the public's feedback on these issues when relevant rulemakings and policy decisions are under consideration.

IV. Final Rule Requirements

A. Guarantees on Commingled Securities

The proposed rule would reduce the risk weight under the standardized approach for guarantees on commingled securities from 20 percent to 5 percent and the credit conversion factor for guarantees on commingled securities from 100 percent to 50 percent. A commingled security is a security issued by one Enterprise that is backed, in whole or in part, by collateral issued by the other Enterprise, subject to certain restrictions. FHFA posited that the 20 percent risk weight and 100 percent credit conversion factor for guarantees on commingled securities may not accurately reflect the counterparty risks posed by commingling activities and in certain circumstances may impair the liquidity of the Enterprises' securities, which may adversely affect the nation's housing finance market.

Many commenters supported FHFA's proposal to lower the risk weight and credit conversion factor for guarantees on commingled securities. Several commenters supported the proposed 5 percent risk weight and 50 percent credit conversion factor. Others expressed the view that guarantees on commingled securities should have a risk weight and credit conversion factor lower than 5 percent and 50 percent, respectively, stating that lower capital requirements would enhance the liquidity of the common MBS known as the Uniform Mortgage-Backed Security (UMBS) and foster the stability and liquidity of the secondary mortgage market. Several commenters recommended that FHFA eliminate all capital requirements for guarantees on commingled securities, suggesting that any provisions in the ERCF that might deter commingling activity by hindering the fungibility of the Enterprises' MBS or by driving commingling fees should be removed. One commenter opposed any non-zero risk weight because in the commenter's view, it results in a double capital charge on the securities underlying the UMBS, as each Enterprise is already required to hold capital for the underlying securities it guarantees.

The final rule adopts FHFA's proposal to reduce the risk weight for guarantees on commingled securities from 20 percent to 5 percent and the credit conversion factor for guarantees on commingled securities from 100 percent to 50 percent. FHFA is adopting a non-zero risk weight and a non-zero credit conversion factor because a key tenet of the ERCF is that all exposures with risk, however small, are capitalized. The Enterprises' obligations do not have an unlimited explicit guarantee of the full faith and credit of the United States, despite the current support of the U.S. Department of the Treasury under the senior preferred stock purchase agreements (PSPAs). Therefore, the counterparty credit risk arising from guarantees on commingled securities is unique to the guaranteeing Enterprise and is not a double counting of the borrower credit risk on the underlying mortgage exposures.

FHFA is retaining the 5 percent risk weight as proposed because the credit exposures arising out of these guarantees and the resultant losses an Enterprise would experience from commingled securities would likely occur in remote circumstances through sustained catastrophic levels of loss after the other Enterprise has exhausted its loss-absorbing financial resources. FHFA will continue to monitor the impact of a non-zero risk weight on the performance of the UMBS in keeping with the intent and purpose of the Single Security Initiative. Conceptually, the risk weight for guarantees on commingled securities in the final rule aligns with the risk-weight floor for retained CRT exposures. In addition, the final rule's 50 percent credit conversion factor for guarantees on commingled securities aligns with the prevailing regulatory capital treatment for off-balance sheet undrawn commitments with an original maturity of more than one year that are not unconditionally cancelable by the Enterprise.

B. Multifamily Government Subsidy Risk Multiplier

The proposed rule would introduce a risk multiplier under the standardized approach equal to 0.6 for any multifamily mortgage exposures secured by one or more properties each with at

[3] *See* comments on Enterprise Regulatory Capital Framework—Commingled Securities, Multifamily Government Subsidy, Derivatives, and Other Enhancements, *available at https://www.fhfa.gov/SupervisionRegulation/Rules/Pages/Comment-List.aspx?RuleID=754.* The comment period for the proposed rule closed on May 12, 2023.

[4] More information on the steps FHFA has taken to evaluate and address climate-related risks can be found on FHFA's website, *available at https://www.fhfa.gov/PolicyProgramsResearch/Programs/Pages/Climate-Change-and-ESG.aspx.*

least one applicable government subsidy, subject to certain affordability criteria. Under the proposed rule, the applicable government subsidies would be limited to the following three primary subsidy programs: (i) Low-Income Housing Tax Credit (LIHTC),[5] (ii) Section 8 project-based rental assistance, and (iii) State and local affordable housing programs that require the provision of affordable housing for the life of the loan. A multifamily mortgage exposure meeting the collateral criteria would qualify for the 0.6 risk multiplier if the Enterprise can verify that each property securing the exposure has at least 20 percent of its units restricted as affordable units, where the affordability restriction means the income of the renter is less than or equal to 80 percent of area median income (AMI).

The current rule does not differentiate between multifamily mortgage exposures secured by properties with a government subsidy and by properties without a government subsidy. Properties with government subsidies represent an important segment of the Enterprises' multifamily business models, and as part of the annual acquisition limits, FHFA directs the Enterprises to meet specific affordable housing or mission goals by acquiring multifamily loans collateralized by properties that charge rents affordable to certain segments of the population with specified income levels. Affordable property units are available to renters at a rental rate below the typical market rate, leading to generally strong demand for affordable property units and therefore to relatively stable vacancy rates.

Many commenters expressed support for FHFA's proposal to introduce a government subsidy risk multiplier to reflect that multifamily mortgage exposures associated with government-subsidized properties are less risky than those associated with unsubsidized properties, all else equal. Many commenters supported the 0.6 risk multiplier as proposed, while a few commenters recommended that FHFA adopt a multiplier smaller than 0.6. One commenter recommended that FHFA consider a pro-rated risk multiplier scaled between 0.6 and 1.0 when a multifamily mortgage exposure is secured by multiple properties and some but not all of the properties have an applicable government subsidy.

One commenter recommended that FHFA require an Enterprise to measure the percentage of affordable units at each property only at acquisition rather than on a quarterly basis, which the commenter understood was FHFA's intent, to avoid operational constraints and be consistent with the application of the housing goals regulation. Multiple commenters recommended that FHFA expand the affordability criteria to allow for exceptions in high-cost and very-high-cost markets. For example, one commenter suggested that an 80 percent of AMI threshold could be used in standard markets, while thresholds of 100 percent of AMI and 120 percent of AMI could be used high-cost and very-high-cost markets, respectively. Several commenters recommended that FHFA expand the list of applicable government subsidies, with suggested additions including the rural rental housing program under Section 515 of the Housing Act of 1949 (Section 515 Rural Rental Housing Loans), Fannie Mae's Sponsor-Initiated Affordability (SIA) and Freddie Mac's Tenant Advancement Commitment (TAC) programs, block grant programs such as HOME Investment Partnerships or Community Development Block Grants, and tax-exempt private activity bonds used for multifamily housing.

The final rule adopts a multifamily government subsidy risk multiplier that is scaled between 0.6 and 1.0 depending on the properties securing the multifamily mortgage exposure. When some but not all properties securing a multifamily mortgage exposure have an applicable government subsidy, each property with an applicable government subsidy will receive a property multiplier of 0.6 and each property without an applicable government subsidy will receive a property multiplier of 1.0, and the government subsidy risk multiplier for the multifamily mortgage exposure will be calculated as a weighted average of the property multipliers using the total number of units per building as weights.

In addition, the final rule adopts the affordability criteria and list of applicable government subsidies substantially as proposed, with the addition of Section 515 Rural Rental Housing Loans as an applicable government subsidy. Section 515 Rural Rental Housing Loans are direct loans made by the United States Department of Agriculture (USDA) to finance affordable rental housing for low- to moderate-income (50 percent to 80 percent of AMI) renters in rural communities. This program is analogous to Section 8 project-based rental assistance, and as with LIHTC and Section 8, affordability is required for the life of the loan and accompanied by a use restriction. For these reasons, the final rule includes Section 515 Rural Housing Loans as an applicable government subsidy.

To ensure that the applicable subsidy programs meet the affordability criteria without creating ongoing compliance and operational burdens for the Enterprises, the final rule requires that at least 20 percent of the property's units are restricted to be affordable units *per a regulatory agreement, recorded use restriction, a housing-assistance payments contract, or other restrictions codified in loan agreements.* Each program included in the list of applicable government subsidies has its own requirements that ensure the subsidies are significant, long-term, and continuous. By requiring the affordability criteria to be included in contractual provisions, FHFA believes it is not necessary for the final rule to specify that the percentage of affordable units be measured only at acquisition. FHFA expects an Enterprise to validate that a property is receiving a valid government subsidy at acquisition in order for the multifamily mortgage exposure secured by that property to receive a government subsidy risk multiplier less than 1.0, and subsequently not to undertake additional compliance exercises on top of what is required by the subsidy programs themselves.

The final rule does not include a government subsidy risk multiplier less than 0.6. In a data-driven exercise, FHFA determined that a 40 percent decrease in regulatory capital appropriately captures the lower credit risk associated with multifamily mortgage exposures secured by properties with a significant, long-term, and continuous government subsidy. The final rule does not include exceptions for high-cost and very-high-cost markets in order to mitigate the operational complexity of applying the government subsidy risk multiplier, as rental costs and income levels within metro areas change over time.

Finally, the final rule does not include the Enterprises' voluntary rent restriction programs (SIA and TAC), block grant programs, or tax-exempt private activity bonds as applicable government subsidies. While these programs do often support affordable housing and provide benefits to lenders, FHFA sought to include as applicable government subsidies programs administered by the Federal or a State government that span most of the

[5] Section 42 of the Internal Revenue Code (26 U.S.C.A. § 42); 26 CFR 1.42 (Treasury regulations); each State agency's qualified allocation plan, regulations and compliance manual, along with a list of State and local LIHTC-allocating agencies, can be found at *https://www.huduser.gov/portal/datasets/lihtc.html.*

Enterprises' affordable businesses and that have significant performance data available. Many of the additional programs identified by commenters as recommended inclusions are either non-governmental, are used as a layer in a financing stack in conjunction with an already applicable government subsidy, do not have performance data readily available for FHFA to assess, or are not specifically oriented to the creation or preservation of affordable rental housing.

C. Derivatives and Cleared Transactions

The proposed rule would require an Enterprise to calculate risk-weighted assets for the standardized approach based on the exposure amounts of its over-the-counter (OTC) derivative contracts, cleared derivative contracts, and contributions of commitments to mutualized loss sharing agreements with central counterparties (*i.e.,* default fund contributions) calculated using SA–CCR. The proposed rule would also require an Enterprise to use these same exposure amounts for inclusion in adjusted total assets. The current regulation requires an Enterprise to use the CEM to determine the exposure amounts of its OTC derivative contracts and cleared derivative contracts and the risk-weighted assets amounts of its default fund contributions.

The proposed rule would require an Enterprise to apply SA–CCR in the following ways:

1. Netting Sets

The proposed rule would require an Enterprise to calculate the exposure amount of its derivative contract at the netting set level. The proposed rule would define a netting set to mean either one derivative contract between an Enterprise and a single counterparty, or a group of derivative contracts between an Enterprise and a single counterparty that are subject to a qualifying master netting agreement (QMNA).

2. Hedging Sets

To calculate potential future exposure (PFE), the proposed rule would require an Enterprise to fully or partially net derivative contracts within the same netting set that share similar risk factors. This approach would recognize that derivative contracts with similar risk factors share economically meaningful relationships with close correlations that make netting appropriate.

Under SA–CCR, a hedging set means those derivative contracts within the same netting set that share similar risk factors. The proposed rule would define five types of hedging sets—interest rate, exchange rate, credit, equity, and commodities—and would provide formulas for netting within each hedging set. Each formula would be particular to each hedging set type and would reflect the regulatory correlation assumptions between risk factors in the hedging set.

3. Derivative Contract Amount for the PFE Component Calculation

The proposed rule would require an Enterprise to use an adjusted derivative contract amount for the PFE component calculation under SA–CCR. However, as part of the estimate, SA–CCR would use updated supervisory factors that reflect the stress volatilities observed during the financial crisis. The supervisory factors would reflect the variability of the primary risk factors of the derivative contract over a one-year time horizon. In addition, SA–CCR would apply a separate maturity factor to each derivative contract that would scale down, if necessary, the default one-year risk horizon of the supervisory factor to the risk horizon appropriate for the derivative contract.

4. Collateral Recognition and Differentiation Between Margined and Unmargined Derivative Contracts

Under the proposed rule, SA–CCR would account for collateral directly within the exposure amount calculation. For replacement cost, the proposed rule would recognize collateral on a one-for-one basis. For PFE, SA–CCR would use the concept of a PFE multiplier, which would allow an Enterprise to reduce the PFE amount through recognition of over-collateralization, in the form of both variation margin and independent collateral. It would also account for negative fair value amounts of the derivative contracts within the netting set. In addition, the proposed rule would differentiate between margined and unmargined derivative contracts, such that the netting set subject to variation margin would always have an exposure amount no higher than an equivalent netting set that is not subject to a variation margin agreement.

To accommodate the introduction of the SA–CCR into the ERCF's standardized approach, the proposed rule would make a series of corresponding modifications, including adding appropriate defined terms to ERCF's definitions and updating the calculation of total risk-weighted assets. Notably, the proposed rule would replace the current requirements for cleared transactions (12 CFR 1240.37) and collateralized transactions (12 CFR 1240.39) with modified requirements from the U.S. banking framework's advanced approaches (12 CFR 217.133 and 12 CFR 217.132(b)). As a result, the proposed rule's requirements for cleared transactions would reflect the U.S. banking framework's risk weights on cleared transactions and risk-weighted assets on default fund contributions. The proposal would omit exposure calculations related to internal model methodology to reduce reliance on the Enterprises' internal model results.

The proposed rule would maintain the current collateral haircut approach and standard supervisory haircuts for collateralized transactions. However, the proposed rule would remove the current simple approach and add the U.S. banking framework's simple value-at-risk (VaR) methodology.

The proposed rule would also add credit valuation adjustment (CVA) risk-weighted assets to the calculation of standardized total risk-weighted assets. The CVA is a fair value adjustment that reflects counterparty credit risk in the valuation of OTC derivative contracts. CVA risk-weighted assets cover the risk of incurring mark-to-market losses because of the deterioration in the creditworthiness of an Enterprise's counterparties. The proposed rule would include the U.S. banking framework's formulaic simple CVA approach but not the advanced CVA approach to reduce reliance on the Enterprises' internal model results.

Two commenters supported FHFA's proposal to replace CEM with SA–CCR, with certain revisions. Both commenters recommended an implementation timeline of no less than 24 months due to the complexity of implementing SA–CCR and to be generally consistent with the transition period offered to large U.S. banking organizations when they implemented similar financial regulatory reforms.[6] One commenter recommended that FHFA provide optionality allowing an Enterprise to use either CEM or SA–CCR after any regulatory transition period. The commenter stated that Enterprise derivative portfolios more closely resemble the derivative portfolios of U.S. banking organizations subject to the standardized approach than those subject to the advanced approaches, so CEM might be more appropriate.

The final rule adopts the requirements that an Enterprise must determine the exposure amounts of its OTC derivative contracts, cleared derivative contracts, and default fund contributions, for use in calculating risk-weighted assets under the standardized approach and adjusted total assets, using SA–CCR substantially as proposed, with a

[6] *See* 85 FR 4362 (Jan. 24, 2020).

transition period resulting in an effective date of January 1, 2026. FHFA continues to believe that relative to CEM, SA–CCR provides important improvements to risk sensitivity and calibration, including by differentiating between margined and unmargined derivative contracts and recognizing the benefits of netting agreements, resulting in more appropriate capital requirements for derivative contracts. The final rule also adopts the requirement to add CVA risk-weighted assets to the calculation of standardized total risk-weighted assets.

FHFA agrees with commenters that a 24-month transition period will allow the Enterprises a suitable amount of time to update their systems and processes to implement SA–CCR. During the transition period, the Enterprises must continue to use CEM to calculate exposure amounts for derivatives and cleared transactions, as provided in prior §§ 1240.36, 1240.37, and 1240.39.[7] On January 1, 2026, an Enterprise must calculate exposure amounts for derivates and cleared transactions using SA–CCR as detailed in this §§ 1240.36, 1240.37, and 1240.39.

Regarding the commenter's suggestion to make SA–CCR an optional requirement, although the Enterprises' derivatives portfolios are relatively uncomplicated today, that may not be the case after the Enterprises exit their conservatorships. Furthermore, in constructing the ERCF, FHFA has consistently developed requirements similar to those applicable to banking organizations subject to the advanced approaches rather than those subject to the standardized approach. For example, the ERCF includes a stability capital buffer (analogous to surcharge for global systemically important banks), a leverage buffer, market risk capital requirements, and operational risk capital requirements, none of which are applicable to banking organizations subject to the standardized approach. Following this reasoning, and to limit certain capital arbitrage opportunities between Enterprises and between the Enterprises and large banking organizations, the final rule does not include CEM as an option for calculating regulatory capital ratios after the transition period.

D. Original Credit Scores for Single-Family Mortgage Exposures Without a Representative Original Credit Score

The proposed rule would require an Enterprise to assign an original credit score of 680 under the standardized approach to a single-family mortgage exposure without a permissible credit score at origination (unscored), subject to Enterprise verification that none of the borrowers have a credit score at one of the repositories. The current regulation requires an Enterprise to assign a credit score of 600 to any single-family mortgage exposure that is unscored. The current regulation's conservative assignation places single-family mortgage exposures with unscored borrowers in the lowest possible ERCF credit score buckets across the single-family base grids, implying the highest level of risk.

Four commenters expressed full support for FHFA's proposal to increase the assigned original credit score for unscored single-family mortgage exposures from 600 to 680. Therefore, to reflect post-crisis improvements in regulatory, underwriting, and lending standards, as well as the recent inclusions of positive rental payment histories in the Enterprises' automated underwriting systems,[8] the final rule adopts the requirement to assign an original credit score of 680 to unscored single-family mortgage exposures without a permissible credit score, subject to Enterprise verification that none of the borrowers have a credit score at one of the repositories, as proposed.

E. Guarantee Assets

The proposed rule would introduce a 20 percent risk weight under the standardized approach for an Enterprise's guarantee assets. A guarantee asset is an on-balance sheet asset that represents the present value of a future consideration for providing a financial guarantee on a portfolio of mortgage exposures not recognized on the balance sheet. Examples of such off-balance sheet exposures include, but are not limited to, Freddie Mac's multifamily K-deals, Fannie Mae's multifamily bond credit enhancements, and certain single-family guarantee arrangements without securitization. The current ERCF does not include an explicit risk weight for guarantee assets. As an ''other asset'' not specifically assigned a different risk weight, an Enterprise is currently required to assign a 100 percent risk weight (§ 1240.32(i)(5)) to guarantee assets.

One commenter supported FHFA's proposed 20 percent credit risk weight for guarantee assets. In addition, in response to a question posed in the proposed rule, the commenter recommended that FHFA not include guarantee assets in the definition of covered positions subject to market risk capital requirements. The commenter expressed the view that because guarantee assets are not positions held for the purpose of short-term resale or with the intent of benefitting from short-term price movements, the positions do not contribute to an Enterprise's interest rate risk.

The final rule adopts the risk weight of 20 percent for guarantee assets as proposed. In addition, and in consideration of the feedback FHFA received, the final rule does not include guarantee assets in the definition of covered positions subject to market risk capital requirements.

F. Mortgage Servicing Assets

The proposed rule would modify the definition of MSAs to include the contractual right to service any mortgage loans, regardless of the owner of the loan at the time the servicing rights are acquired. Currently, the ERCF defines an MSA as the contractual right to service for a fee mortgage loans that are owned by *others.* Therefore, this definition omits MSAs created when an Enterprise acquires servicing rights on mortgage loans already owned by the Enterprise, bifurcating the capital treatment for MSAs by the owner of the underlying loans.

One commenter supported FHFA's proposal to expand the definition of MSA to include servicing rights on mortgage loans owned by the acquiring Enterprise. No commenters raised objections or provided alternative recommendations to the proposal. The final rule adopts the definition of MSA as proposed.

G. Time-Based Calls for CRT Exposures

The proposed rule would amend the ERCF to permit eligible time-based calls for CRT exposures under the standardized approach, defining an eligible time-based call as a time-based call that:

(i) Is exercisable solely at the discretion of the issuing Enterprise, and with a non-objection letter from FHFA prior to being exercised;

(ii) Is not structured to avoid allocating losses to securitization exposures held by investors or otherwise structured to provide at most

[7] *See* 85 FR 82150 (Dec. 17, 2020).

[8] In August 2021, FHFA announced that to expand access to credit in a safe and sound manner, Fannie Mae would begin to consider rental payment history as part of its mortgage underwiring processes (*https://www.fhfa.gov/mobile/Pages/public-affairs-detail.aspx?PageName=FHFA-Announces-Inclusion-of-Rental-Payment-History-in-Fannie-Maes-Underwriting-Process.aspx*). In July 2022, Freddie Mac made a similar announcement (*https://freddiemac.gcs-web.com/news-releases/news-release-details/freddie-mac-takes-further-action-help-renters-achieve*).

de minimis credit protection to the securitization; and

(iii) Is only exercisable five years after the securitization exposure's issuance date.

Under the current regulation, time-based calls, which are integral to the Enterprises' credit risk management and are routinely used by the Enterprises to manage CRT economics, are not explicitly included as eligible clean-up calls in the credit risk transfer approach.[9]

Three commenters supported FHFA's proposal to permit eligible time-based calls for CRT exposures. One commenter recommended that FHFA modify the proposed definition of time-based calls to be a contractual provision that permits an originating Enterprise to redeem a securitization *or credit risk transfer* exposure on or after a specified redemption or cancellation date to clarify FHFA's intent that eligible time-based calls will be permitted for all CRT exposures. While this is FHFA's intent, the Agency believes that the proposed definition without the phrase ''or credit risk transfer'' is sufficient because the definition of a securitization exposure in § 1240.2 explicitly includes both retained CRT and acquired CRT exposures. Further, the proposed rule would only modify the operational criteria for credit risk transfers (§ 1240.2(c)), implying that the only securitization exposures that would be affected by the amendment are CRT exposures. One commenter recommended that FHFA modify proposed restriction (i) to be ''is exercisable no less than five years after the securitization or credit risk transfer issuance *or effective* date,'' because the commenter expressed the view that adding ''or effective date'' would clarify FHFA's intent that eligible time-based calls will be permitted for CRT that do not involve securitizations, such as reinsurance transactions. Finally, one commenter recommended that for CRT involving single-family mortgage exposures with terms less than or equal to 20 years, the proposed five-year exercise restriction be shortened to four years.

The final rule adopts the ERCF amendment permitting eligible time-based calls for CRT exposures substantially as proposed, with revisions reflecting two commenter suggestions. First, the final rule adopts the suggested clarification that an eligible time-based call is one that is exercisable no less than a certain number of years after the securitization or CRT issuance *or effective* date. This revision reflects FHFA's intent that eligible time-based calls will be permitted for CRT that do not involve securitizations. Second, the final rule adopts the suggested modification to shorten the exercise restriction for CRT involving single-family mortgage exposures with terms less than or equal to 20 years to no less than four years after the CRT issuance or effective date. This revision reflects the risk reduction associated with the faster amortization of shorter-term loans relative to longer-term loans.

H. Interest-Only Mortgage-Backed Securities

The proposed rule would clarify that, under the standardized approach, an Enterprise must assign a zero percent risk weight to an IO MBS issued and guaranteed by the Enterprise, a 20 percent risk weight to an IO MBS issued and guaranteed by the other Enterprise, and a 100 percent risk weight to an IO MBS issued by a non-Enterprise entity. Currently, the ERCF contains conflicting requirements that an Enterprise must assign a zero percent risk weight to any MBS guaranteed by the Enterprise (other than any retained CRT exposure), but also that the risk weight for a non-credit-enhancing IO MBS must not be less than 100 percent.

One commenter supported FHFA's proposal to amend the risk weights for IO MBS to clarify which risk weight must be applied when an IO MBS is issued and guaranteed by the Enterprise versus when an IO MBS is issued by a non-Enterprise entity. No commenters raised objections or provided alternative recommendations to the proposal. The final rule adopts the updated IO MBS risk weights as proposed.

I. Single-Family Countercyclical Adjustment

The proposed rule would require under the standardized approach an Enterprise to apply to a single-family mortgage exposure's loan-to-value ratio (LTV) the first single-family countercyclical adjustment simultaneously with the first property value adjustment, six months after acquisition. Currently, an Enterprise is required to apply the first single-family countercyclical adjustment after acquisition without delay, while the Enterprise is required to apply the first property value adjustment after a six-month delay to allow for a rate of change to be computed following the quarterly release of FHFA's Purchase-only State-level House Price Index.

One commenter supported FHFA's proposal to align the timing between the application of the first single-family countercyclical adjustment and the first property value adjustment. However, the commenter recommended that both adjustments be applied immediately rather than after a six-month delay. The commenter did not provide analytical support for this recommendation.

The final rule adopts the timing adjustment to the application of the first single-family countercyclical adjustment as proposed. FHFA believes this modification will reduce the volatility in the capital requirement for a single-family mortgage exposure over the first six months after origination and mitigate the incentive for the Enterprises to delay acquiring credit protection.

J. Stability Capital Buffer

The proposed rule would clarify that if an increase and decrease in the stability capital buffer are scheduled for the same date, the Enterprise should rely on the more recent data and implement the decrease, disregarding the increase. Under the ERCF, increases in the stability capital buffer are implemented with a two-year delay, while decreases are implemented with a one-year delay. This delay difference potentially creates a situation where an increase and a decrease in the stability capital buffer are scheduled to become effective at the same time.

One commenter supported FHFA's proposed clarification to the calculation of the stability capital buffer. No commenters raised objections or provided alternative recommendations to the proposal. The final rule adopts the clarification as proposed.

K. Advanced Approaches

The proposed rule would extend the compliance date for an Enterprise's advanced approaches from January 1, 2025, to January 1, 2028. The ERCF's advanced approaches for determining risk-weighted assets rely on an Enterprise's internal models, and require an Enterprise to maintain its own processes for identifying and assessing credit, market, and operational risk. They are intended to ensure that an Enterprise continues to enhance its risk management and analytical systems and not rely solely on its regulator's views on risk tolerance, risk measurement, and capital allocation.

Commenters fully supported FHFA's proposal to extend the compliance date of the advanced approaches. One commenter expressed the view that the advanced approaches are exceptionally burdensome and undermine the capital visibility provided by the ERCF's standardized approach.

[9] 12 CFR 1240.44.

The final rule extends the compliance date for an Enterprise's advanced approaches to January 1, 2028, as proposed. In the proposed rule, FHFA discussed how U.S. banking regulators were signaling potential changes in the U.S. banking framework that would further strengthen capital rules by reducing reliance on internal bank models. To this end, the OCC, Federal Reserve Board, and the Federal Deposit Insurance Corporation (FDIC) recently issued a notice of proposed rulemaking [10] that would substantially revise the regulatory capital framework for banking organizations with total assets of $100 billion or more and banking organizations with significant trading activity, including by replacing the advanced approaches with a new expanded risk-based approach.

V. Representative Credit Scores for Single-Family Mortgage Exposures

FHFA currently is not adopting the proposed modification to the procedure for selecting a representative credit score for a single-family mortgage exposure when multiple credit scores have been submitted for at least one borrower. The proposed methodology would have required an Enterprise to use an average credit score for each borrower whenever multiple scores are present as opposed to the current methodology which requires an Enterprise to select the median borrower credit score when three scores are present or the lower borrower credit score when two scores are present.

FHFA proposed this modification to prevent a downward shift in representative credit scores under the current methodology once the Enterprises require a minimum of two, rather than three, credit reports (bi-merge credit score requirement) from the repositories.[11] While the implementation date for the bi-merge credit score requirement has yet to be announced, the proposed modification would have positioned the Enterprises to account for the new requirement upon implementation.

Many commenters supported FHFA's proposal to modify the current procedure for selecting a representative credit score for single-family mortgage exposures. However, other commenters expressed concern over the proposed change. Several commenters stated that it is difficult or impossible to evaluate the proposed change without additional data and when the eventual effects of the bi-merge credit score requirement and the transition to alternative credit scores are not yet known. Others expressed concern that changes to the ERCF could lead to policy changes at the Enterprises that would front-run the implementation of the bi-merge credit score requirement and the transition to alternative credit scores. FHFA also received a number of comments on the bi-merge credit score requirement and on the use of alternative credit scores more generally, but those initiatives are outside the scope of this rulemaking.

One commenter provided empirical support for FHFA's proposal to use the average credit score when multiple scores are present rather than the median/lower score. However, the commenter also suggested that FHFA should require a third score when the two submitted scores are more than 30 points apart to minimize the impact of outliers. In addition, the commenter requested further analysis on, among other things, the potential impact of the bi-merge credit score requirement on race, gender, and geographic location for high-LTV loans with bi-merge representative credit scores greater than or equal to 10 points higher or lower than the score derived under the tri-merge process. Several commenters expressed the view that they could not comment on the appropriateness of the representative credit score proposal until FHFA or the Enterprises released additional data on the bi-merge credit score requirement under Classic FICO scores and under the new alternative credit scoring models. Several commenters also expressed criticism that FHFA's analysis only considered Classic FICO scores, suggesting that the results of the analysis might differ after the Enterprises begin accepting alternative credit scores.

FHFA proposed this narrow change to the calculation of a representative credit scores to prepare the ERCF for the eventual transition to the bi-merge credit score requirement. In March 2023, FHFA and the Enterprises announced plans for stakeholder input on proposed milestones as the Enterprises work to replace the Classic FICO credit score model with the FICO 10T and the VantageScore 4.0 credit score models and transition from the tri-merge requirement to the bi-merge requirement.[12] In September 2023, FHFA announced additional opportunities for ongoing public engagement to facilitate the transition to updated credit score models and credit report requirements for loans acquired by the Enterprises, and also that the Agency expects the implementation date for the bi-merge requirement to occur later than the first quarter of 2024, as was initially proposed.[13] In consideration of the delayed implementation date for the bi-merge requirement and the ongoing public engagement related to credit scores, FHFA has determined to not adopt the proposed change to the calculation of representative credit scores at this time.

FHFA may, in the future, finalize this aspect of the proposed rule. The Agency's options for doing so include adopting the changes substantially as proposed without another notice and comment period, reopening the comment period for the proposed change, or reproposing this item in another notice of proposed rulemaking.

VI. Effective Dates

Under the rule establishing the ERCF published on December 17, 2020, an Enterprise will not be subject to any requirement in the ERCF until the compliance date for the requirement as detailed in the ERCF. The effective date for the ERCF was February 16, 2021. With the exception of the amendments related to derivatives and cleared transactions, the effective date for the amendments in this final rule will be April 1, 2024. The effective date for the amendments implementing SA–CCR and for the other amendments to §§ 1240.36, 1240.37, and 1240.39 will be January 1, 2026.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (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). The final rule contains no such collection of information requiring OMB approval under the PRA. Therefore, no information has been submitted to OMB for review.

VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility

[10] *See* 88 FR 64028 (Sept. 18, 2023).

[11] FHFA Announces Validation of FICO 10T and VantageScore 4.0 for Use by Fannie Mae and Freddie Mac | Federal Housing Finance Agency, *available at https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Announces-Validation-of-FICO10T-and-Vantage-Score4-for-FNM-FRE.aspx.*

[12] *See https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Announces-Public-Engagement-Process-for-Implementation-of-Updated-Credit-Score-Requirements.aspx.*

[13] *See https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Announces-Next-Phase-of-Public-Engagement-Process-for-Updated-Credit-Score-Requirements.aspx.*

analysis describing the regulation's impact on small entities. FHFA need not undertake such an analysis if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)). FHFA has considered the impact of the final rule under the RFA. FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities because the final rule is applicable only to the Enterprises, which are not small entities for purposes of the RFA.

IX. Congressional Review Act

In accordance with the Congressional Review Act (5 U.S.C. 801 *et seq.*), FHFA has determined that this final rule is a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects for 12 CFR Part 1240

Capital, Credit, Enterprise, Investments, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, under the authority of 12 U.S.C. 4511, 4513, 4513b, 4514, 4515–17, 4526, 4611–4612, 4631–36, FHFA amends part 1240 of subchapter C of title 12 of the Code of Federal Regulations chapter XII, as follows:

PART 1240—CAPITAL ADEQUACY OF ENTERPRISES

■ 1. The authority citation for part 1240 continues to read as follows:

Authority: 12 U.S.C. 4511, 4513, 4513b, 4514, 4515, 4517, 4526, 4611–4612, 4631–36.

■ 2. Effective April 1, 2024, amend § 1240.2 by:
■ a. Revising paragraphs (1) through (3) in the definition of ''Adjusted total assets'';
■ b. Adding in alphabetical order definitions for ''Backtesting,'' ''Basis derivative contract,'' ''Commercial end-user,'' ''Commingled security,'' ''Credit default swap,'' and ''Credit valuation adjustment'';
■ c. Removing the definitions of ''Current exposure'' and ''Current exposure methodology'';
■ d. Adding in alphabetical order a definition for ''Eligible time-based call'';
■ e. In the definition of ''Exposure amount'':
■ i. In paragraph (1), removing the words ''; an OTC derivative contract'' and adding in their place the words ''(other than an OTC derivative contract''; and
■ ii. In paragraph (3), adding the words ''or exposure at default (EAD)'' after the word ''amount'';
■ f. Revising paragraph (2) in the definition of ''Financial collateral'';
■ g. Adding in alphabetical order definitions for ''Guarantee asset'' and ''Independent collateral'';
■ h. Revising the definition of ''Mortgage servicing assets (MSAs)'';
■ i. Adding in alphabetical order a definition for ''Net independent collateral amount'';
■ j. Revising the definition of ''Netting set'';
■ k. Adding in alphabetical order definitions for ''Qualifying cross-product master netting agreement'' and ''Speculative grade'';
■ l. In the definition of ''Standardized total risk-weighted assets'', redesignating paragraphs (1)(vi) and (1)(vii) as paragraphs (1)(vii) and (1)(viii), adding new paragraph (1)(vi), and revising newly designated paragraph (i)(viii); and
■ m. Adding in alphabetical order definitions for ''Sub-speculative grade'', ''Time-based call'', ''Uniform Mortgage-backed Security'', ''Value-at-Risk'', ''Variation margin'', ''Variation margin amount'', and ''Volatility derivative contract''.

The revisions and additions read as follows:

§ 1240.2 Definitions.

* * * * *

Adjusted total assets * * *

(1) The balance sheet carrying value of all of the Enterprise's on-balance sheet assets, plus the value of securities sold under a repurchase transaction or a securities lending transaction that qualifies for sales treatment under Generally Accepted Accounting Principles (GAAP), less amounts deducted from tier 1 capital under § 1240.22(a), (c), and (d), and less the value of securities received in security-for-security repo-style transactions, where the Enterprise acts as a securities lender and includes the securities received in its on-balance sheet assets but has not sold or re-hypothecated the securities received, *less* the fair value of any derivative contracts;

(2)(i) The potential future exposure (PFE) for each netting set to which the Enterprise is a counterparty (including cleared transactions except as provided in paragraph (9) of this definition and, at the discretion of the Enterprise, excluding a forward agreement treated as a derivative contract that is part of a repurchase or reverse repurchase or a securities borrowing or lending transaction that qualifies for sales treatment under GAAP), as determined under § 1240.36(c)(7), in which the term C in § 1240.36(c)(7)(i) equals zero, and, for any counterparty that is not a commercial end-user, multiplied by 1.4. For purposes of this paragraph, an Enterprise may set the value of the term C in § 1240.36(c)(7)(i) equal to the amount of collateral posted by a clearing member client of the Enterprise in connection with the client-facing derivative transactions within the netting set; and

(ii) An Enterprise may choose to exclude the PFE of all credit derivatives or other similar instruments through which it provides credit protection when calculating the PFE under § 1240.36(c), provided that it does so consistently over time for the calculation of the PFE for all such instruments;

(3)(i)(A) The replacement cost of each derivative contract or single product netting set of derivative contracts to which the Enterprise is a counterparty, calculated according to the following formula, and, for any counterparty that is not a commercial end-user, multiplied by 1.4:

$$\textit{Replacement Cost} = \max\{V - CVM_r + CVM_p; 0\}$$

Where:

(*1*) V equals the fair value for each derivative contract or each single-product netting set of derivative contracts (including a cleared transaction except as provided in paragraph (9) of this definition and, at the discretion of the Enterprise, excluding a forward agreement treated as a derivative contract that is part of a repurchase or reverse repurchase or a securities borrowing or lending transaction that qualifies for sales treatment under GAAP);

(*2*) CVM_r equals the amount of cash collateral received from a counterparty to a derivative contract and that satisfies the conditions in paragraphs (3)(ii) through (vi) of this definition, or, in the case of a client-facing derivative transaction, the amount of collateral received from the clearing member client; and

(*3*) CVM_p equals the amount of cash collateral that is posted to a counterparty to a derivative contract and that has not offset the fair value of the derivative contract and that satisfies the conditions in paragraphs (3)(ii) through (vi) of this definition, or, in the case of a client-facing derivative transaction, the amount of collateral posted to the clearing member client;

(B) Notwithstanding paragraph (3)(i)(A) of this definition, where multiple netting sets are subject to a single variation margin agreement, an Enterprise must apply the formula for replacement cost provided in § 1240.36(c)(10)(i), in which the term C_{MA} may only include cash collateral that satisfies the conditions in paragraphs (3)(ii) through (vi) of this definition; and

(C) For purposes of paragraph (3)(i)(A) of this definition, an Enterprise must treat a derivative contract that references an index as if it were multiple derivative contracts each referencing one component of the index if the Enterprise elected to treat the derivative contract as multiple derivative contracts under § 1240.36(c)(5)(vi);

(ii) For derivative contracts that are not cleared through a QCCP, the cash collateral received by the recipient counterparty is not segregated (by law, regulation, or an agreement with the counterparty);

(iii) Variation margin is calculated and transferred on a daily basis based on the mark-to-fair value of the derivative contract;

(iv) The variation margin transferred under the derivative contract or the governing rules of the CCP or QCCP for a cleared transaction is the full amount that is necessary to fully extinguish the net current credit exposure to the counterparty of the derivative contracts, subject to the threshold and minimum transfer amounts applicable to the counterparty under the terms of the derivative contract or the governing rules for a cleared transaction;

(v) The variation margin is in the form of cash in the same currency as the currency of settlement set forth in the derivative contract, provided that for the purposes of this paragraph, currency of settlement means any currency for settlement specified in the governing qualifying master netting agreement and the credit support annex to the qualifying master netting agreement, or in the governing rules for a cleared transaction; and

(vi) The derivative contract and the variation margin are governed by a qualifying master netting agreement between the legal entities that are the counterparties to the derivative contract or by the governing rules for a cleared transaction, and the qualifying master netting agreement or the governing rules for a cleared transaction must explicitly stipulate that the counterparties agree to settle any payment obligations on a net basis, taking into account any variation margin received or provided under the contract if a credit event involving either counterparty occurs;

* * * * *

Backtesting means the comparison of an Enterprise's internal estimates with actual outcomes during a sample period not used in model development. In this context, backtesting is one form of out-of-sample testing.

* * * * *

Basis derivative contract means a non-foreign-exchange derivative contract (*i.e.,* the contract is denominated in a single currency) in which the cash flows of the derivative contract depend on the difference between two risk factors that are attributable solely to one of the following derivative asset classes: Interest rate, credit, equity, or commodity.

* * * * *

Commercial end-user means an entity that:

(1)(i) Is using derivative contracts to hedge or mitigate commercial risk; and

(ii)(A) Is not an entity described in section 2(h)(7)(C)(i)(I) through (VIII) of the Commodity Exchange Act (7 U.S.C. 2(h)(7)(C)(i)(I) through (VIII)); or

(B) Is not a ''financial entity'' for purposes of section 2(h)(7) of the Commodity Exchange Act (7 U.S.C. 2(h)) by virtue of section 2(h)(7)(C)(iii) of the Act (7 U.S.C. 2(h)(7)(C)(iii)); or

(2)(i) Is using derivative contracts to hedge or mitigate commercial risk; and

(ii) Is not an entity described in section 3C(g)(3)(A)(i) through (viii) of the Securities Exchange Act of 1934 (15 U.S.C. 78c–3(g)(3)(A)(i) through (viii)); or

(3) Qualifies for the exemption in section 2(h)(7)(A) of the Commodity Exchange Act (7 U.S.C. 2(h)(7)(A)) by virtue of section 2(h)(7)(D) of the Act (7 U.S.C. 2(h)(7)(D)); or

(4) Qualifies for an exemption in section 3C(g)(1) of the Securities Exchange Act of 1934 (15 U.S.C. 78c–3(g)(1)) by virtue of section 3C(g)(4) of the Act (15 U.S.C. 78c–3(g)(4)).

Commingled security means a resecuritization of UMBS in which one or more of the underlying exposures is a UMBS guaranteed by the other Enterprise or is a resecuritization of UMBS guaranteed by the other Enterprise.

* * * * *

Credit default swap (CDS) means a financial contract executed under standard industry documentation that allows one party (the protection purchaser) to transfer the credit risk of one or more exposures (reference exposure(s)) to another party (the protection provider) for a certain period of time.

* * * * *

Credit valuation adjustment (CVA) means the fair value adjustment to reflect counterparty credit risk in valuation of OTC derivative contracts.

* * * * *

Eligible time-based call means a time-based call that:

(1) Is exercisable solely at the discretion of the originating Enterprise, provided the Enterprise obtains FHFA's non-objection prior to exercising the time-based call;

(2) Is not structured to avoid allocating credit losses to investors or otherwise structured to provide at most *de minimis* credit protection to the securitization or credit risk transfer; and

(3) Is exercisable no less than five years after the securitization or credit risk transfer issuance date or effective date, where the underlying collateral is mortgage exposures with amortization terms greater than 20 years.

(4) Is exercisable no less than four years after the securitization or credit risk transfer issuance date or effective date, where the underlying collateral is mortgage exposures with amortization terms of 20 years or less.

* * * * *

Financial collateral * * *

(2) In which the Enterprise has a perfected, first-priority security interest or, outside of the United States, the legal equivalent thereof, (with the exception of cash on deposit; and notwithstanding the prior security interest of any custodial agent or any priority security interest granted to a CCP in connection with collateral posted to that CCP).

* * * * *

Guarantee asset means the present value of a future consideration to be received for providing a financial guarantee on a portfolio of mortgage exposures not recognized on the balance sheet.

Independent collateral means financial collateral, other than variation margin, that is subject to a collateral agreement, or in which an Enterprise has a perfected, first-priority security interest or, outside of the United States, the legal equivalent thereof (with the exception of cash on deposit; notwithstanding the prior security interest of any custodial agent or any prior security interest granted to a CCP in connection with collateral posted to that CCP), and the amount of which does not change directly in response to the value of the derivative contract or contracts that the financial collateral secures.

* * * * *

Mortgage servicing assets (MSAs) means the contractual rights to service mortgage loans for a fee.

* * * * *

Net independent collateral amount means the fair value amount of the independent collateral, as adjusted by the standard supervisory haircuts under § 1240.39(b)(2)(ii), as applicable, that a counterparty to a netting set has posted to an Enterprise less the fair value amount of the independent collateral, as

adjusted by the standard supervisory haircuts under § 1240.39(b)(2)(ii), as applicable, posted by the Enterprise to the counterparty, excluding such amounts held in a bankruptcy remote manner or posted to a QCCP and held in conformance with the operational requirements in § 1240.3.

Netting set means a group of transactions with a single counterparty that are subject to a qualifying master netting agreement or a qualifying cross-product master netting agreement. For derivative contracts, netting set also includes a single derivative contract between an Enterprise and a single counterparty.

* * * * *

Qualifying cross-product master netting agreement means a qualifying master netting agreement that provides for termination and close-out netting across multiple types of financial transactions or qualifying master netting agreements in the event of a counterparty's default, provided that the underlying financial transactions are OTC derivative contracts, eligible margin loans, or repo-style transactions. In order to treat an agreement as a qualifying cross-product master netting agreement for purposes of this subpart, an Enterprise must comply with the requirements of § 1240.3(c) with respect to that agreement.

* * * * *

Speculative grade means the reference entity has adequate capacity to meet financial commitments in the near term, but is vulnerable to adverse economic conditions, such that should economic conditions deteriorate, the reference entity would present an elevated default risk.

* * * * *

Standardized total risk-weighted assets * * *

(1) * * *

(vi) Credit valuation adjustment (CVA) risk-weighted assets as calculated under § 1240.36(d);

* * * * *

(viii) Standardized market risk-weighted assets, as calculated under § 1240.204; minus

* * * * *

Sub-speculative grade means the reference entity depends on favorable economic conditions to meet its financial commitments, such that should such economic conditions deteriorate the reference entity likely would default on its financial commitments.

* * * * *

Time-based call means a contractual provision that permits an originating Enterprise to redeem a securitization exposure on or after a specified redemption or cancellation date.

* * * * *

Uniform Mortgage-backed Security (UMBS) means the same as that defined in § 1248.1.

Value-at-Risk (VaR) means the estimate of the maximum amount that the value of one or more exposures could decline due to market price or rate movements during a fixed holding period within a stated confidence interval.

Variation margin means financial collateral that is subject to a collateral agreement provided by one party to its counterparty to meet the performance of the first party's obligations under one or more transactions between the parties as a result of a change in value of such obligations since the last time such financial collateral was provided.

* * * * *

Variation margin amount means the fair value amount of the variation margin, as adjusted by the standard supervisory haircuts under § 1240.39(b)(2)(ii), as applicable, that a counterparty to a netting set has posted to an Enterprise less the fair value amount of the variation margin, as adjusted by the standard supervisory haircuts under § 1240.39(b)(2)(ii), as applicable, posted by the Enterprise to the counterparty.

* * * * *

Volatility derivative contract means a derivative contract in which the payoff of the derivative contract explicitly depends on a measure of the volatility of an underlying risk factor to the derivative contract.

* * * * *

§1240.4 [Amended]

■ 3. Effective April 1, 2024, amend § 1240.4 in paragraph (c) by removing the year ''2025'' and adding in its place the year ''2028''.

■ 4. Effective April 1, 2024, amend § 1240.31 by:

■ a. In paragraph (a)(1)(iv) removing the word ''or'' after the semicolon;

■ b. In paragraph (a)(1)(v) removing the period after ''1240.52'' and adding ''; or'' in its place; and

■ c. Adding paragraph (a)(1)(vi).

The addition reads as follows:

§ 1240.31 Mechanics for calculating risk-weighted assets for general credit risk.

(a) * * *

(1) * * *

(vi) CVA risk-weighted assets subject to § 1240.36(d).

* * * * *

■ 5. Effective April 1, 2024, amend § 1240.32 by:

■ a. Redesignating paragraph (c)(2) as paragraph (c)(3), adding new paragraph (c)(2), and revising redesignated paragraph (c)(3); and

■ b. Redesignating paragraph (i)(5) as paragraph (i)(6) and adding new paragraph (i)(5).

The additions and revision read as follows:

§ 1240.32 General risk weights.

* * * * *

(c) * * *

(2) An Enterprise must assign a 5 percent risk weight to an exposure to the other Enterprise in a commingled security.

(3) An Enterprise must assign a 20 percent risk weight to an exposure to another GSE, including an MBS guaranteed by the other Enterprise, except for exposures under paragraph (c)(2) of this section.

* * * * *

(i) * * *

(5) An Enterprise must assign a 20 percent risk weight to guarantee assets.

* * * * *

■ 6. Effective April 1, 2024, amend § 1240.33 in paragraph (a) by:

■ a. Revising paragraph (ii) in the definition of ''Adjusted MTMLTV''; and

■ b. Revising table 1 to paragraph (a).

The revisions read as follows:

§ 1240.33 Single-family mortgage exposures.

(a) * * *

Adjusted MTMLTV * * *

(ii) The amount equal to 1 plus either:

(A) The single-family countercyclical adjustment available at the time of the exposure's origination if the loan age of the single-family mortgage exposure is less than or equal to 5; or

(B) The single-family countercyclical adjustment available as of that time if the loan age of the single-family mortgage exposure is greater than or equal to 6.

* * * * *

TABLE 1 TO PARAGRAPH (a)—PERMISSIBLE VALUES AND ADDITIONAL INSTRUCTIONS

Defined term	Permissible values	Additional instructions
Cohort burnout	''No burnout,'' if the single-family mortgage exposure has not had a refinance opportunity since the loan age of the single-family mortgage exposure was 6.. ''Low,'' if the single-family mortgage exposure has had 12 or fewer refinance opportunities since the loan age of the single-family mortgage exposure was 6. ''Medium,'' if the single-family mortgage exposure has had between 13 and 24 refinance opportunities since the loan age of the single-family mortgage exposure was 6. ''High,'' if the single-family mortgage exposure has had more than 24 refinance opportunities since the loan age of the single-family mortgage exposure was 6.	High if unable to determine.
Coverage percent	0 percent <= coverage percent <= 100 percent	0 percent if outside of permissible range or unable to determine.
Days past due	Non-negative integer	210 if negative or unable to determine.
Debt-to-income (DTI) ratio.	0 percent < DTI < 100 percent	42 percent if outside of permissible range or unable to determine.
Interest-only (IO)	Yes, no	Yes if unable to determine.
Loan age	0 <= loan age <= 500	500 if outside of permissible range or unable to determine.
Loan documentation	None, low, full	None if unable to determine.
Loan purpose	Purchase, cashout refinance, rate/term refinance	Cashout refinance if unable to determine.
MTMLTV	0 percent < MTMLTV <= 300 percent	If the property securing the single-family mortgage exposure is located in Puerto Rico or the U.S. Virgin Islands, use the FHFA House Price Index of the United States. If the property securing the single-family mortgage exposure is located in Hawaii, use the FHFA Purchase-only State-level House Price Index of Guam. If the single-family mortgage exposure was originated before 1991, use the Enterprise's proprietary housing price index. Use geometric interpolation to convert quarterly housing price index data to monthly data. 300 percent if outside of permissible range or unable to determine.
Mortgage concentration risk.	High, not high	High if unable to determine.
MI cancellation feature	Cancellable mortgage insurance, non-cancellable mortgage insurance.	Cancellable mortgage insurance, if unable to determine.
Occupancy type	Investment, owner-occupied, second home	Investment if unable to determine.
OLTV	0 percent < OLTV <= 300 percent	300 percent if outside of permissible range or unable to determine.
Original credit score	300 <= original credit score <= 850	If there are credit scores from multiple credit repositories for a borrower, use the following logic to determine a single original credit score: • If there are credit scores from two repositories, take the lower credit score. • If there are credit scores from three repositories, use the middle credit score. • If there are credit scores from three repositories and two of the credit scores are identical, use the identical credit score. If there are multiple borrowers, use the following logic to determine a single original credit score: • Using the logic above, determine a single credit score for each borrower. • Select the lowest single credit score across all borrowers. The original credit score for the single-family mortgage exposure is 680 if the Enterprise has verified that no borrower has a credit score at any of the three repositories. 600 if outside of permissible range or unable to determine.
Origination channel	Retail, third-party origination (TPO)	TPO includes broker and correspondent channels. TPO if unable to determine.
Payment change from modification.	−80 percent < payment change from modification < 50 percent	If the single-family mortgage exposure initially had an adjustable or step-rate feature, the monthly payment after a permanent modification is calculated using the initial modified rate. 0 percent if unable to determine. −79 percent if less than or equal to −80 percent. 49 percent if greater than or equal to 50 percent.
Previous maximum days past due.	Non-negative integer	181 months if negative or unable to determine.
Product type	''FRM30'' means a fixed-rate single-family mortgage exposure with an original amortization term greater than 309 months and less than or equal to 429 months. ''FRM20'' means a fixed-rate single-family mortgage exposure with an original amortization term greater than 189 months and less than or equal to 309 months. ''FRM15'' means a fixed-rate single-family mortgage exposure with an amortization term less than or equal to 189 months. ''ARM1/1'' is an adjustable-rate single-family mortgage exposure that has a mortgage rate and required payment that adjust annually.	Product types other than FRM30, FRM20, FRM15 or ARM 1/1 should be assigned to FRM30. Use the post-modification product type for modified mortgage exposures. ARM 1/1 if unable to determine.
Property type	1-unit, 2–4 units, condominium, manufactured home	Use condominium for cooperatives. 2–4 units if unable to determine.
Refreshed credit score	300 <= refreshed credit score <= 850	If there are credit scores from multiple credit repositories for a borrower, use the following logic to determine a single refreshed credit score:

TABLE 1 TO PARAGRAPH (a)—PERMISSIBLE VALUES AND ADDITIONAL INSTRUCTIONS—Continued

Defined term	Permissible values	Additional instructions
		• If there are credit scores from two repositories, take the lower credit score. • If there are credit scores from three repositories, use the middle credit score. • If there are credit scores from three repositories and two of the credit scores are identical, use the identical credit score. If there are multiple borrowers, use the following logic to determine a single Refreshed Credit Score: • Using the logic above, determine a single credit score for each borrower. • Select the lowest single credit score across all borrowers. 600 if outside of permissible range or unable to determine.
Streamlined refi	Yes, no	No if unable to determine.
Subordination	0 percent <= Subordination <= 80 percent	80 percent if outside permissible range.

* * * * *

■ 7. Effective April 1, 2024, amend § 1240.34 by:

■ a. Adding in alphabetical order definitions for ''Affordable unit'' and ''Government subsidy'' in paragraph (a); and

■ b. Revising table 1 to paragraph (a) and table 4 to paragraph (d).

The additions and revisions read as follows:

§ 1240.34 Multifamily mortgage exposures.

(a) * * *

Affordable unit means a unit within a property securing a multifamily mortgage exposure that can be rented by occupants with income less than or equal to 80 percent of the area median income where the property resides.

* * * * *

Government subsidy means that the property satisfies both of the following criteria:

(i) At least 20 percent of the property's units are restricted to be affordable units per a regulatory agreement, recorded use restriction, a housing-assistance payments contract, or other restrictions codified in loan agreements; and

(ii) The property benefits from one of the following government programs:

(A) Low Income Housing Tax Credits (LIHTC);

(B) Section 8 project-based rental assistance;

(C) Section 515 Rural Rental Housing Loans; or

(D) State/Local affordable housing programs that require the provision of affordable housing for the life of the loan.

* * * * *

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Table 1 to Paragraph (a)—Permissible Values and Additional Instructions

Defined Term	Permissible Values	Additional Instructions
Acquisition DSCR	Greater than or equal to 0.	Origination DSCR if negative or unable to determine. If origination DSCR is unavailable, use underwriting DSCR. If underwriting DSCR is unavailable, use 1.00.
Acquisition LTV	Greater than or equal to 0.	Origination LTV if negative or unable to determine. If origination LTV is unavailable, use underwriting LTV. If underwriting LTV is unavailable, use 100 percent.
Government Subsidy	Yes, no	Yes if at least one property securing the multifamily mortgage exposure has a government subsidy. If the multifamily mortgage exposure is secured by more than one property, calculate a weighted average government subsidy multiplier per the instructions in Table 4 to Paragraph (d). No otherwise
Interest-only	Yes, no.	Yes if unable to determine.
Loan Term	Non-negative integer in years.	11 years if negative or unable to determine.
MTMDSCR	Greater than or equal to 0.	If the MTMDSCR is unavailable, the last observed DSCR can be marked to market using a property NOI index or an NOI estimate based on rent and expense indices. If the index is not sufficiently granular, either because of its frequency or geography, or with respect to a certain multifamily property type, use a more geographically broad index or a recently estimated mark-to-market value.
MTMLTV	Greater than or equal to 0.	If the MTMLTV is unavailable, mark to market using an index. If the index is not sufficiently granular, either because of its frequency or geography or with respect to a certain multifamily property type, use a more geographically broad index or a recently estimated mark-to-market value.
Net Operating Income (NOI) / Net Cash Flow (NCF)	Greater than or equal to 0.	Infer using origination LTV or origination DSCR if NOI/NCF is unavailable. Alternatively, infer using actual MTMLTV or actual MTMDSCR.
Original Amortization Term	Non-negative integer in years.	31 years if negative or unable to determine.
Original Loan Size	Non-negative dollar value.	$3,000,000 if negative or unable to determine
Payment Performance	Performing, delinquent 60 days or more, re-performing (without modification), modified.	Modified if unable to determine.
Special Product	Not a special product, student housing, rehab/value-add/lease-up, supplemental mortgage exposure.	Rehab/value-add/lease-up if unable to determine.
UPB	UPB > $0	$100,000,000 if negative or unable to determine.

* * * * *

(d) * * *

Table 4 to Paragraph (d)—Multifamily Risk Multipliers

Risk Factor	Value or Range	Risk Multiplier
Payment Performance	Performing	1.00
	Delinquent more than 60 days	1.10
	Re-performing (without modification)	1.10
	Modified	1.20
Government Subsidy[1]	No	1.00
	Yes	0.60
Interest-Only	No	1.00
	Yes (during the interest-only period)	1.10
Loan Term	Loan term <= 1Yr	0.70
	1Yr < loan term <= 2Yr	0.75
	2Yr < loan term <= 3Yr	0.80
	3Yr < loan term <= 4Yr	0.85
	4Yr < loan term <= 5Yr	0.90
	5Yr < loan term <= 7Yr	0.95
	7Yr < loan term <= 10Yr	1.00
	Loan term > 10Yr	1.15
Original Amortization Term	Original amortization term <= 20Yr	0.70
	20Yr < original amortization term <= 25Yr	0.80
	25Yr < original amortization term <= 30Yr	1.00
	Original amortization term > 30Yr	1.10
Original Loan Size (in millions)	Loan size <= $2m	1.45
	$2m < loan size <= $3m	1.35
	$3m < loan size <= $4m	1.25
	$4m < loan size <= $5m	1.15
	$5m < loan size <= $6m	1.08
	$6m < loan size <= $7m	1.02
	$7m < loan size <= $8m	0.96
	$8m < loan size <= $9m	0.92
	$9m < loan size <= $10m	0.88
	$10m < loan size <= $11m	0.86
	$11m < loan size <= $12m	0.84
	$12m < loan size <= $13m	0.82
	$13m < loan size <= $15m	0.81
	$15m < loan size <= $22m	0.80
	$22m < loan size <= $23m	0.79
	$23m < loan size <= $24m	0.78
	$24m < loan size <= $25m	0.76
	Loan size >$25m	0.70
Special Products	Not a special product	1.00
	Student housing	1.15
	Rehab/value-add/lease-up	1.25

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[1] If a multifamily mortgage exposure is collateralized by multiple properties, calculate a weighted average government subsidy multiplier by assigning a 0.6 multiplier to each property with a government subsidy and 1.0 multiplier to each property without a government subsidy, and using the total number of units in a property as weights.

■ 8. Effective April 1, 2024, amend § 1240.35 by revising paragraphs (b)(3) and (b)(4)(i) to read as follows:

§ 1240.35 Off-balance sheet exposures.

* * * * *

(b) * * *

(3) *50 percent CCF.* An Enterprise must apply a 50 percent CCF to:

(i) The amount of commitments with an original maturity of more than one year that are not unconditionally cancelable by the Enterprise; and

(ii) Guarantees on exposures to the other Enterprise in commingled securities.

(4) * * *

(i) Guarantees, except guarantees included in paragraph (b)(3)(ii) of this section;

* * * * *

■ 9. Effective January 1, 2026, revise § 1240.36 to read as follows:

§ 1240.36 Derivative contracts.

(a) *Exposure amount for derivative contracts.* An Enterprise must calculate the exposure amount or EAD for all its derivative contracts using the standardized approach for counterparty credit risk (SA–CCR) in paragraph (c) of this section for purposes of standardized total risk-weighted assets. An Enterprise must apply the treatment of cleared transactions under § 1240.37 to its derivative contracts that are cleared transactions and to all default fund contributions associated with such derivative contracts for purposes of standardized total risk-weighted assets.

(b) *Methodologies for collateral recognition.* (1) An Enterprise may use the methodologies under § 1240.39 to recognize the benefits of financial collateral in mitigating the counterparty credit risk of repo-style transactions, eligible margin loans, collateralized OTC derivative contracts and single product netting sets of such transactions.

(2) An Enterprise must use the methodology in paragraph (c) of this section to calculate EAD for an OTC derivative contract or a set of OTC derivative contracts subject to a qualifying master netting agreement.

(3) An Enterprise must also use the methodology in paragraph (d) of this section to calculate the risk-weighted asset amounts for CVA for OTC derivatives.

(c) *EAD for derivative contracts*—(1) *Options for determining EAD.* An Enterprise must determine the EAD for a derivative contract using SA–CCR under paragraph (c)(5) of this section. The exposure amount determined under SA–CCR is the EAD for the derivative contract or derivatives contracts. An Enterprise must use the same methodology to calculate the exposure amount for all its derivative contracts. An Enterprise may reduce the EAD calculated according to paragraph (c)(5) of this section by the credit valuation adjustment that the Enterprise has recognized in its balance sheet valuation of any derivative contracts in the netting set. For purposes of this paragraph (c)(1), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the Enterprise's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

(2) *Definitions.* For purposes of this paragraph (c), the following definitions apply:

(i) *End date* means the last date of the period referenced by an interest rate or credit derivative contract or, if the derivative contract references another instrument, by the underlying instrument, except as otherwise provided in this paragraph (c).

(ii) *Start date* means the first date of the period referenced by an interest rate or credit derivative contract or, if the derivative contract references the value of another instrument, by underlying instrument, except as otherwise provided in this paragraph (c).

(iii) *Hedging set* means:

(A) With respect to interest rate derivative contracts, all such contracts within a netting set that reference the same reference currency;

(B) With respect to exchange rate derivative contracts, all such contracts within a netting set that reference the same currency pair;

(C) With respect to credit derivative contracts, all such contracts within a netting set;

(D) With respect to equity derivative contracts, all such contracts within a netting set;

(E) With respect to a commodity derivative contract, all such contracts within a netting set that reference one of the following commodity categories: Energy, metal, agricultural, or other commodities;

(F) With respect to basis derivative contracts, all such contracts within a netting set that reference the same pair of risk factors and are denominated in the same currency; or

(G) With respect to volatility derivative contracts, all such contracts within a netting set that reference one of interest rate, exchange rate, credit, equity, or commodity risk factors, separated according to the requirements under paragraphs (c)(2)(iii)(A) through (E) of this section.

(H) If the risk of a derivative contract materially depends on more than one of interest rate, exchange rate, credit, equity, or commodity risk factors, FHFA may require an Enterprise to include the derivative contract in each appropriate hedging set under paragraphs (c)(2)(iii)(A) through (E) of this section.

(3) *Credit derivatives.* Notwithstanding paragraphs (c)(1) and (2) of this section:

(i) An Enterprise that purchases a credit derivative that is recognized under § 1240.38 as a credit risk mitigant for an exposure is not required to calculate a separate counterparty credit risk capital requirement under this section so long as the Enterprise does so consistently for all such credit derivatives and either includes or excludes all such credit derivatives that are subject to a master netting agreement from any measure used to determine counterparty credit risk exposure to all relevant counterparties for risk-based capital purposes.

(ii) An Enterprise that is the protection provider in a credit derivative must treat the credit derivative as an exposure to the reference obligor and is not required to calculate a counterparty credit risk capital requirement for the credit derivative under this section, so long as it does so consistently for all such credit derivatives and either includes all or excludes all such credit derivatives that are subject to a master netting agreement from any measure used to determine counterparty credit risk exposure to all relevant counterparties for risk-based capital purposes.

(4) *Equity derivatives.* An Enterprise must treat an equity derivative contract as an equity exposure and compute a risk-weighted asset amount for the equity derivative contract under § 1240.51. In addition, if an Enterprise is treating the contract as a covered position under subpart F of this part, the Enterprise must also calculate a risk-based capital requirement for the counterparty credit risk of an equity derivative contract under this section.

(5) *Exposure amount.* (i) The exposure amount of a netting set, as calculated under this paragraph (c), is equal to 1.4 multiplied by the sum of the replacement cost of the netting set, as calculated under paragraph (c)(6) of this section, and the potential future exposure of the netting set, as calculated under paragraph (c)(7) of this section.

(ii) Notwithstanding the requirements of paragraph (c)(5)(i) of this section, the exposure amount of a netting set subject to a variation margin agreement, excluding a netting set that is subject to a variation margin agreement under which the counterparty to the variation margin agreement is not required to post variation margin, is equal to the lesser of the exposure amount of the netting set calculated under paragraph (c)(5)(i) of this section and the exposure amount of the netting set calculated under paragraph (c)(5)(i) as if the netting set

were not subject to a variation margin agreement.

(iii) Notwithstanding the requirements of paragraph (c)(5)(i) of this section, the exposure amount of a netting set that consists of only sold options in which the premiums have been fully paid by the counterparty to the options and where the options are not subject to a variation margin agreement is zero.

(iv) Notwithstanding the requirements of paragraph (c)(5)(i) of this section, the exposure amount of a netting set in which the counterparty is a commercial end-user is equal to the sum of replacement cost, as calculated under paragraph (c)(6) of this section, and the potential future exposure of the netting set, as calculated under paragraph (c)(7) of this section.

(v) For purposes of the exposure amount calculated under paragraph (c)(5)(i) of this section and all calculations that are part of that exposure amount, an Enterprise may elect to treat a derivative contract that is a cleared transaction that is not subject to a variation margin agreement as one that is subject to a variation margin agreement, if the derivative contract is subject to a requirement that the counterparties make daily cash payments to each other to account for changes in the fair value of the derivative contract and to reduce the net position of the contract to zero. If an Enterprise makes an election under this paragraph (c)(5)(v) for one derivative contract, it must treat all other derivative contracts within the same netting set that are eligible for an election under this paragraph (c)(5)(v) as derivative contracts that are subject to a variation margin agreement.

(vi) For purposes of the exposure amount calculated under paragraph (c)(5)(i) of this section and all calculations that are part of that exposure amount, an Enterprise may elect to treat a credit derivative contract, equity derivative contract, or commodity derivative contract that references an index as if it were multiple derivative contracts each referencing one component of the index.

(6) *Replacement cost of a netting set*—(i) *Netting set subject to a variation margin agreement under which the counterparty must post variation margin.* The replacement cost of a netting set subject to a variation margin agreement, excluding a netting set that is subject to a variation margin agreement under which the counterparty is not required to post variation margin, is the greater of:

(A) The sum of the fair values (after excluding any valuation adjustments) of the derivative contracts within the netting set less the sum of the net independent collateral amount and the variation margin amount applicable to such derivative contracts;

(B) The sum of the variation margin threshold and the minimum transfer amount applicable to the derivative contracts within the netting set less the net independent collateral amount applicable to such derivative contracts; or

(C) Zero.

(ii) *Netting sets not subject to a variation margin agreement under which the counterparty must post variation margin.* The replacement cost of a netting set that is not subject to a variation margin agreement under which the counterparty must post variation margin to the Enterprise is the greater of:

(A) The sum of the fair values (after excluding any valuation adjustments) of the derivative contracts within the netting set less the sum of the net independent collateral amount and variation margin amount applicable to such derivative contracts; or

(B) Zero.

(iii) *Multiple netting sets subject to a single variation margin agreement.* Notwithstanding paragraphs (c)(6)(i) and (ii) of this section, the replacement cost for multiple netting sets subject to a single variation margin agreement must be calculated according to paragraph (c)(10)(i) of this section.

(iv) *Netting set subject to multiple variation margin agreements or a hybrid netting set.* Notwithstanding paragraphs (c)(6)(i) and (ii) of this section, the replacement cost for a netting set subject to multiple variation margin agreements or a hybrid netting set must be calculated according to paragraph (c)(11)(i) of this section.

(7) *Potential future exposure of a netting set.* The potential future exposure of a netting set is the product of the PFE multiplier and the aggregated amount.

(i) *PFE multiplier.* The PFE multiplier is calculated according to the following formula:

$$PFE\ multiplier = \min\left(1; 0.05 + 0.95 * e^{\left(\frac{V-C}{1.9*A}\right)}\right)$$

Where:

(A) V is the sum of the fair values (after excluding any valuation adjustments) of the derivative contracts within the netting set;

(B) C is the sum of the net independent collateral amount and the variation margin amount applicable to the derivative contracts within the netting set; and

(C) A is the aggregated amount of the netting set.

(ii) *Aggregated amount.* The aggregated amount is the sum of all hedging set amounts, as calculated under paragraph (c)(8) of this section, within a netting set.

(iii) *Multiple netting sets subject to a single variation margin agreement.* Notwithstanding paragraphs (c)(7)(i) and (ii) of this section and when calculating the potential future exposure for purposes of adjusted total assets, the potential future exposure for multiple netting sets subject to a single variation margin agreement must be calculated according to paragraph (c)(10)(ii) of this section.

(iv) *Netting set subject to multiple variation margin agreements or a hybrid netting set.* Notwithstanding paragraphs (c)(7)(i) and (ii) of this section and when calculating the potential future exposure for purposes of adjusted total assets, the potential future exposure for a netting set subject to multiple variation margin agreements or a hybrid netting set must be calculated according to paragraph (c)(11)(ii) of this section.

(8) *Hedging set amount*—(i) *Interest rate derivative contracts.* To calculate the hedging set amount of an interest rate derivative contract hedging set, an Enterprise may use either of the formulas provided in paragraphs (c)(8)(i)(A) and (B) of this section:

(A) Formula 1 is as follows:

$$Hedging\ set\ amount = [(AddOn_{TB1}^{IR})^2 + (AddOn_{TB2}^{IR})^2 + (AddOn_{TB3}^{IR})^2 + 1.4 * AddOn_{TB1}^{IR} * AddOn_{TB2}^{IR} + 1.4 * AddOn_{TB2}^{IR} * AddOn_{TB3}^{IR} + 0.6 * AddOn_{TB1}^{IR} * AddOn_{TB3}^{IR}]^{\frac{1}{2}}\text{; or}$$

(B) Formula 2 is as follows:

$$Hedging\ set\ amount = |AddOn_{TB1}^{IR}| + |AddOn_{TB2}^{IR}| + |AddOn_{TB3}^{IR}|.$$

Where in paragraphs (c)(8)(i)(A) and (B) of this section:

(*1*) $AddOn_{TB1}{}^{IR}$ is the sum of the adjusted derivative contract amounts, as calculated under paragraph (c)(9) of this section, within the hedging set with an end date of less than one year from the present date;

(*2*) $AddOn_{TB2}{}^{IR}$ is the sum of the adjusted derivative contract amounts, as calculated under paragraph (c)(9) of this section, within the hedging set with an end date of one to five years from the present date; and

(*3*) $AddOn_{TB3}{}^{IR}$ is the sum of the adjusted derivative contract amounts, as calculated under paragraph (c)(9) of this section, within the hedging set with an end date of more than five years from the present date.

(ii) *Exchange rate derivative contracts.* For an exchange rate derivative contract hedging set, the hedging set amount equals the absolute value of the sum of the adjusted derivative contract amounts, as calculated under paragraph (c)(9) of this section, within the hedging set.

(iii) *Credit derivative contracts and equity derivative contracts.* The hedging set amount of a credit derivative contract hedging set or equity derivative contract hedging set within a netting set is calculated according to the following formula:

$$Hedging\ set\ amount = \left[\left(\sum_{k=1}^{K} \rho_k * AddOn(Ref_k)\right)^2 + \sum_{k=1}^{K} (1 - (\rho_k)^2) * \left(AddOn(Ref_k)\right)^2\right]^{\frac{1}{2}}$$

Where:

(A) k is each reference entity within the hedging set.

(B) K is the number of reference entities within the hedging set.

(C) $AddOn(Ref_k)$ equals the sum of the adjusted derivative contract amounts, as determined under paragraph (c)(9) of this section, for all derivative contracts within the hedging set that reference reference entity k.

(D) ρ_kPkequals the applicable supervisory correlation factor, as provided in table 2 to paragraph (c)(11)(ii)(B)(*2*).

(iv) *Commodity derivative contracts.* The hedging set amount of a commodity derivative contract hedging set within a netting set is calculated according to the following formula:

$$Hedging\ set\ amount = \left[\left(\rho * \sum_{k=1}^{K} AddOn(Type_k)\right)^2 + (1 - (\rho)^2) * \sum_{k=1}^{K} \left(AddOn(Type_k)\right)^2\right]^{\frac{1}{2}}$$

Where:

(A) k is each commodity type within the hedging set.

(B) K is the number of commodity types within the hedging set.

(C) $AddOn\ (Type_k)$ equals the sum of the adjusted derivative contract amounts, as determined under paragraph (c)(9) of this section, for all derivative contracts within the hedging set that reference commodity type.

(D) *P* equals the applicable supervisory correlation factor, as provided in table 2 to paragraph (c)(11)(ii)(B)(*2*).

(v) *Basis derivative contracts and volatility derivative contracts.* Notwithstanding paragraphs (c)(8)(i) through (iv) of this section, an Enterprise must calculate a separate hedging set amount for each basis derivative contract hedging set and each volatility derivative contract hedging set. An Enterprise must calculate such hedging set amounts using one of the formulas under paragraphs (c)(8)(i) through (iv) that corresponds to the primary risk factor of the hedging set being calculated.

(9) *Adjusted derivative contract amount*—(i) *Summary.* To calculate the adjusted derivative contract amount of a derivative contract, an Enterprise must determine the adjusted notional amount of derivative contract, pursuant to paragraph (c)(9)(ii) of this section, and multiply the adjusted notional amount by each of the supervisory delta adjustment, pursuant to paragraph (c)(9)(iii) of this section, the maturity factor, pursuant to paragraph (c)(9)(iv) of this section, and the applicable supervisory factor, as provided in table 2 to paragraph (c)(11)(ii)(B)(*2*).

(ii) *Adjusted notional amount.* (A)(*1*) For an interest rate derivative contract or a credit derivative contract, the adjusted notional amount equals the product of the notional amount of the derivative contract, as measured in U.S. dollars using the exchange rate on the date of the calculation, and the

supervisory duration, as calculated by the following formula:

$$Supervisory\ duration = max\left\{\frac{e^{-0.05*\left(\frac{S}{250}\right)} - e^{-0.05*\left(\frac{E}{250}\right)}}{0.05}, 0.04\right\}$$

Where:

(*i*) S is the number of business days from the present day until the start date of the derivative contract, or zero if the start date has already passed; and

(*ii*) E is the number of business days from the present day until the end date of the derivative contract.

(*2*) For purposes of paragraph (c)(9)(ii)(A)(*1*) of this section:

(*i*) For an interest rate derivative contract or credit derivative contract that is a variable notional swap, the notional amount is equal to the time-weighted average of the contractual notional amounts of such a swap over the remaining life of the swap; and

(*ii*) For an interest rate derivative contract or a credit derivative contract that is a leveraged swap, in which the notional amount of all legs of the derivative contract are divided by a factor and all rates of the derivative contract are multiplied by the same factor, the notional amount is equal to the notional amount of an equivalent unleveraged swap.

(B)(*1*) For an exchange rate derivative contract, the adjusted notional amount is the notional amount of the non-U.S. denominated currency leg of the derivative contract, as measured in U.S. dollars using the exchange rate on the date of the calculation. If both legs of the exchange rate derivative contract are denominated in currencies other than U.S. dollars, the adjusted notional amount of the derivative contract is the largest leg of the derivative contract, as measured in U.S. dollars using the exchange rate on the date of the calculation.

(*2*) Notwithstanding paragraph (c)(9)(ii)(B)(*1*) of this section, for an exchange rate derivative contract with multiple exchanges of principal, the Enterprise must set the adjusted notional amount of the derivative contract equal to the notional amount of the derivative contract multiplied by the number of exchanges of principal under the derivative contract.

(C)(*1*) For an equity derivative contract or a commodity derivative contract, the adjusted notional amount is the product of the fair value of one unit of the reference instrument underlying the derivative contract and the number of such units referenced by the derivative contract.

(*2*) Notwithstanding paragraph (c)(9)(ii)(C)(*1*) of this section, when calculating the adjusted notional amount for an equity derivative contract or a commodity derivative contract that is a volatility derivative contract, the Enterprise must replace the unit price with the underlying volatility referenced by the volatility derivative contract and replace the number of units with the notional amount of the volatility derivative contract.

(iii) *Supervisory delta adjustments.* (A) For a derivative contract that is not an option contract or collateralized debt obligation tranche, the supervisory delta adjustment is 1 if the fair value of the derivative contract increases when the value of the primary risk factor increases and −1 if the fair value of the derivative contract decreases when the value of the primary risk factor increases.

(B)(*1*) For a derivative contract that is an option contract, the supervisory delta adjustment is determined by the following formulas, as applicable:

Table 1 to Paragraph (c)(9)(iii)(B)(*1*)—Supervisory Delta Adjustment for Options Contracts

	Bought	Sold
Call Options	$\Phi\left(\frac{ln\left(\frac{P+\lambda}{K+\lambda}\right)+0.5*\sigma^2*T/250}{\sigma*\sqrt{T/250}}\right)$	$-\Phi\left(\frac{ln\left(\frac{P+\lambda}{K+\lambda}\right)+0.5*\sigma^2*T/250}{\sigma*\sqrt{T/250}}\right)$
Put Options	$-\Phi\left(-\frac{ln\left(\frac{P+\lambda}{K+\lambda}\right)+0.5*\sigma^2*T/250}{\sigma*\sqrt{T/250}}\right)$	$\Phi\left(-\frac{ln\left(\frac{P+\lambda}{K+\lambda}\right)+0.5*\sigma^2*T/250}{\sigma*\sqrt{T/250}}\right)$

(*2*) As used in the formulas in table 1 to paragraph (c)(9)(iii)(B)(*1*):

(*i*) *E* is the standard normal cumulative distribution function;

(*ii*) P equals the current fair value of the instrument or risk factor, as applicable, underlying the option;

(*iii*) K equals the strike price of the option;

(*iv*) T equals the number of business days until the latest contractual exercise date of the option;

(*v*) λ equals zero for all derivative contracts except interest rate options for the currencies where interest rates have negative values. The same value of λ must be used for all interest rate options that are denominated in the same currency. To determine the value of λ for a given currency, an Enterprise must find the lowest value L of P and K of all interest rate options in a given currency that the Enterprise has with all counterparties. Then, λ is set according to this formula:

$\lambda = \max\{-L + 0.1\%, 0\}$; and

(*vi*) σ equals the supervisory option volatility, as provided in table 2 to paragraph (c)(11)(ii)(B)(*2*).

(C)(*1*) For a derivative contract that is a collateralized debt obligation tranche, the supervisory delta adjustment is determined by the following formula:

$$\text{Supervisory Delta Adjustment} = \frac{15}{(1 + 14 * A) * (1 + 14 * D)}$$

(*2*) As used in the formula in paragraph (c)(9)(iii)(C)(1) of this section:

(*i*) A is the attachment point, which equals the ratio of the notional amounts of all underlying exposures that are subordinated to the Enterprise's exposure to the total notional amount of all underlying exposures, expressed as a decimal value between zero and one; [1]

(*ii*) D is the detachment point, which equals one minus the ratio of the notional amounts of all underlying exposures that are senior to the Enterprise's exposure to the total notional amount of all underlying exposures, expressed as a decimal value between zero and one; and

(*iii*) The resulting amount is designated with a positive sign if the collateralized debt obligation tranche was purchased by the Enterprise and is designated with a negative sign if the collateralized debt obligation tranche was sold by the Enterprise.

(iv) *Maturity factor.* (A)(*1*) The maturity factor of a derivative contract that is subject to a variation margin agreement, excluding derivative contracts that are subject to a variation margin agreement under which the counterparty is not required to post variation margin, is determined by the following formula:

$$\text{Maturity factor} = \frac{3}{2}\sqrt{\frac{\text{MPOR}}{250}}$$

Where Margin Period of Risk (MPOR) refers to the period from the most recent exchange of collateral covering a netting set of derivative contracts with a defaulting counterparty until the derivative contracts are closed out and the resulting market risk is re-hedged.

(*2*) Notwithstanding paragraph (c)(9)(iv)(A)(*1*) of this section:

(*i*) For a derivative contract that is not a client-facing derivative transaction, MPOR cannot be less than ten business days plus the periodicity of re-margining expressed in business days minus one business day;

(*ii*) For a derivative contract that is a client-facing derivative transaction, cannot be less than five business days plus the periodicity of re-margining expressed in business days minus one business day; and

(*iii*) For a derivative contract that is within a netting set that is composed of more than 5,000 derivative contracts that are not cleared transactions, or a netting set that contains one or more trades involving illiquid collateral or a derivative contract that cannot be easily replaced, MPOR cannot be less than twenty business days.

(*3*) Notwithstanding paragraphs (c)(9)(iv)(A)(*1*) and (*2*) of this section, for a netting set subject to more than two outstanding disputes over margin that lasted longer than the MPOR over the previous two quarters, the applicable floor is twice the amount provided in paragraphs (c)(9)(iv)(A)(*1*) and (*2*) of this section.

(B) The maturity factor of a derivative contract that is not subject to a variation margin agreement, or derivative contracts under which the counterparty is not required to post variation margin, is determined by the following formula:

$$\text{Maturity factor} = \sqrt{\frac{\min(M; 250)}{250}}$$

Where M equals the greater of 10 business days and the remaining maturity of the contract, as measured in business days.

(C) For purposes of paragraph (c)(9)(iv) of this section, if an Enterprise has elected pursuant to paragraph (c)(5)(v) of this section to treat a derivative contract that is a cleared transaction that is not subject to a variation margin agreement as one that is subject to a variation margin agreement, the Enterprise must treat the derivative contract as subject to a variation margin agreement with maturity factor as determined according to (c)(9)(iv)(A) of this section, and daily settlement does not change the end date of the period referenced by the derivative contract.

(v) *Derivative contract as multiple effective derivative contracts.* An Enterprise must separate a derivative contract into separate derivative contracts, according to the following rules:

(A) For an option where the counterparty pays a predetermined amount if the value of the underlying asset is above or below the strike price and nothing otherwise (binary option), the option must be treated as two separate options. For purposes of paragraph (c)(9)(iii)(B) of this section, a binary option with strike K must be represented as the combination of one bought European option and one sold European option of the same type as the original option (put or call) with the strikes set equal to 0.95 * K and 1.05 * K so that the payoff of the binary option is reproduced exactly outside the region between the two strikes. The absolute value of the sum of the adjusted derivative contract amounts of the bought and sold options is capped at the payoff amount of the binary option.

(B) For a derivative contract that can be represented as a combination of standard option payoffs (such as collar, butterfly spread, calendar spread, straddle, and strangle), an Enterprise must treat each standard option component as a separate derivative contract.

(C) For a derivative contract that includes multiple-payment options, (such as interest rate caps and floors), an Enterprise may represent each payment option as a combination of effective single-payment options (such as interest rate caplets and floorlets).

(D) An Enterprise may not decompose linear derivative contracts (such as swaps) into components.

(10) *Multiple netting sets subject to a single variation margin agreement*—(i) *Calculating replacement cost.* Notwithstanding paragraph (c)(6) of this section, an Enterprise shall assign a single replacement cost to multiple netting sets that are subject to a single variation margin agreement under which the counterparty must post variation margin, calculated according to the following formula:

$$\textit{Replacement Cost} = max\{\Sigma_{NS} max\{V_{NS}; 0\} - max\{C_{MA}; 0\}; 0\} + max\{\Sigma_{NS} min\{V_{NS}; 0\} - min\{C_{MA}; 0\}; 0\}$$

Where:

(A) NS is each netting set subject to the variation margin agreement MA;

V_{NS} is the sum of the fair values (after excluding any valuation adjustments) of the derivative contracts within the netting set NS; and

(B) C_{MA} is the sum of the net independent collateral amount and the variation margin amount applicable to the

[1] In the case of a first-to-default credit derivative, there are no underlying exposures that are subordinated to the Enterprise's exposure. In the case of a second-or-subsequent-to-default credit derivative, the smallest (n − 1) notional amounts of the underlying exposures are subordinated to the Enterprise's exposure.

derivative contracts within the netting sets subject to the single variation margin agreement.

(ii) *Calculating potential future exposure.* Notwithstanding paragraph (c)(5) of this section, an Enterprise shall assign a single potential future exposure to multiple netting sets that are subject to a single variation margin agreement under which the counterparty must post variation margin equal to the sum of the potential future exposure of each such netting set, each calculated according to paragraph (c)(7) of this section as if such nettings sets were not subject to a variation margin agreement.

(11) *Netting set subject to multiple variation margin agreements or a hybrid netting set*—(i) *Calculating replacement cost.* To calculate replacement cost for either a netting set subject to multiple variation margin agreements under which the counterparty to each variation margin agreement must post variation margin, or a netting set composed of at least one derivative contract subject to variation margin agreement under which the counterparty must post variation margin and at least one derivative contract that is not subject to such a variation margin agreement, the calculation for replacement cost is provided under paragraph (c)(6)(i) of this section, except that the variation margin threshold equals the sum of the variation margin thresholds of all variation margin agreements within the netting set and the minimum transfer amount equals the sum of the minimum transfer amounts of all the variation margin agreements within the netting set.

(ii) *Calculating potential future exposure.* (A) To calculate potential future exposure for a netting set subject to multiple variation margin agreements under which the counterparty to each variation margin agreement must post variation margin, or a netting set composed of at least one derivative contract subject to variation margin agreement under which the counterparty to the derivative contract must post variation margin and at least one derivative contract that is not subject to such a variation margin agreement, an Enterprise must divide the netting set into sub-netting sets (as described in paragraph (c)(11)(ii)(B) of this section) and calculate the aggregated amount for each sub-netting set. The aggregated amount for the netting set is calculated as the sum of the aggregated amounts for the sub-netting sets. The multiplier is calculated for the entire netting set.

(B) For purposes of paragraph (c)(11)(ii)(A) of this section, the netting set must be divided into sub-netting sets as follows:

(*1*) All derivative contracts within the netting set that are not subject to a variation margin agreement or that are subject to a variation margin agreement under which the counterparty is not required to post variation margin form a single sub-netting set. The aggregated amount for this sub-netting set is calculated as if the netting set is not subject to a variation margin agreement.

(*2*) All derivative contracts within the netting set that are subject to variation margin agreements in which the counterparty must post variation margin and that share the same value of the MPOR form a single sub-netting set. The aggregated amount for this sub-netting set is calculated as if the netting set is subject to a variation margin agreement, using the MPOR value shared by the derivative contracts within the netting set.

TABLE 2 TO PARAGRAPH (c)(11)(ii)(B)(*2*)—SUPERVISORY OPTION VOLATILITY, SUPERVISORY CORRELATION PARAMETERS, AND SUPERVISORY FACTORS FOR DERIVATIVE CONTRACTS

Asset class	Category	Type	Supervisory option volatility (percent)	Supervisory correlation factor (percent)	Supervisory factor [1] (percent)
Interest rate	N/A	N/A	50	N/A	0.50
Exchange rate	N/A	N/A	15	N/A	4.0
Credit, single name	Investment grade	N/A	100	50	0.46
	Speculative grade	N/A	100	50	1.3
	Sub-speculative grade	N/A	100	50	6.0
Credit, index	Investment Grade	N/A	80	80	0.38
	Speculative Grade	N/A	80	80	1.06
Equity, single name	N/A	N/A	120	50	32
Equity, index	N/A	N/A	75	80	20
Commodity	Energy	Electricity	150	40	40
		Other	70	40	18
	Metals	N/A	70	40	18
	Agricultural	N/A	70	40	18
	Other	N/A	70	40	18

[1] The applicable supervisory factor for basis derivative contract hedging sets is equal to one-half of the supervisory factor provided in this table 2, and the applicable supervisory factor for volatility derivative contract hedging sets is equal to 5 times the supervisory factor provided in this table 2.

(d) *Credit valuation adjustment (CVA) risk-weighted assets*—(1) *In general.* With respect to its OTC derivative contracts, an Enterprise must calculate a CVA risk-weighted asset amount for its portfolio of OTC derivative transactions that are subject to the CVA capital requirement using the simple CVA approach described in paragraph (d)(5) of this section.

(2) [Reserved]

(3) *Recognition of hedges.* (i) An Enterprise may recognize a single name CDS, single name contingent CDS, any other equivalent hedging instrument that references the counterparty directly, and index credit default swaps (CDS_{ind}) as a CVA hedge under paragraph (d)(5)(ii) of this section or paragraph (d)(6) of this section, provided that the position is managed as a CVA hedge in accordance with the Enterprise's hedging policies.

(ii) An Enterprise shall not recognize as a CVA hedge any tranched or n^{th}-to-default credit derivative.

(4) *Total CVA risk-weighted assets.* Total CVA risk-weighted assets is the CVA capital requirement, K_{CVA}, calculated for an Enterprise's entire portfolio of OTC derivative counterparties that are subject to the CVA capital requirement, multiplied by 12.5.

(5) *Simple CVA approach.* (i) Under the simple CVA approach, the CVA capital requirement, K_{CVA}, is calculated according to the following formula:

$$K_{CVA} = 2.33 \times \sqrt{\left(\sum_i 0.5 \times w_i \times \left(M_i \times EAD_i^{total} - M_i^{hedge} \times B_i\right) - \sum_{ind} w_{ind} \times M_{ind} \times B_{ind}\right)^2 + A}$$

Where:

$A = \Sigma_i\ 0.75 \times w_i^2 \times (M_i \times EAD_i^{total} - M_i^{hedge} \times B_i)^2$

(A) w_i = the weight applicable to counterparty i under table 3 to paragraph (d)(5)(ii);

(B) M_i = the EAD-weighted average of the effective maturity of each netting set with counterparty i (where each netting set's effective maturity can be no less than one year.)

(C) EAD_i^{total} = the sum of the EAD for all netting sets of OTC derivative contracts with counterparty i calculated using the standardized approach to counterparty credit risk described in paragraph (c) of this section. When the Enterprise calculates EAD under paragraph (c) of this section, such EAD may be adjusted for purposes of calculating EAD_i^{total} by multiplying EAD by $(1\text{-}\exp(-0.05 \times M_i))/(0.05 \times M_i)$, where ''exp'' is the exponential function.

(D) M_i^{hedge} = the notional weighted average maturity of the hedge instrument.

(E) B_i = the sum of the notional amounts of any purchased single name CDS referencing counterparty i that is used to hedge CVA risk to counterparty i multiplied by $(1\text{-}\exp(-0.05 \times M_i^{hedge}))/(0.05 \times M_i^{hedge})$.

(F) M_{ind} = the maturity of the CDS_{ind} or the notional weighted average maturity of any CDS_{ind} purchased to hedge CVA risk of counterparty i.

(G) B_{ind} = the notional amount of one or more CDS_{ind} purchased to hedge CVA risk for counterparty i multiplied by $(1\text{-}\exp(-0.05 \times M_{ind}))/(0.05 \times M_{ind})$

(H) w_{ind} = the weight applicable to the CDS_{ind} based on the average weight of the underlying reference names that comprise the index under table 3 to paragraph (d)(5)(ii).

(ii) The Enterprise may treat the notional amount of the index attributable to a counterparty as a single name hedge of counterparty i (B_i,) when calculating K_{CVA}, and subtract the notional amount of B_i from the notional amount of the CDS_{ind}. An Enterprise must treat the CDS_{ind} hedge with the notional amount reduced by B_i as a CVA hedge.

TABLE 3 TO PARAGRAPH (d)(5)(ii)—ASSIGNMENT OF COUNTERPARTY WEIGHT

Internal PD (in percent)	Weight *wi* (in percent)
0.00–0.07	0.70
>0.070–0.15	0.80
>0.15–0.40	1.00
>0.40–2.00	2.00
>2.00–6.00	3.00
>6.00	10.00

■ 10. Effective January 1, 2026, revise § 1240.37 to read as follows:

§ 1240.37 Cleared transactions.

(a) *General requirements*—(1) *Clearing member clients.* An Enterprise that is a clearing member client must use the methodologies described in paragraph (b) of this section to calculate risk-weighted assets for a cleared transaction.

(2) *Clearing members.* An Enterprise that is a clearing member must use the methodologies described in paragraph (c) of this section to calculate its risk-weighted assets for a cleared transaction and paragraph (b) of this section to calculate its risk-weighted assets for its default fund contribution to a CCP.

(b) *Clearing member client Enterprises*—(1) *Risk-weighted assets for cleared transactions.* (i) To determine the risk-weighted asset amount for a cleared transaction, an Enterprise that is a clearing member client must multiply the trade exposure amount for the cleared transaction, calculated in accordance with paragraph (b)(2) of this section, by the risk weight appropriate for the cleared transaction, determined in accordance with paragraph (b)(3) of this section.

(ii) A clearing member client Enterprise's total risk-weighted assets for cleared transactions is the sum of the risk-weighted asset amounts for all of its cleared transactions.

(2) *Trade exposure amount.* (i) For a cleared transaction that is a derivative contract or a netting set of derivative contracts, trade exposure amount equals the EAD for the derivative contract or netting set of derivative contracts calculated using the methodology used to calculate EAD for derivative contracts set forth in § 1240.36(c), plus the fair value of the collateral posted by the clearing member client Enterprise and held by the CCP or a clearing member in a manner that is not bankruptcy remote.

(ii) For a cleared transaction that is a repo-style transaction or netting set of repo-style transactions, trade exposure amount equals the EAD for the repo-style transaction calculated using the methodology set forth in § 1240.39(b)(2) or (3), plus the fair value of the collateral posted by the clearing member client Enterprise and held by the CCP or a clearing member in a manner that is not bankruptcy remote.

(3) *Cleared transaction risk weights.* (i) For a cleared transaction with a QCCP, a clearing member client Enterprise must apply a risk weight of:

(A) 2 percent if the collateral posted by the Enterprise to the QCCP or clearing member is subject to an arrangement that prevents any loss to the clearing member client Enterprise due to the joint default or a concurrent insolvency, liquidation, or receivership proceeding of the clearing member and any other clearing member clients of the clearing member; and the clearing member client Enterprise has conducted sufficient legal review to conclude with a well-founded basis (and maintains sufficient written documentation of that legal review) that in the event of a legal challenge (including one resulting from an event of default or from liquidation, insolvency, or receivership proceedings) the relevant court and administrative authorities would find the arrangements to be legal, valid, binding, and enforceable under the law of the relevant jurisdictions.

(B) 4 percent, if the requirements of paragraph (b)(3)(i)(A) of this section are not met.

(ii) For a cleared transaction with a CCP that is not a QCCP, a clearing member client Enterprise must apply the risk weight applicable to the CCP under this subpart D.

(4) *Collateral.* (i) Notwithstanding any other requirement of this section, collateral posted by a clearing member client Enterprise that is held by a custodian (in its capacity as a custodian) in a manner that is bankruptcy remote

from the CCP, clearing member, and other clearing member clients of the clearing member, is not subject to a capital requirement under this section.

(ii) A clearing member client Enterprise must calculate a risk-weighted asset amount for any collateral provided to a CCP, clearing member or a custodian in connection with a cleared transaction in accordance with requirements under this subpart D, as applicable.

(c) *Clearing member Enterprise*—(1) *Risk-weighted assets for cleared transactions.* (i) To determine the risk-weighted asset amount for a cleared transaction, a clearing member Enterprise must multiply the trade exposure amount for the cleared transaction, calculated in accordance with paragraph (c)(2) of this section by the risk weight appropriate for the cleared transaction, determined in accordance with paragraph (c)(3) of this section.

(ii) A clearing member Enterprise's total risk-weighted assets for cleared transactions is the sum of the risk-weighted asset amounts for all of its cleared transactions.

(2) *Trade exposure amount.* A clearing member Enterprise must calculate its trade exposure amount for a cleared transaction as follows:

(i) For a cleared transaction that is a derivative contract or a netting set of derivative contracts, trade exposure amount equals the EAD calculated using the methodology used to calculate EAD for derivative contracts set forth in § 1240.36(c), plus the fair value of the collateral posted by the clearing member Enterprise and held by the CCP in a manner that is not bankruptcy remote.

(ii) For a cleared transaction that is a repo-style transaction or netting set of repo-style transactions, trade exposure amount equals the EAD calculated under § 1240.39(b)(2) or (3), plus the fair value of the collateral posted by the clearing member Enterprise and held by the CCP in a manner that is not bankruptcy remote.

(3) *Cleared transaction risk weights.* (i) A clearing member Enterprise must apply a risk weight of 2 percent to the trade exposure amount for a cleared transaction with a QCCP.

(ii) For a cleared transaction with a CCP that is not a QCCP, a clearing member Enterprise must apply the risk weight applicable to the CCP according to this subpart D.

(iii) Notwithstanding paragraphs (c)(3)(i) and (ii) of this section, a clearing member Enterprise may apply a risk weight of zero percent to the trade exposure amount for a cleared transaction with a QCCP where the clearing member Enterprise is acting as a financial intermediary on behalf of a clearing member client, the transaction offsets another transaction that satisfies the requirements set forth in § 1240.3(a), and the clearing member Enterprise is not obligated to reimburse the clearing member client in the event of the QCCP default.

(4) *Collateral.* (i) Notwithstanding any other requirement of this section, collateral posted by a clearing member Enterprise that is held by a custodian (in its capacity as a custodian) in a manner that is bankruptcy remote from the CCP, clearing member, and other clearing member clients of the clearing member, is not subject to a capital requirement under this section.

(ii) A clearing member Enterprise must calculate a risk-weighted asset amount for any collateral provided to a CCP, clearing member or a custodian in connection with a cleared transaction in accordance with requirements under this subpart D.

(d) *Default fund contributions*—(1) *General requirement.* A clearing member Enterprise must determine the risk-weighted asset amount for a default fund contribution to a CCP at least quarterly, or more frequently if, in the opinion of the Enterprise or FHFA, there is a material change in the financial condition of the CCP.

(2) *Risk-weighted asset amount for default fund contributions to nonqualifying CCPs.* A clearing member Enterprise's risk-weighted asset amount for default fund contributions to CCPs that are not QCCPs equals the sum of such default fund contributions multiplied by 1,250 percent, or an amount determined by FHFA, based on factors such as size, structure, and membership characteristics of the CCP and riskiness of its transactions, in cases where such default fund contributions may be unlimited.

(3) *Risk-weighted asset amount for default fund contributions to QCCPs.* A clearing member Enterprise's risk-weighted asset amount for default fund contributions to QCCPs equals the sum of its capital requirement, K_{CM} for each QCCP, as calculated under the methodology set forth in paragraph (d)(4) of this section, multiplied by 12.5.

(4) *Capital requirement for default fund contributions to a QCCP.* A clearing member Enterprise's capital requirement for its default fund contribution to a QCCP (K_{CM}) is equal to:

$$K_{CM} = \max\left\{K_{CCP} * \left(\frac{DF^{pref}}{DF_{CCP} + DF^{pref}_{CCPCM}}\right); 0.16\ percent * DF^{pref}\right\}$$

Where:

(i) K_{CCP} is the hypothetical capital requirement of the QCCP, as determined under paragraph (d)(5) of this section;

(ii) DF^{pref} is prefunded default fund contribution of the clearing member Enterprise to the QCCP;

(iii) DF_{CCP} is the QCCP's own prefunded amount that are contributed to the default waterfall and are junior or *pari passu* with prefunded default fund contributions of clearing members of the QCCP; and

(iv) $DF_{CCPCM}{}^{pref}$ is the total prefunded default fund contributions from clearing members of the QCCP to the QCCP.

(5) *Hypothetical capital requirement of a QCCP.* Where a QCCP has provided its K_{CCP}, an Enterprise must rely on such disclosed figure instead of calculating K_{CCP} under this paragraph (d)(5), unless the Enterprise determines that a more conservative figure is appropriate based on the nature, structure, or characteristics of the QCCP. The hypothetical capital requirement of a QCCP (K_{CCP}), as determined by the Enterprise, is equal to:

$$K_{CCP} = \sum_{CM_i} EAD_i * 1.6\ percent$$

Where:

(i) CM_i is each clearing member of the QCCP; and

(ii) EAD_i is the exposure amount of the QCCP to each clearing member of the QCCP, as determined under paragraph (d)(6) of this section.

(6) *EAD of a QCCP to a clearing member.* (i) The EAD of a QCCP to a clearing member is equal to the sum of the EAD for derivative contracts determined under paragraph (d)(6)(ii) of this section and the EAD for repo-style transactions determined under paragraph (d)(6)(iii) of this section.

(ii) With respect to any derivative contracts between the QCCP and the clearing member that are cleared transactions and any guarantees that the clearing member has provided to the QCCP with respect to performance of a clearing member client on a derivative contract, the EAD is equal to the exposure amount of the QCCP to the clearing member for all such derivative contracts and guarantees of derivative contracts calculated under SA–CCR in § 1240.36(c) (or, with respect to a QCCP located outside the United States, under a substantially identical methodology in effect in the jurisdiction) using a value of 10 business days for purposes of § 1240.36(c)(9)(iv); less the value of all collateral held by the QCCP posted by the clearing member or a client of the clearing member in connection with a derivative contract for which the clearing member has provided a guarantee to the QCCP and the amount of the prefunded default fund contribution of the clearing member to the QCCP.

(iii) With respect to any repo-style transactions between the QCCP and a clearing member that are cleared transactions, EAD is equal to:

$$EAD_i = \max\{EBRM_i - IM_i - DF_i; 0\}$$

Where:

(A) $EBRM_i$ is the exposure amount of the QCCP to each clearing member for all repo-style transactions between the QCCP and the clearing member, as determined under § 1240.39(b)(2) and without recognition of the initial margin collateral posted by the clearing member to the QCCP with respect to the repo-style transactions or the prefunded default fund contribution of the clearing member institution to the QCCP;

(B) IM_i is the initial margin collateral posted by each clearing member to the QCCP with respect to the repo-style transactions; and

(C) DF_i is the prefunded default fund contribution of each clearing member to the

(D) QCCP that is not already deducted in paragraph (d)(6)(ii) of this section.

(iv) EAD must be calculated separately for each clearing member's sub-client accounts and sub-house account (*i.e.,* for the clearing member's proprietary activities). If the clearing member's collateral and its client's collateral are held in the same default fund contribution account, then the EAD of that account is the sum of the EAD for the client-related transactions within the account and the EAD of the house-related transactions within the account. For purposes of determining such EADs, the independent collateral of the clearing member and its client must be allocated in proportion to the respective total amount of independent collateral posted by the clearing member to the QCCP.

(v) If any account or sub-account contains both derivative contracts and repo-style transactions, the EAD of that account is the sum of the EAD for the derivative contracts within the account and the EAD of the repo-style transactions within the account. If independent collateral is held for an account containing both derivative contracts and repo-style transactions, then such collateral must be allocated to the derivative contracts and repo-style transactions in proportion to the respective product specific exposure amounts, calculated, excluding the effects of collateral, according to § 1240.39(b) for repo-style transactions and to § 1240.36(c)(5) for derivative contracts.

■ 11. Effective January 1, 2026, revise § 1240.39 to read as follows:

§ 1240.39 Collateralized transactions.

(a) *General.* (1) An Enterprise may use the following methodologies to recognize the benefits of financial collateral (other than with respect to a retained CRT exposure) in mitigating the counterparty credit risk of repo-style transactions, eligible margin loans, collateralized OTC derivative contracts and single product netting sets of such transactions:

(i) The collateral haircut approach set forth in paragraph (b)(2) of this section; and

(ii) For single product netting sets of repo-style transactions and eligible margin loans, the simple VaR methodology set forth in paragraph (b)(3) of this section.

(2) An Enterprise may use any combination of the two methodologies for collateral recognition; however, it must use the same methodology for similar exposures or transactions.

(b) *EAD for eligible margin loans and repo-style transactions*—(1) *General.* An Enterprise may recognize the credit risk mitigation benefits of financial collateral that secures an eligible margin loan, repo-style transaction, or single-product netting set of such transactions by determining the EAD of the exposure using:

(i) The collateral haircut approach described in paragraph (b)(2) of this section; or

(ii) For netting sets only, the simple VaR methodology described in paragraph (b)(3) of this section.

(2) *Collateral haircut approach*—(i) *EAD equation.* An Enterprise may determine EAD for an eligible margin loan, repo-style transaction, or netting set by setting EAD equal to

$$\max\{0, [(\Sigma E - \Sigma C) + \Sigma(E_s \times H_s) + \Sigma(E_{fx} \times H_{fx})]\},$$

Where:

(A) ΣE equals the value of the exposure (the sum of the current fair values of all instruments, gold, and cash the Enterprise has lent, sold subject to repurchase, or posted as collateral to the counterparty under the transaction (or netting set));

(B) ΣC equals the value of the collateral (the sum of the current fair values of all instruments, gold, and cash the Enterprise has borrowed, purchased subject to resale, or taken as collateral from the counterparty under the transaction (or netting set));

(C) E_s equals the absolute value of the net position in a given instrument or in gold (where the net position in a given instrument or in gold equals the sum of the current fair values of the instrument or gold the Enterprise has lent, sold subject to repurchase, or posted as collateral to the counterparty minus the sum of the current fair values of that same instrument or gold the Enterprise has borrowed, purchased subject to resale, or taken as collateral from the counterparty);

(D) H_s equals the market price volatility haircut appropriate to the instrument or gold referenced in E_s;

(E) E_{fx} equals the absolute value of the net position of instruments and cash in a currency that is different from the settlement currency (where the net position in a given currency equals the sum of the current fair values of any instruments or cash in the currency the Enterprise has lent, sold subject to repurchase, or posted as collateral to the counterparty minus the sum of the current fair values of any instruments or cash in the currency the Enterprise has borrowed, purchased subject to resale, or taken as collateral from the counterparty); and

(F) H_{fx} equals the haircut appropriate to the mismatch between the currency referenced in Efx and the settlement currency.

(ii) *Standard supervisory haircuts.* Under the standard supervisory haircuts approach:

(A) An Enterprise must use the haircuts for market price volatility (H_s) in table 1 to paragraph (b)(2)(ii)(A) as adjusted in certain circumstances as provided in paragraphs (b)(2)(ii)(C) and (D) of this section;

TABLE 1 TO PARAGRAPH (b)(2)(ii)(A)—STANDARD SUPERVISORY MARKET PRICE VOLATILITY HAIRCUTS [1]

Residual maturity	Haircut (in percent) assigned based on:						Investment grade securitization exposures (in percent)
	Sovereign issuers risk weight under § 1240.32 [2] (in percent)			Non-sovereign issuers risk weight under § 1240.32 (in percent)			
	Zero	20 or 50	100	20	50	100	
Less than or equal to 1 year	0.5	1.0	15.0	1.0	2.0	4.0	4.0
Greater than 1 year and less than or equal to 5 years	2.0	3.0	15.0	4.0	6.0	8.0	12.0
Greater than 5 years	4.0	6.0	15.0	8.0	12.0	16.0	24.0
Main index equities (including convertible bonds) and gold	15.0						
Other publicly traded equities (including convertible bonds)	25.0						
Mutual funds	Highest haircut applicable to any security in which the fund can invest.						
Cash collateral held	Zero.						
Other exposure types	25.0						

[1] The market price volatility haircuts in table 1 are based on a 10 business-day holding period.
[2] Includes a foreign PSE that receives a zero percent risk weight.

(B) For currency mismatches, an Enterprise must use a haircut for foreign exchange rate volatility (H_{fx}) of 8 percent, as adjusted in certain circumstances as provided in paragraphs (b)(2)(ii)(C) and (D) of this section.

(C) For repo-style transactions and client-facing derivative transactions, an Enterprise may multiply the supervisory haircuts provided in paragraphs (b)(2)(ii)(A) and (B) of this section by the square root of ½ (which equals 0.707107). If the Enterprise determines that a longer holding period is appropriate for client-facing derivative transactions, then it must use a larger scaling factor to adjust for the longer holding period pursuant to paragraph (b)(2)(ii)(F) of this section.

(D) An Enterprise must adjust the supervisory haircuts upward on the basis of a holding period longer than ten business days (for eligible margin loans) or five business days (for repo-style transactions), using the formula provided in paragraph (b)(2)(ii)(F) of this section where the conditions in this paragraph (b)(2)(ii)(D) apply. If the number of trades in a netting set exceeds 5,000 at any time during a quarter, an Enterprise must adjust the supervisory haircuts upward on the basis of a minimum holding period of twenty business days for the following quarter (except when an Enterprise is calculating EAD for a cleared transaction under § 1240.37). If a netting set contains one or more trades involving illiquid collateral, an Enterprise must adjust the supervisory haircuts upward on the basis of a minimum holding period of twenty business days. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted longer than the holding period, then the Enterprise must adjust the supervisory haircuts upward for that netting set on the basis of a minimum holding period that is at least two times the minimum holding period for that netting set.

(E)(*1*) An Enterprise must adjust the supervisory haircuts upward on the basis of a holding period longer than ten business days for collateral associated with derivative contracts (five business days for client-facing derivative contracts) using the formula provided in paragraph (b)(2)(ii)(F) of this section where the conditions in this paragraph (b)(2)(ii)(E)(*1*) apply. For collateral associated with a derivative contract that is within a netting set that is composed of more than 5,000 derivative contracts that are not cleared transactions, an Enterprise must use a minimum holding period of twenty business days. If a netting set contains one or more trades involving illiquid collateral or a derivative contract that cannot be easily replaced, an Enterprise must use a minimum holding period of twenty business days.

(*2*) Notwithstanding paragraph (b)(2)(ii)(A) or (C) or (b)(2)(ii)(E)(*1*) of this section, for collateral associated with a derivative contract in a netting set under which more than two margin disputes that lasted longer than the holding period occurred during the two previous quarters, the minimum holding period is twice the amount provided under paragraph (b)(2)(ii)(A) or (C) or (b)(2)(ii)(E)(*1*).

(F) An Enterprise must adjust the standard supervisory haircuts upward, pursuant to the adjustments provided in paragraphs (b)(2)(ii)(C) through (E) of this section, using the following formula:

$$H_A = H_S \sqrt{\frac{T_M}{T_S}}$$

Where:

(*1*) T_M equals a holding period of longer than 10 business days for eligible margin loans and derivative contracts other than client-facing derivative transactions or longer than 5 business days for repo-style transactions and client-facing derivative transactions; H_s equals the standard supervisory haircut; and

(*2*) T_s equals 10 business days for eligible margin loans and derivative contracts other than client-facing derivative transactions or 5 business days for repo-style transactions and client-facing derivative transactions.

(G) If the instrument an Enterprise has lent, sold subject to repurchase, or posted as collateral does not meet the definition of financial collateral, the Enterprise must use a 25.0 percent haircut for market price volatility (H_s).

(iii) *Own internal estimates for haircuts.* With the prior written notice to FHFA, an Enterprise may calculate haircuts (H_s and H_{fx}) using its own internal estimates of the volatilities of market prices and foreign exchange rates.

(A) To use its own internal estimates, an Enterprise must satisfy the following minimum quantitative standards:

(*1*) An Enterprise must use a 99th percentile one-tailed confidence interval.

(*2*) The minimum holding period for a repo-style transaction is five business days and for an eligible margin loan is ten business days except for transactions or netting sets for which paragraph (b)(2)(iii)(A)(*3*) of this section applies. When an Enterprise calculates an own-estimates haircut on a T_N-day holding period, which is different from

the minimum holding period for the transaction type, the applicable haircut (H_M) is calculated using the following square root of time formula:

$$H_M = H_N \sqrt{\frac{T_M}{T_N}}$$

Where:

(*i*) T_M equals 5 for repo-style transactions and 10 for eligible margin loans;

(*ii*) T_N equals the holding period used by the Enterprise to derive H_N; and

(*iii*) H_N equals the haircut based on the holding period T_N

(*3*) If the number of trades in a netting set exceeds 5,000 at any time during a quarter, an Enterprise must calculate the haircut using a minimum holding period of twenty business days for the following quarter (except when an Enterprise is calculating EAD for a cleared transaction under § 1240.37). If a netting set contains one or more trades involving illiquid collateral or an OTC derivative that cannot be easily replaced, an Enterprise must calculate the haircut using a minimum holding period of twenty business days. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted more than the holding period, then the Enterprise must calculate the haircut for transactions in that netting set on the basis of a holding period that is at least two times the minimum holding period for that netting set.

(*4*) An Enterprise is required to calculate its own internal estimates with inputs calibrated to historical data from a continuous 12-month period that reflects a period of significant financial stress appropriate to the security or category of securities.

(*5*) An Enterprise must have policies and procedures that describe how it determines the period of significant financial stress used to calculate the Enterprise's own internal estimates for haircuts under this section and must be able to provide empirical support for the period used. The Enterprise must obtain the prior approval of FHFA for, and notify FHFA if the Enterprise makes any material changes to, these policies and procedures.

(*6*) Nothing in this section prevents FHFA from requiring an Enterprise to use a different period of significant financial stress in the calculation of own internal estimates for haircuts.

(*7*) An Enterprise must update its data sets and calculate haircuts no less frequently than quarterly and must also reassess data sets and haircuts whenever market prices change materially.

(B) With respect to debt securities that are investment grade, an Enterprise may calculate haircuts for categories of securities. For a category of securities, the Enterprise must calculate the haircut on the basis of internal volatility estimates for securities in that category that are representative of the securities in that category that the Enterprise has lent, sold subject to repurchase, posted as collateral, borrowed, purchased subject to resale, or taken as collateral. In determining relevant categories, the Enterprise must at a minimum take into account:

(*1*) The type of issuer of the security;

(*2*) The credit quality of the security;

(*3*) The maturity of the security; and

(*4*) The interest rate sensitivity of the security.

(C) With respect to debt securities that are not investment grade and equity securities, an Enterprise must calculate a separate haircut for each individual security.

(D) Where an exposure or collateral (whether in the form of cash or securities) is denominated in a currency that differs from the settlement currency, the Enterprise must calculate a separate currency mismatch haircut for its net position in each mismatched currency based on estimated volatilities of foreign exchange rates between the mismatched currency and the settlement currency.

(E) An Enterprise's own estimates of market price and foreign exchange rate volatilities may not take into account the correlations among securities and foreign exchange rates on either the exposure or collateral side of a transaction (or netting set) or the correlations among securities and foreign exchange rates between the exposure and collateral sides of the transaction (or netting set).

(3) *Simple VaR methodology.* With the prior written notice to FHFA, an Enterprise may estimate EAD for a netting set using a VaR model that meets the requirements in paragraph (b)(3)(iii) of this section. In such event, the Enterprise must set EAD equal to max $\{0, [(\Sigma E - \Sigma C) + PFE]\}$, where:

(i) ΣE equals the value of the exposure (the sum of the current fair values of all instruments, gold, and cash the Enterprise has lent, sold subject to repurchase, or posted as collateral to the counterparty under the netting set);

(ii) ΣC equals the value of the collateral (the sum of the current fair values of all instruments, gold, and cash the Enterprise has borrowed, purchased subject to resale, or taken as collateral from the counterparty under the netting set); and

(iii) PFE (potential future exposure) equals the Enterprise's empirically based best estimate of the 99th percentile, one-tailed confidence interval for an increase in the value of $(\Sigma E - \Sigma C)$ over a five-business-day holding period for repo-style transactions, or over a ten-business-day holding period for eligible margin loans except for netting sets for which paragraph (b)(3)(iv) of this section applies using a minimum one-year historical observation period of price data representing the instruments that the Enterprise has lent, sold subject to repurchase, posted as collateral, borrowed, purchased subject to resale, or taken as collateral. The Enterprise must validate its VaR model by establishing and maintaining a rigorous and regular backtesting regime.

(iv) If the number of trades in a netting set exceeds 5,000 at any time during a quarter, an Enterprise must use a twenty-business-day holding period for the following quarter (except when an Enterprise is calculating EAD for a cleared transaction under § 1240.37). If a netting set contains one or more trades involving illiquid collateral, an Enterprise must use a twenty-business-day holding period. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted more than the holding period, then the Enterprise must set its PFE for that netting set equal to an estimate over a holding period that is at least two times the minimum holding period for that netting set.

■ 12. Effective April 1, 2024, amend § 1240.41 by revising paragraph (c)(5), redesignating paragraph (c)(6) as paragraph (c)(7), and adding new paragraph (c)(6).

The revision and addition read as follows:

§ 1240.41 Operational requirements for CRT and other securitization exposures.

* * * * *

(c) * * *

(5) Any clean-up calls relating to the credit risk transfer are eligible clean-up calls;

(6) Any time-based calls relating to the credit risk transfer are eligible time-based calls; and

* * * * *

■ 13. Effective April 1, 2024, amend § 1240.42 by revising paragraph (f) to read as follows.

§ 1240.42 Risk-weighted assets for CRT and other securitization exposures.

* * * * *

(f) *Interest-only mortgage-backed securities.* For non-credit-enhancing interest-only mortgage-backed securities

that are not subject to § 1240.32(c), the risk weight may not be less than 100 percent.

* * * * *

■ 14. Effective April 1, 2024, amend § 1240.400 by revising paragraph (c)(1) and removing paragraph (d).

The revision reads as follows:

§ 1240.400 Stability capital buffer.

* * * * *

(c) * * *

(1) *Increase in stability capital buffer.* An increase in the stability capital buffer of an Enterprise under this section will take effect (*i.e.,* be incorporated into the maximum payout ratio under table 1 to paragraph (b)(5) in § 1240.11) on January 1 of the year that is one full calendar year after the increased stability capital buffer was calculated, provided that where a stability capital buffer under paragraph (c)(2) of this section is calculated to be a decrease in the stability capital buffer from the previously calculated scheduled increase applicable on the same January 1, the decreased stability capital buffer under paragraph (c)(2) shall take effect.

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Sandra L. Thompson,

Director, Federal Housing Finance Agency.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1888; Project Identifier MCAI–2023–00298–E; Amendment 39–22615; AD 2023–23–13]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211–Trent 800 engines. This AD is prompted by reports of cracks on certain intermediate-pressure compressor (IPC) rotor shaft balance lands. This AD requires initial and repetitive on-wing or in-shop borescope inspections (BSIs) of certain IPC rotor shaft balance lands for cracks, dents, and nicks, and replacement of the IPC rotor shaft if necessary, and would prohibit the installation of a certain IPC rotor shaft on any engine, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference (IBR). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 4, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 4, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1888; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2023–1888.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all RRD Model RB211–Trent 800 engines. The NPRM published in the **Federal Register** on September 15, 2023 (88 FR 63539); corrected on September 27, 2023 (88 FR 66314). The NPRM was prompted by EASA AD 2023–0040, dated February 16, 2023 (EASA AD 2023–0040) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that cracking on the IPC rotor shaft balance land has been historically observed on RRD Model RB211–Trent 800 engines. To address this unsafe condition, the manufacturer developed a modification, which introduced a revised balancing method that removed the original balancing weights from the IPC rotor shaft, and published service information to provide instructions for in-service modification. In addition, the manufacturer published service information to provide instructions for in-shop eddy current (EC) inspection of the IPC rotor shaft balance land. Consequently, EASA issued EASA AD 2014–0152, dated June 20, 2014; corrected June 25, 2014; revised March 2, 2018 (EASA AD 2014–0152R1).

Since EASA issued EASA AD 2014–0152R1, the manufacturer determined that certain RB211–Trent 800 engines were not inspected during engine refurbishment. The manufacturer then identified the IPC rotor shaft balance lands that were not inspected and published service information that describes procedures to perform a BSI of the IPC rotor shaft balance land until the in-shop EC inspection is accomplished. To address this, EASA issued the MCAI.

In the NPRM, the FAA proposed to require initial and repetitive on-wing or in-shop BSIs of certain IPC rotor shaft balance lands for cracks, dents, and nicks, and replacement of the IPC rotor shaft if necessary, and proposed to prohibit the installation of a certain IPC rotor shaft on any engine. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1888.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from The Boeing Company (Boeing). Boeing supported the NPRM without change.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires

adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2023–0040, which specifies procedures for performing initial and repetitive on-wing or in-shop BSIs of the IPC rotor shaft balance land for cracks, dents, and nicks, and replacing the IPC rotor shaft if necessary. The MCAI also specifies prohibiting the installation of a certain IPC rotor shaft on any engine and that accomplishing an in-shop EC inspection of the IPC rotor shaft balance land or replacing the IPC rotor shaft constitutes as terminating action for the repetitive BSIs.

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

Costs of Compliance

The FAA estimates that this AD affects 194 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
BSI of IPC rotor shaft balance land	4.5 work-hours × $85 per hour = $382.50	$0	$382.50	$74,205

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace IPC rotor shaft	50 work-hours × $85 per hour = $4,250	$2,123,908	$2,128,158

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–23–13 Rolls-Royce Deutschland Ltd & Co KG: Amendment 39–22615; Docket No. FAA–2023–1888; Project Identifier MCAI–2023–00298–E.

(a) Effective Date

This airworthiness directive (AD) is effective January 4, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 engines.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of cracks on the intermediate-pressure compressor (IPC) rotor shaft balance land. The FAA is issuing this AD to detect cracks on the IPC rotor shaft balance land. The unsafe condition, if not addressed, could lead to IPC rotor shaft failure and consequent uncontained high-energy debris, resulting in damage to the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0040, dated February 16, 2023 (EASA AD 2023–0040).

(h) Exceptions to EASA AD 2023–0040

(1) Where EASA AD 2023–0040 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the Remarks paragraph of EASA AD 2023–0040.

(3) Where the service information referenced in EASA AD 2023–0040 specifies to use certain tooling, equivalent tooling may be used.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0040 specifies to notify the manufacturer or supply pictures to the manufacturer of any cracks, dents, or nicks, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

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

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0040, dated February 16, 2023.

(ii) [Reserved]

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

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on November 20, 2023.

Ross Landes,

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

[FR Doc. 2023–26302 Filed 11–29–23; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2228; Project Identifier AD–2023–01095–T; Amendment 39–22616; AD 2023–23–14]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 747 airplanes. This AD was prompted by reports of latent failures of the lightning protection features for the engine fuel feed system. This AD requires an inspection for damage and a measurement of the electrical bonding resistance of the out-tank fuel feed tube bonding jumper in the strut for each of the four engines, a measurement of the electrical bonding resistance of the forward side of the front spar bulkhead fitting adapter for each of the four engines, and applicable related investigative and corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 15, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 15, 2023.

The FAA must receive comments on this AD by January 16, 2024.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2023–2228; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Boeing material identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.
- You may view this referenced material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2023–2228.

FOR FURTHER INFORMATION CONTACT: Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *Samuel.j.dorsey@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2023–2228 and Project Identifier AD–2023–01095–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other

information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *Samuel.j.dorsey@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The electrical bonding of the engine fuel feed tube penetrating the fuel tanks of Boeing Model 747–8 series airplanes and other models is the primary design feature to prevent the development of an ignition source inside the fuel tank during a lightning strike to the engine nacelle. The fuel feed lightning protection features include the spar fitting that redirects the majority of current during a lightning event. A separate bonding jumper outside the fuel tank provides a second electrical path for current from lightning strikes. The encapsulation sealant over the fuel tank wall fitting inside the fuel tank provides additional protection.

However, Boeing has recently discovered that the bonding jumper outside the fuel tank is failing at an excessive rate in addition to the known degradation of the primary electrical bonding path through the spar fitting. Furthermore, Boeing has reported finding a complete crack around the circumference of the fuel feed fitting encapsulation inside a fuel tank of a Model 747–8 series airplane. This encapsulation is designed to isolate any sparks/arcing generated during a lightning strike because of failed electrical bonds from flammable fuel vapors in the tank. This is an urgent safety issue, as all fuel feed lightning protection features now have evidence of compromise. The FAA has determined that all Model 747 airplanes are affected by the unsafe condition.

A lightning strike to an engine nacelle combined with a latent failure of the lightning protection features for the engine fuel feed system, if not addressed, could result in the potential for ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following service information. These documents are distinct since they apply to different airplane models.

- For Model 747–8 and 747–8F series airplanes: Boeing Multi Operator Message MOM–MOM–23–0885–01B–R1, dated November 13, 2023.
- For Model 747–400, 747–400D, and 747–400F series airplanes: Boeing Multi Operator Message MOM–MOM–23–0899–01B–R1, dated November 13, 2023. (For the 747–400D, see the Differences Between this AD and the Service Information section below.)
- For Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes: Boeing Multi Operator Message MOM–MOM–23–0907–01B, dated November 13, 2023.

This service information specifies procedures for a detailed inspection for damage and a measurement of the electrical bonding resistance of the out-tank fuel feed tube bonding jumper in the strut for each of the four engines, and a measurement of the electrical bonding resistance of the forward side of the front spar bulkhead fitting adapter for each of the four engines. The detailed inspection for damage includes making sure the bonding jumper installation is secure.

This service information also specifies related investigative actions, which include, depending on the airplane configuration, a general visual inspection of the aft side of the front spar to identify the configuration of the fuel feed tube and bulkhead fitting adapter, a detailed inspection for damage and measurements of the electrical bonding resistance of the in-tank bonding jumper, a general visual inspection of the wet-side front spar bulkhead fitting adapter for missing and damaged sealant or for missing sealant and damage to the encapsulation seal, and a general visual inspection of the seal for the welded tube fitting configuration for missing and damaged sealant.

This service information also specifies corrective actions, which include, depending on the airplane configuration, adjusting the installation and reworking the bonding jumper bonding path, replacement of the bonding jumper; and re-installing the front spar bulkhead fitting and applying sealant.

This service information also specifies reporting findings of the inspections and measurements to Boeing.

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

AD Requirements

This AD requires an inspection for damage and a measurement of the electrical bonding resistance of the out-tank fuel feed tube bonding jumper in the strut for each of the four engines, a measurement of the electrical bonding resistance of the forward side of the front spar bulkhead fitting adapter for each of the four engines, applicable related investigative and corrective actions, and reporting inspection and measurement findings to Boeing.

Differences Between This AD and the Service Information

For Boeing Multi Operator Message MOM–MOM–23–0899–01B–R1, dated November 13, 2023, which applies to Model 747–400 and 747–400F series airplanes, the FAA has determined that Model 747–400D airplanes can also accomplish the required actions using that service information. Model 747–400D airplanes are similar in design to Model 747–400 and 747–400F series airplanes.

Interim Action

This AD is considered to be interim action. The inspection reports that are required by this AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the bonding degradation and failures, and eventually to develop final action to

address the unsafe condition. Once final action has been identified, the FAA might consider further rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because the lightning protection features for the engine fuel feed system could fail without being detected. This could result in no lightning protection features remaining due to the latent failure. A lightning strike to an engine nacelle, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 211 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections/measurements of the out-tank bonding jumper and front spar bulkhead fitting adapter.	Up to 6 work-hours × $85 per hour = Up to $510 per inspection/measurement cycle.	$0	Up to $510 per inspection/measurement cycle.	Up to $107,610 per inspection/measurement cycle.
Reporting	1 work-hour × 85 per hour = 85 per inspection/measurement cycle.	0	85 per inspection/measurement cycle.	85 per inspection/measurement cycle.

The FAA estimates the following costs to do any necessary related investigative and corrective actions that would be required based on the results of the inspections/measurements. The FAA has no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost
Related Investigative Actions	Up to 2 work-hours × $85 per hour = $170	$0.
Corrective Actions	Up to 34 work-hours × 85 per hour = 2,890	Up to 1,000.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–23–14 The Boeing Company: Amendment 39–22616; Docket No. FAA–2023–2228; Project Identifier AD–2023–01095–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 15, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, 747SP, 747–8F, and 747–8 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by reports of latent failures of the lightning protection features for the engine fuel feed system. The FAA is issuing this AD to address latent failures of the lightning protection features for the engine fuel feed system. A lightning strike to an engine nacelle combined with latent failures of the lightning protection features for the engine fuel feed system, if not addressed, could result in the potential for ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Repetitive Inspections/Measurements, Related Investigative, and Corrective Actions

Within 90 days after the effective date of this AD for Model 747 airplanes operated in a passenger configuration, and within 120 days after the effective date of this AD for Model 747 airplanes operated in an all-cargo configuration: Do a detailed inspection for damage and measure the electrical bonding resistance of the out-tank fuel feed tube bonding jumper in the strut for each of the four engines, measure the electrical bonding resistance of the forward side of the front spar bulkhead fitting adapter for each of the four engines, and do all applicable related investigative and corrective actions, in accordance with Part 2 of the applicable Boeing multi operator message specified in paragraphs (g)(1) through (3) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspection and measurements thereafter at intervals not to exceed 12 months.

(1) For Model 747–8 and 747–8F series airplanes: Boeing Multi Operator Message MOM–MOM–23–0885–01B–R1, dated November 13, 2023.

(2) For Model 747–400, 747–400D, and 747–400F series airplanes: Boeing Multi Operator Message MOM–MOM–23–0899–01B–R1, dated November 13, 2023.

(3) For Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes: Boeing Multi Operator Message MOM–MOM–23–0907–01B, dated November 13, 2023.

(h) Repetitive Reporting Requirement for All Airplanes

At the applicable compliance times specified in paragraphs (h)(1) and (2) of this AD: Submit a report of all findings from each work package performed as required by paragraph (g) of this AD, in accordance with Appendix C of the applicable Boeing multi operator message identified in paragraphs (g)(1) though (3) of this AD.

(1) For the initial inspections and measurements required by paragraph (g) of this AD, submit the report at the applicable compliance time specified in paragraph (h)(1)(i) or (ii) of this AD.

(i) For Model 747 airplanes operated in a passenger configuration: Within 120 days after the effective date of this AD.

(ii) For Model 747 airplanes operated in an all-cargo configuration: Within 150 days after the effective date of this AD.

(2) For each repetitive inspection and measurement required by paragraph (g) of this AD, submit the report at intervals not to exceed 30 days after completing all four work packages.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *Samuel.j.dorsey@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Boeing Multi Operator Message MOM–MOM–23–0885–01B–R1, dated November 13, 2023.

(ii) Boeing Multi Operator Message MOM–MOM–23–0899–01B–R1, dated November 13, 2023.

(iii) Boeing Multi Operator Message MOM–MOM–23–0907–01B, dated November 13, 2023.

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA,

visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on November 20, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–26367 Filed 11–27–23; 4:15 pm]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Chapter I

Regulatory Review Schedule

AGENCY: Federal Trade Commission.

ACTION: Notification of intent to request public comments: initiation and termination of regulatory review.

SUMMARY: As part of its ongoing, systematic review of all Federal Trade Commission rules and guides, the Commission announces an updated ten-year regulatory review schedule. No Commission determination on the need for, or the substance of, the rules and guides listed below should be inferred from this notification.

DATES: The schedule set out in this document is applicable November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Further details about specific rules or guides may be obtained from the contact person listed below for the rule or guide. For information about this document, please contact Jock Chung (202–326–2984), Federal Trade Commission, Bureau of Consumer Protection, Division of Enforcement, 600 Pennsylvania Ave. NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: To ensure its rules and industry guides remain relevant and are not unduly burdensome, the Commission reviews each on a ten-year schedule. Every year the Commission publishes its review schedule, with adjustments made in response to public input, changes in the marketplace, and resource demands.

When the Commission reviews a rule or guide, it publishes a document in the **Federal Register** seeking public comment on the continuing need for the rule or guide, as well as the rule's or guide's costs and benefits to consumers and businesses. Based on this feedback, the Commission may modify or repeal the rule or guide to address public concerns, changed conditions, or to reduce undue regulatory burden.

The Commission posts information about its review schedule on its website [1] to facilitate comment. This website contains an updated review schedule, a list of rules and guides previously eliminated in the regulatory review process, and the Commission's regulatory review plan.

Updated Ten-Year Schedule for Review of FTC Rules and Guides

For 2023, the Commission intends to initiate a review of, and solicit public comments on, the following guide and rules:

(1) Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles, 16 CFR part 309 (https://www.ecfr.gov/current/title-16/chapter-I/subchapter-C/part-309). Agency Contact: Hampton Newsome, (202) 326–2889, Federal Trade Commission, Bureau of Consumer Protection, Division of Enforcement, 600 Pennsylvania Ave. NW, Washington, DC 20580.

(2) Rule Concerning Cooling-Off Period for Sales Made at Homes or at Certain Other Locations, 16 CFR part 429 (https://www.ecfr.gov/current/title-16/chapter-I/subchapter-D/part-429). Agency Contact: Marguerite Moeller, (404) 656–1364, Federal Trade Commission, Southeast Region, 233 Peachtree St. NE, Suite 1000, Atlanta, GA 30303.

The Commission is currently reviewing 16 of its 63 rules and guides. Since the Commission last published its schedule, it has completed or terminated reviews of one guide and two rules: 16 CFR part 255, Guides Concerning Use of Endorsements and Testimonials in Advertising; 16 CFR part 308, Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 [Pay Per Call Rule]; and 16 CFR part 423, Care Labeling of Textile Wearing Apparel and Certain Piece Goods. During that period, it has started reviews of one guide and one rule: 16 CFR part 260, Guides for the Use of Environmental Marketing Claims; and 16 CFR part 437, Business Opportunity Rule.

The Commission appends a copy of its updated regulatory review schedule, indicating initiation dates for reviews through 2033. In its discretion, the Commission may modify or reorder the schedule in the future to incorporate new rules, or to respond to external factors (such as changes in the law) or other considerations.

Authority: 15 U.S.C. 41 through 58.

By direction of the Commission.

April J. Tabor,

Secretary.

Appendix

REGULATORY REVIEW—UPDATED TEN-YEAR SCHEDULE

16 CFR part	Topic	Year to initiate review
24	Guides for Select Leather and Imitation Leather Products	Currently Under Review.
260	Guides for the Use of Environmental Marketing Claims	Currently Under Review.
310	Telemarketing Sales Rule	Currently Under Review.
312	Children's Online Privacy Protection Rule	Currently Under Review.
314	Standards for Safeguarding Customer Information	Currently Under Review.
318	Health Breach Notification Rule	Currently Under Review.
425	Use of Prenotification Negative Option Plans [Negative Option Rule]	Currently Under Review.
432	Power Output Claims for Amplifiers Utilized in Home Entertainment Products	Currently Under Review.
436	Disclosure Requirements and Prohibitions Concerning Franchising	Currently Under Review.
437	Business Opportunity Rule	Currently Under Review.
453	Funeral Industry Practices	Currently Under Review.
456	Ophthalmic Practice Rules (Eyeglass Rule)	Currently Under Review.
681	Identity Theft [Red Flag] Rules	Currently Under Review.
801	[Hart-Scott-Rodino Antitrust Improvements Act] Coverage Rules	Currently Under Review.
802	[Hart-Scott-Rodino Antitrust Improvements Act] Exemption Rules	Currently Under Review.
803	[Hart-Scott-Rodino Antitrust Improvements Act] Transmittal Rules	Currently Under Review.

[1] *https://www.ftc.gov/enforcement/rulemaking/retrospective-review-ftc-rules-guides.*

REGULATORY REVIEW—UPDATED TEN-YEAR SCHEDULE—Continued

16 CFR part	Topic	Year to initiate review
309	Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles	2023.
429	Rule Concerning Cooling-Off Period for Sales Made at Homes or at Certain Other Locations	2023.
20	Guides for the Rebuilt, Reconditioned, and Other Used Automobile Parts Industry	2024.
240	Guides for Advertising Allowances and Other Merchandising Payments and Services [Fred Meyer Guides].	2024.
300	Rules and Regulations under the Wool Products Labeling Act of 1939	2024.
301	Rules and Regulations under Fur Products Labeling Act	2024.
303	Rules and Regulations under the Textile Fiber Products Identification Act	2024.
424	Retail Food Store Advertising and Marketing Practices [Unavailability Rule]	2024.
435	Mail, Internet, or Telephone Order Merchandise	2024.
239	Guides for the Advertising of Warranties and Guarantees	2025.
254	Guides for Private Vocational and Distance Education Schools	2025.
305	Energy Labeling Rule	2025.
306	Automotive Fuel Ratings, Certification and Posting	2025.
444	Credit Practices	2025.
500	Regulations under Section 4 of the Fair Packaging and Labeling Act	2025.
501	Exemptions from Requirements and Prohibitions under Part 500	2025.
502	Regulations under Section 5(c) of the Fair Packaging and Labeling Act	2025.
503	Statements of General Policy or Interpretation [under the Fair Packaging and Labeling Act]	2025.
700	Interpretations of Magnuson-Moss Warranty Act	2025.
701	Disclosure of Written Consumer Product Warranty Terms and Conditions	2025.
702	Pre-Sale Availability of Written Warranty Terms	2025.
703	Informal Dispute Settlement Procedures	2025.
304	Rules and Regulations under the Hobby Protection Act	2026.
455	Used Motor Vehicle Trade Regulation Rule	2026.
233	Guides Against Deceptive Pricing	2027.
238	Guides Against Bait Advertising	2027.
251	Guide Concerning Use of the Word ''Free'' and Similar Representations	2027.
259	Guide Concerning Fuel Economy Advertising for New Automobiles	2027.
682	Disposal of Consumer Report Information and Records	2027.
23	Guides for the Jewelry, Precious Metals, and Pewter Industries	2028.
311	Test Procedures and Labeling Standards for Recycled Oil	2028.
460	Labeling and Advertising of Home Insulation	2028.
316	CAN–SPAM Rule	2029.
433	Preservation of Consumers' Claims and Defenses [Holder in Due Course Rule]	2029.
315	Contact Lens Rule	2030.
313	Privacy of Consumer Financial Information	2031.
317	Prohibition of Energy Market Manipulation Rule	2031.
323	Made in USA Labeling	2031.
640	Duties of Creditors Regarding Risk Based Pricing	2031.
641	Duties of Users of Consumer Reports Regarding Address Discrepancies	2031.
642	Prescreen Opt-Out Notice	2031.
660	Duties of Furnishers of Information to Consumer Reporting Agencies	2031.
680	Affiliate Marketing	2031.
698	Model Forms and Disclosures	2031.
255	Guides Concerning Use of Endorsements and Testimonials in Advertising	2033.
308	Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 [Pay Per Call Rule].	2033.
423	Care Labeling of Textile Wearing Apparel and Certain Piece Goods	2033.

[FR Doc. 2023–26064 Filed 11–29–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

RIN 1506–AB62

Beneficial Ownership Information Reporting Deadline Extension for Reporting Companies Created or Registered in 2024

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Final rule.

SUMMARY: FinCEN is amending the beneficial ownership information (BOI) reporting rule (the ''Reporting Rule'') to extend the filing deadline for certain BOI reports. Under the Reporting Rule prior to this amendment, entities created or registered on or after the rule's effective date of January 1, 2024, had to file initial BOI reports with FinCEN within 30 calendar days of notice of their creation or registration. This amendment extends that filing deadline from 30 calendar days to 90 calendar days for entities created or registered on or after January 1, 2024, and before January 1, 2025, to give those entities additional time to understand the new reporting obligation and collect the necessary information to complete their filings. Entities created or registered on or after January 1, 2025, will continue to have 30 calendar days to file their BOI reports with FinCEN.

DATES: This rule is effective January 1, 2024.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

In this final rule, FinCEN is amending the Reporting Rule [1] to extend the deadline to file initial BOI reports for entities created or registered on or after the rule's effective date of January 1, 2024, and before January 1, 2025. The Reporting Rule had required such entities to file initial BOI reports with FinCEN within 30 calendar days of notice of their creation or registration. This final rule extends that filing deadline to 90 calendar days for entities created or registered on or after January 1, 2024, and before January 1, 2025. The extension will give those entities additional time to understand the new reporting obligation and collect the necessary information to complete their filings. Entities created or registered on or after January 1, 2025, will continue to have 30 calendar days from notice of their creation or registration to file their BOI reports with FinCEN.

II. Background

A. The Reporting Rule

On September 30, 2022, FinCEN published the Reporting Rule, with an effective date of January 1, 2024.[2] The Reporting Rule requires certain corporations, limited liability companies, and other similar entities (''reporting companies'') [3] to report certain identifying information about the beneficial owners who own or control such entities and the company applicants who form or register them.[4] These requirements are intended to facilitate access to BOI for certain authorized recipients, including law enforcement and regulators, for the purpose of countering money laundering, the financing of terrorism, and other illicit activity.[5] The Corporate Transparency Act (CTA) directs FinCEN to promulgate regulations that achieve the objectives of the statute, while minimizing burdens on reporting companies to the greatest extent practicable and ensuring that the BOI collected is ''highly useful'' for national security, intelligence, and law enforcement activities.[6]

For domestic or foreign reporting companies created or registered to do business in the United States before the rule's effective date of January 1, 2024, the Reporting Rule requires that they file initial BOI reports with FinCEN by January 1, 2025.[7] Prior to the amendment of this final rule, a reporting company created or registered on or after January 1, 2024, however, would have been required to file its initial BOI report within 30 calendar days of the earlier of the date on which it receives actual notice or public notice that it has been created or registered.[8] The Reporting Rule requires reporting companies created on or after January 1, 2024, to report to FinCEN information about themselves, as well as information about two categories of individuals: (1) their beneficial owners; and (2) their company applicants, who are the individuals who filed a document to create the reporting company or registered it to do business.[9]

B. The Reporting Deadline Extension NPRM

On September 28, 2023, FinCEN published a notice of proposed rulemaking that would amend the Reporting Rule by extending the period for certain reporting companies to file initial BOI reports (the ''Reporting Extension NPRM'').[10] Under this proposed amendment, reporting companies created or registered on or after January 1, 2024, and before January 1, 2025, would have 90 calendar days to submit their initial BOI reports, instead of 30 calendar days. Reporting companies created or registered on or after January 1, 2025, would continue to be required to submit their initial BOI reports within 30 calendar days. FinCEN proposed the extension based on comments from trade associations, non-profits, and other key stakeholder organizations. As explained in the Reporting Extension NPRM, extending the deadline for reporting companies created or registered on or after January 1, 2024, and before January 1, 2025, would give those entities additional time to: (1) understand and comply with the Reporting Rule; (2) obtain the information necessary to complete their initial BOI reports; and (3) resolve questions that may arise in the process of completing the initial BOI reports.[11] The Reporting Extension NPRM also explained that the Reporting Rule establishes a legal regime that is entirely new to the United States, and the NPRM explained that FinCEN assessed that entrepreneurs and their service providers that create or register new business entities in the United States need additional time to learn about the Reporting Rule's requirements during the first year in which this regulation is effective.

In response to the Reporting Extension NPRM, FinCEN received 50 comments. Submissions came from a variety of corporate organization professionals, small business owners, trade groups, and individual members of the public. Many of these commenters supported FinCEN's proposed rule. Other commenters, while supportive of the intent behind the proposed rule, suggested alternative reporting deadlines such as 120 days after reporting companies are created or registered. Numerous commenters wanted FinCEN to apply the 90-day timeframe to *all* entities created or registered on or after January 1, 2024, not just those created or registered before January 1, 2025. Still other commenters suggested aligning the BOI reporting deadline with a reporting company's tax filing deadline. One comment was critical of the proposed rule, claiming that the proposal did not offer sufficient relief to reporting companies. Lastly, FinCEN received comments on several topics that were not relevant to the Reporting Extension NPRM, and which FinCEN has addressed or will address in other CTA-related rulemakings or guidance.

III. Discussion of Comments Received

A. Support for the 90-Day Reporting Extension

Comments Received. A majority of the commenters agreed with the proposed rule's extended deadline and encouraged FinCEN to promulgate the rule as written. Generally, these comments stressed the importance for

[1] U.S. Department of the Treasury (Treasury), FinCEN, *Beneficial Ownership Information Reporting Requirements,* 87 FR 59498 (September 30, 2022).

[2] The Reporting Rule is the first in a series of rulemakings to implement the Corporate Transparency Act (CTA), enacted on January 1, 2021, as part of the Anti-Money Laundering Act of 2020 and codified at 31 U.S.C. 5336. The CTA is Title LXIV of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (January 1, 2021) (NDAA). Division F of the NDAA is the Anti-Money Laundering Act of 2020, which includes the CTA.

[3] *See* 31 U.S.C. 5336(a)(11).

[4] *See supra* footnote 1, at 59498–99.

[5] CTA, Section 6402 (January 1, 2021).

[6] *Id.*

[7] Reporting Rule, 31 CFR 1010.380(a)(iii).

[8] *Id.* at 1010.380(a)(i)–(ii).

[9] *Id.* at 1010.380(a)(ii).

[10] Treasury, FinCEN, *Beneficial Ownership Information Reporting Deadline Extension for Reporting Companies Created or Registered in 2024,* Proposed Rule, 88 FR 66730 (September 28, 2023).

[11] Although the CTA provides that reports are to be filed by entities created or registered on or after January 1, 2024, ''at the time of formation or registration,'' 31 U.S.C. 5336(b)(1)(C), FinCEN may prescribe an exemption from that requirement consistent with the directive to ensure that the database is highly useful to law enforcement while at the same time minimizing burdens on reporting companies. *See* CTA, Section 6402(8). FinCEN believes it is appropriate to do so for entities created or registered on or after January 1, 2024, and before January 1, 2025, for the reasons noted here. Under 31 U.S.C. 5318(a)(7), FinCEN has authority to ''prescribe an appropriate exemption from a requirement under this subchapter,'' which includes the CTA in section 5336.

small businesses to receive additional time to comply with the BOI filing deadline. One commenter observed that small businesses have a ''myriad of administrative tasks'' and opined that entities would feel rushed when attempting to comply with the original BOI filing deadline of 30 calendar days. This sentiment was echoed by another commenter who noted that new entities must typically gather numerous documents in coordination with other parties, such as attorneys, and that the original 30-day filing deadline would be ''stressful.'' This commenter argued that the 90-day extension would reduce the number of entities that would later have to file corrective reports, and consequently reduce the overall amount of paperwork and expenses associated with filing. Further, one commenter noted that entity formation can take longer than 30 days as other governmental entities may require greater than 30 days to ''process'' entities' respective registration applications.

A commenter noted that the proposed extension would give attorneys and others providing filing assistance to reporting companies more time to understand BOI reporting requirements. One commenter noted that an extension to this deadline would lighten entities' initial regulatory burden.

Commenters also argued that the extension will give FinCEN additional time to implement the BOI regulations. One commenter opined that this proposed extension would give FinCEN additional time so as not to be ''overwhelmed'' with new reports, while another commenter stated that the additional time would allow FinCEN to publish frequently asked questions (FAQs) or related guidance. One commenter suggested that an extension would reduce non-compliance and potential penalties. No commenters explicitly opposed extending the deadline, though as discussed below in Section III.B, one commenter was critical of the proposed rule for not offering sufficient relief to reporting companies.

Final Rule. FinCEN has carefully considered commenters' views and agrees that extending the reporting deadline for reporting companies created or registered on January 1, 2024, and before January 1, 2025, will help such companies to become aware of their reporting obligations and submit BOI reports to FinCEN. FinCEN therefore adopts the rule as proposed and extends the deadline for these reporting companies from 30 to 90 calendar days.

B. Alternatives to the 90-Day Reporting Extension

Comments Received. Numerous commenters, while in favor of extending the initial filing deadline for reporting companies created or registered on or after January 1, 2024, and before January 1, 2025, argued for making the deadline more than 90 calendar days after creation or registration or, alternatively, for an initial BOI report filing deadline aligned to tax filing deadlines. These commenters generally did not distinguish between entities created or registered in the first year of the new reporting requirement (on or after January 1, 2024, and before January 1, 2025), and new entities generally. One commenter argued that with January 1, 2024, quickly approaching and FinCEN having provided relatively little guidance (in the commenter's opinion), all new entities should be given 120 days to file their initial BOI reports. The commenter stated that a 120-day timeframe would promote greater accuracy in information submitted to FinCEN. Another commenter suggested the deadline be either 90 days or ''within the calendar year,'' whichever was longer. The commenter argued that this flexibility would help certified public accountants (CPAs), who might only discover a reporting company's BOI reporting obligation at tax time.

A trade organization representing CPAs was critical of the extension because it found the 90-day timeline to be inadequate. This commenter argued for an initial filing deadline of one year from creation or registration. The commenter cited various concerns, such as the need for greater awareness of the reporting requirements among small businesses and the potential for these businesses facing penalties for non-compliance.

Similarly, multiple commenters argued that all new reporting companies' deadlines should be either 90 days or the income tax return deadline specifically, whichever was longer. These commenters argued that new businesses, and in particular small businesses, rely upon CPAs to assist with filing income tax returns. To this point, three commenters echoed others' sentiments in stating that individuals often make CPAs aware of new businesses having been created when seeking assistance with tax return filings. Therefore, the commenters argued that a deadline based upon the tax return deadline would allow CPAs to assist with both tax return filings and BOI filings at the same time.

Final Rule. FinCEN has carefully considered each comment supporting an extension greater than 90 calendar days, or a deadline to be aligned with IRS tax return filing deadlines, but declines to adopt these changes to the proposed rule. FinCEN believes the additional published guidance, the availability of the contact center FinCEN is preparing that will allow members of the public to contact FinCEN with questions concerning BOI reporting, and the 90-day timeframe will provide members of the general public with sufficient time, awareness, and opportunity to consult third parties (such as CPAs or attorneys) as the BOI regulatory framework is first implemented. It will also provide both those third parties and the general public with guidance and other information to assist in providing advice and making decisions. FinCEN further declines to extend the deadline to the longer of 90 days or the ''end of the year.'' [12] This arrangement would allow a reporting company created or registered in January to wait until December 31 of the same year to file its initial BOI report, while a reporting company created or registered at or near the end of September of that same year would be required to file within 90 days. Such disparate treatment of similarly situated reporting companies is unwarranted and would not address any difficulties caused by a novel reporting requirement more effectively than the filing extension that FinCEN proposed.

FinCEN also declines to align its filing deadline for initial BOI reports to income tax return deadlines. Were FinCEN to align the initial BOI report deadline to the income tax return filing deadline, some reporting companies could file their BOI reports many months, and even the following year, after they have been created or registered. This would create significant discrepancies between the filing time allotted to otherwise similarly situated reporting companies. In addition, such a delay would mean that filed information about new reporting companies would be significantly out of date for the entire period from January 1, 2024, until after the 2025 tax filing season, which would not align with the CTA's mandate to ''collect information in a form and manner that is reasonably designed to generate a database that is highly useful to national security,

[12] Some comments discussed the merits of an extended reporting deadline without reference to the January 1, 2025, endpoint that FinCEN proposed. FinCEN understands these comments to be effectively in favor of a permanent alteration of reporting deadline to 90 calendar days for all new reporting companies, regardless of when created or registered, and addresses those comments in section III.C.

intelligence, and law enforcement agencies and Federal functional regulators.'' [13] Preserving the utility of the database to the greatest extent possible dictates that an extension of the filing deadline should be only as long as needed to provide meaningful relief in the first year that the BOI reporting framework is in effect.

C. The Timeframe To File for Entities Created or Registered After 2024

Comments Received. Some commenters urged FinCEN to apply the 90-day BOI reporting deadline extension to *all* reporting companies created or formed on or after January 1, 2024, instead of limiting the 90-day extension to only those new entities created in calendar year 2024. One commenter argued that the 90-day extension should apply to all reporting companies created or formed on or after January 1, 2024, because law firms and corporate formation services will find it burdensome to create systems for a 90-day BOI reporting timeframe in 2024 and then have to change their systems in 2025 to account for the 30-day timeline. Other commenters cited the logic in the preamble to the Reporting Extension NPRM as supportive of extending the 90-day extension beyond 2024. These commenters noted the rationale behind the proposed rule, including the need to give reporting companies additional time to understand their obligations under the Reporting Rule and obtain the information required under the rule during the first year the Reporting Rule is effective. The reasons FinCEN provided for giving reporting companies more time in 2024 would also justify giving reporting companies more time in the years beyond 2024, according to these commenters.

Final Rule. FinCEN has carefully considered commenters' arguments to make the 90-day reporting extension permanent, but FinCEN is declining to adopt this change to the Reporting Rule. FinCEN believes that new reporting companies that are created or registered in 2024 will be in a different position than those reporting companies created or registered in and after 2025, because 2024 is the first year in which the Reporting Rule is effective. The Reporting Rule creates an entirely new legal framework for newly formed or registered companies in the United States. It is particularly important for companies and company-formation advisers to have additional time to understand the new requirements and learn how to comply with them when the framework is new. After 2024, however, FinCEN believes that the public will be more familiar with this new regime as a result of FinCEN's outreach and educational efforts, which will continue throughout 2024. Consequently, after 2024, newly created or registered reporting companies will have greater awareness of the Reporting Rule's requirements, and they will be in a better position to comply with the requirements within the 30-day timeline set out in the Reporting Rule than they would have been in 2024.

FinCEN recognizes commenters' concerns that the 30-day timeframe for filing BOI reports after 2024 may pose difficulties because many small businesses do not employ lawyers or other corporate service providers and therefore may not learn about the Reporting Rule and associated BOI reporting requirement within a 30-day timeframe. FinCEN is taking into account these concerns as it implements its outreach strategy, in particular by planning for its outreach and educational efforts to reach the general public, not only service providers. FinCEN expects the public to become increasingly aware of the BOI reporting requirements as 2024 progresses, and in the coming years FinCEN will build upon its existing efforts to educate entrepreneurs who start new reporting companies.

Further, while following the CTA's directive to minimize burdens on reporting companies to the greatest extent practicable, which this final rule aims to do, FinCEN must also satisfy the CTA's requirement that the BOI database must be ''highly useful'' in facilitating national security, intelligence, and law enforcement activities.[14] To be ''highly useful,'' the database must be reasonably up-to-date and accurate, and FinCEN believes that the Reporting Rule's 30-day timeframe for filing BOI reports to FinCEN will help achieve this goal. FinCEN gives weight to commenters' concerns that new reporting companies have many challenges to grapple with in their first few months of operation. However, FinCEN does not believe these concerns warrant a permanent departure from the prompt BOI reporting regime specified by Congress.[15]

Considering the balance that FinCEN must strike among reducing burdens on reporting companies, making the BOI database highly useful, and complying with the directive set out in the CTA that companies must report BOI ''at the time of formation or registration,'' [16] FinCEN believes that the 30-day timeframe is appropriate for reporting companies that come into existence or are registered after 2024. FinCEN makes this determination based on the information currently available, including the comments it received in response to the Reporting Extension NPRM, which focused primarily on reducing burdens to reporting companies. During the first few years of the implementation of the Reporting Rule, FinCEN will monitor compliance with the BOI reporting deadlines and will consider whether any adjustments to the permanent reporting timeframe for newly created or registered reporting companies are warranted.

D. Other Issues Raised by Commenters

Commenters also discussed a number of issues that were not relevant to the Reporting Extension NPRM, such as the timeframe for updating or correcting BOI reports, access to FinCEN's BOI database, the FinCEN identifier, and other matters. Some of the issues raised by these commenters have been or will be dealt with in separate FinCEN rulemakings that implement the CTA, while other issues are addressed in guidance. Comments on issues that go beyond the scope of this final rule are briefly discussed here.

Comments Received. A number of comments addressed issues that FinCEN raised, received comments on, and made final determinations about in the course of proposing and finalizing the Reporting Rule. Several commenters requested that FinCEN extend the timeframe that reporting companies have to update or correct their BOI reports. These commenters claimed that reporting companies need more than the 30 calendar days that the Reporting Rule provided for them to update or correct BOI reports. One commenter requested clarification on what it means for reporting companies to be ''created'' for purposes of knowing when to begin the 90-day window within which reporting companies created or formed in 2024 must file their BOI reports with FinCEN. Another commenter claimed that as important as the 90-day extension in the NPRM is, equally important for FinCEN

[13] CTA, Section 6402(8)(C).

[14] CTA, Section 6402(8)(C).

[15] The plain language of the CTA requires reporting companies formed or registered after the effective date of the Reporting Rule to file their BOI reports with FinCEN ''at the time of formation or registration.'' *See* 31 U.S.C. 5336(b)(1)(C). As discussed above, FinCEN is using its exemptive authority under 31 U.S.C. 5318(a)(7) to extend this deadline to 90 days temporarily. *See supra* footnote 12. By not maintaining this extension any longer than necessary to provide relief, however, this final rule better aligns FinCEN's BOI reporting regulations with the overall statutory scheme.

[16] 31 U.S.C. 5336(b)(1)(C).

to consider is making FinCEN's electronic filing system available to corporate formation service providers prior to January 1, 2024, so that they are prepared to quickly assist newly created reporting companies in filing their BOI reports. Other commenters emphasized the need for FinCEN to conduct additional outreach so that small businesses, trade associations, and professional service providers are aware of the requirements of the Reporting Rule. One commenter argued that the Reporting Rule's estimate of the costs that reporting companies will incur in complying with the rule is inaccurate since these companies will need to monitor changes that would require updates to their initial BOI report, and they will often incur costs associated with professional services hired to understand the reporting requirements.

Other comments that addressed issues that went beyond the scope of the Reporting Extension NPRM are more relevant to ongoing FinCEN regulations and guidance related to the CTA. For example, one commenter asked FinCEN to clarify, among other things, how financial institutions will access the FinCEN BOI database, how financial institutions should obtain customer consent to request BOI from the database, how these institutions should approach discrepancies between BOI found in the database and BOI obtained directly from customers pursuant to the final rule on customer due diligence obligations that FinCEN published in 2016 (the ''2016 CDD Rule'').[17] Other commenters had additional questions regarding how financial institutions should reconcile their existing CDD obligations with the Reporting Rule and the proposed requirements under the proposed rule that FinCEN issued on December 16, 2022, concerning access to BOI and safeguards for protecting BOI (the ''Access NPRM'').[18]

Final Rule. FinCEN has reviewed the comments on issues that are not relevant to the Reporting Extension NPRM and is not adopting changes to this final rule as a result of these comments. However, FinCEN is responding to several of the comments in order to provide clarification on certain issues.

First, as for questions about the meaning of when a reporting company is deemed to be ''created'' in order to set the 90-day timeframe for reporting BOI by reporting companies created or formed in 2024, the Reporting Extension NPRM did not propose to alter the approach that FinCEN took in the Reporting Rule. Under the Reporting Rule, a domestic or foreign reporting company is ''created'' or ''registered'' when it receives actual notice or constructive (public) notice, whichever is earlier, that the company has been created or registered.[19] This remains unchanged.

Second, FinCEN considers that a distinction needs to be made between providing additional time for reporting companies to file their initial BOI reports, and providing additional time for them to update or correct those reports. FinCEN believes that extending the deadline for reporting companies created or registered on or after January 1, 2024, and before January 1, 2025, to file their initial BOI reports is appropriate because of the need to give these companies additional time to become aware of the Reporting Rule, collect BOI and company applicant information, and file their initial reports during the first year that the Reporting Rule is effective. But as reporting companies and third party service providers become aware of the Reporting Rule and file their initial BOI reports, FinCEN believes they will also have time to review the rules concerning updates and corrections to these reports and to file updates or corrections with FinCEN, or assist in such filings, as appropriate. Thus, no extension of the deadline to update and correct BOI reports is necessary.

Finally, as for comments concerning access to the BOI database, including how financial institutions should obtain customer consent in order to access the database, these issues are the topic of the Access NPRM and the forthcoming final rule on beneficial ownership access and safeguards. Similarly, issues raised by one commenter concerning discrepancies between BOI financial institutions obtain directly from customers and BOI obtained from the FinCEN database will be addressed in a future rulemaking on revisions to the 2016 CDD Rule required by the CTA.[20] FinCEN is declining to address any other issues raised by commenters to the proposed rule that are not strictly within the scope of the Reporting Extension NPRM.

IV. Regulatory Analysis

FinCEN has analyzed the final rule as required under Executive Orders 12866, 13563, and 14094; the Regulatory Flexibility Act; the Unfunded Mandates Reform Act; and the Paperwork Reduction Act. This rule would not have an annual effect on the economy of $200 million or otherwise constitute a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, as amended. Pursuant to the Regulatory Flexibility Act, FinCEN certifies that the final rule would not have a significant economic impact on a substantial number of small entities. FinCEN has assessed that the rule would result in no additional costs to small businesses. Furthermore, pursuant to the Unfunded Mandates Reform Act, FinCEN has concluded that the final rule would not result in an expenditure of $177 million or more annually by state, local, and Tribal governments or by the private sector.[21] FinCEN does not estimate any burden, as defined by the Paperwork Reduction Act, associated with the final rule.

FinCEN assesses that the extension of the reporting deadline for entities created or registered in the first year of the reporting requirement will not impose new costs. The costs for BOI reporting have been estimated in the regulatory impact analysis (RIA) in the Reporting Rule.[22] In that RIA, FinCEN estimated the total number of reporting companies in 2024, the first year that the Reporting Rule will go into effect, to be approximately 32.6 million. The Reporting Rule RIA also estimated the costs for these reporting companies in filing their initial BOI reports, analyzing the potential cost of each step in the filing process.[23] FinCEN's analysis in the final Reporting Rule would not be changed by the extension of the reporting timeline for new reporting companies created or registered in 2024 from 30 calendar days to 90 calendar days.

FinCEN acknowledges that this 90-day reporting timeframe would shift some of the estimated aggregate cost in the Reporting Rule RIA from ''Year 1'' (2024) to ''Year 2'' (2025) in the analysis. This shift in cost is difficult to quantify. However, FinCEN assesses

[17] Treasury, FinCEN, *Customer Due Diligence Requirements for Financial Institutions,* 81 FR 29398 (May 11, 2016).

[18] Treasury, FinCEN, *Beneficial Ownership Information Access and Safeguards, and Use of FinCEN Identifiers for Entities,* Proposed Rule, 87 FR 77404 (December 16, 2022).

[19] Reporting Rule, 31 CFR 1010.380(a)(i)–(ii).

[20] *See* CTA, Section 6304(d).

[21] The Unfunded Mandates Reform Act requires an assessment of mandates that will result in an annual expenditure of $100 million or more, adjusted for inflation. The U.S. Bureau of Economic Analysis reports the annual value of the gross domestic product (GDP) deflator in 1995, the year of the Unfunded Mandates Reform Act, as 71.823, and as 127.224 in 2022. *See* U.S. Bureau of Economic Analysis, ''Table 1.1.9. Implicit Price Deflators for Gross Domestic Product'' (accessed Friday, June 2, 2023). Thus, the inflation adjusted estimate for $100 million is 127.224/71.823 × 100 = $177 million.

[22] *See* Treasury, FinCEN, *Beneficial Ownership Reporting Requirements,* 87 FR 59549–59591 (December 8, 2021).

[23] *Id.*

that the shift of these costs would be *de minimis* and would not change the conclusions of the Reporting Rule's RIA. Additionally, the per-reporting company burden and cost estimate in the Reporting Rule RIA would not be affected by the final rule.

Furthermore, FinCEN notes that the change in the reporting timeline for reporting companies created or registered in 2024 would likely have multiple benefits. As discussed in Section III.A above, FinCEN received many comments in response to the NPRM that supported the reporting deadline extension and agreed with FinCEN's view that the extension would benefit reporting companies. These benefits include additional time for these companies to understand and comply with the requirements of the Reporting Rule, as well as greater opportunities for FinCEN to efficiently respond to questions and address problems that reporting companies may have in complying.

V. Effective Date

This final rule will be effective January 1, 2024, the same date as the Reporting Rule it is amending but potentially fewer than 30 days after this rule's publication in the **Federal Register**. Under 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), a 30-day delayed effective date is required, except for ''(1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.'' A delayed effective date of fewer than 30 days for this rule is authorized under both 5 U.S.C. 553(d)(1) and 553(d)(3).

First, this rule grants an exemption and relieves a restriction by extending the reporting deadline for certain entities to 90 calendar days, relieving these entities from the shorter 30-day filing deadline under the Reporting Rule. Thus, it may be effective without a 30-day delay under 5 U.S.C. 553(d)(1).

Second, FinCEN finds good cause under 5 U.S.C. 553(d)(3) to make this rule effective on January 1, 2024, because a 30-day delayed effective date is unnecessary. The purpose of the 30-day delayed effective date is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996). The parties affected by this rule, however, do not need time to adjust their behavior because the rule does not impose any new obligations on them; to the contrary, this rule gives affected parties additional time to adjust their behavior to the requirements of the Reporting Rule.

List of Subjects in 31 CFR Parts 1010

Administrative practice and procedure, Aliens, Authority delegations (Government agencies), Banks and banking, Brokers, Business and industry, Citizenship and naturalization, Commodity futures, Currency, Electronic filing, Federal savings associations, Federal-States relations, Foreign persons, Holding companies, Indians, Indian-law, Indians-tribal government, Insurance companies, Investigations, Investment advisers, Investment companies, Law enforcement, Penalties, Reporting and recordkeeping requirements, Securities, Small business, Terrorism, Time.

Authority and Issuance

For the reasons set forth in the preamble, the U.S. Department of the Treasury and Financial Crimes Enforcement Network amend 31 CFR part 1010 as follows:

PART 1010—GENERAL PROVISIONS

■ 1. The authority citation for part 1010 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314 and 5316–5336; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307; sec. 2006, Pub. L. 114–41, 129 Stat. 458–459; sec. 701, Pub. L. 114–74, 129 Stat. 599.

■ 2. In § 1010.380, revise paragraphs (a)(1)(i) and (ii) to read as follows:

§ 1010.380 Reports of beneficial ownership information.

(a) * * *

(1) * * *

(i)(A) Any domestic reporting company created on or after January 1, 2024, and before January 1, 2025, shall file a report within 90 calendar days of the earlier of the date on which it receives actual notice that its creation has become effective or the date on which a secretary of state or similar office first provides public notice, such as through a publicly accessible registry, that the domestic reporting company has been created.

(B) Any domestic reporting company created on or after January 1, 2025, shall file a report within 30 calendar days of the earlier of the date on which it receives actual notice that its creation has become effective or the date on which a secretary of state or similar office first provides public notice, such as through a publicly accessible registry, that the domestic reporting company has been created.

(ii)(A) Any entity that becomes a foreign reporting company on or after January 1, 2024, and before January 1, 2025, shall file a report within 90 calendar days of the earlier of the date on which it receives actual notice that it has been registered to do business or the date on which a secretary of state or similar office first provides public notice, such as through a publicly accessible registry, that the foreign reporting company has been registered to do business.

(B) Any entity that becomes a foreign reporting company on or after January 1, 2025, shall file a report within 30 calendar days of the earlier of the date on which it receives actual notice that it has been registered to do business or the date on which a secretary of state or similar office first provides public notice, such as through a publicly accessible registry, that the foreign reporting company has been registered to do business.

* * * * *

Andrea M. Gacki,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2023–26399 Filed 11–29–23; 8:45 am]

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SELECTIVE SERVICE SYSTEM

32 CFR Part 1665

RIN 3240–AA04

Social Security Number Fraud Prevention Act of 2017 Implementation; Correction

AGENCY: United States Selective Service System.

ACTION: Final rule; request for comments; correction.

SUMMARY: This document makes a technical correction in the preamble to a rule entitled Social Security Number Fraud Prevention Act of 2017 Implementation, which the Selective Service System published in the **Federal Register** of November 16, 2023. This notification corrects the effective date of the final rule.

DATES: This correction is effective November 29, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Cramer, Selective Service System, Office of the General Counsel, 703–605–4069, *kcramer@sss.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 16, 2023, starting on page 78639 in FR Doc 2023–25036, make the following corrections:

1. On page 78639, in the third column, the **ACTION** line is corrected to read ''**ACTION**: Final rule; request for comments.''.

2. On page 78640, in the first column, correct the **DATES** caption to read: **DATES**: The rule is effective November 29, 2023, and applicable beginning November 16, 2023. Comments, if any, are requested by December 13, 2023.

3. On page 78640, in the second column, correct the first sentence under the heading ''Administrative Procedure Act'' to read ''The Agency finds good cause to publish this as a final rule because the notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest because this rule expands protections to the public.''

Daniel A. Lauretano, Sr.,

General Counsel.

[FR Doc. 2023–26305 Filed 11–29–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0910]

RIN 1625–AA00

Safety Zone; Laguna Madre, South Padre Island, TX

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters in the Laguna Madre. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a firework display launched from a stationary barge in the Laguna Madre, South Padre Island, Texas. Entry of vessels or persons into this zone or remaining in the zone when it is in effect is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi or a designated representative.

DATES: This rule is effective from 9:30 p.m. through 11:59 p.m. on December 2, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0910 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Anthony Garofalo, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email *CCWaterways@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 Information and Regulatory History

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

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to address the potential safety hazards associated with fireworks launched from a barge in the waters of the Laguna Madre.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Corpus Christi (COTP) has determined that potential hazards associated with the fireworks displays occurring from 9:30 p.m. through 11:59 p.m. on the night of December 2, 2023, will be a safety concern for anyone in the waters of the Laguna Madre area within a 700 yard radius of the following point; 26°6′02.1″ N, 97°10′17.7″ W. The purpose of this rule is to ensure safety of vessels and persons on these navigable waters in the safety zone while the display of the fireworks takes place in the Laguna Madre.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on the night of December 2, 2023. The safety zone will encompass certain navigable waters of the Laguna Madre, and is defined by a 700 yard radius around the launching platform. The regulated area encompasses a 700 yard radius of the following point: 26°6′02.1″ N, 97°10′17.7″ W. The fireworks display will take place in waters of the Laguna Madre. No vessel or person is permitted to enter the temporary safety zone during the effective period without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF–FM (156.8 MHz), or by telephone at 361–939–0450. The Coast Guard will issue Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts, as appropriate.

V. Regulatory analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule 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. The temporary safety zone will be enforced for a short period of 2.5 hours on the night of December 2, 2023.

The zone is limited to a 700 yard radius from the launching position of in the navigable waters of the Laguna Madre. The rule does not completely restrict the traffic within a waterway and allows mariners to request permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, and Environmental Planning, COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f) and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone for navigable waters of the Laguna Madre in a zone defined by a 700 yard radius from the following coordinate: 26°6′02.1″ N, 97°10′17.7″ W. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks display in the waters of the Laguna Madre. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0910 to read as follows:

§ 165.T08–0910 Safety Zone; Laguna Madre, South Padre Island, TX.

(a) *Location.* The following area is a safety zone: all navigable waters of the Laguna Madre encompassed by a 700-yard radius from the following point; 26°6′02.1″ N, 97°10′17.7″ W.

(b) *Enforcement period.* This section is in effect, and subject to enforcement from 9:30 p.m. through 11:59 p.m. on the night of December 2, 2023.

(c) *Regulations.* (1) According to the general regulations in § 165.23 of this part, remaining in, or entry into this temporary safety zone are prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. They may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

(2) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

Dated: November 21, 2023.

Jason Gunning,

Captain, U.S. Coast Guard, Captain of the Port, Sector Corpus Christi.

[FR Doc. 2023–26334 Filed 11–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0919]

RIN 1625–AA00

Safety Zone; Gulf of Mexico, Lower Mississippi River Below Head of Passes

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River below Head of Passes. The safety zone is needed to protect persons and critical infrastructure from the potential contamination due to an oil spill in the Gulf of Mexico. Entry of vessels or persons into this zone, or movement of vessels within this zone is prohibited unless specifically authorized by the Captain of the Port or a designated representative.

DATES: This rule is effective without actual notice from November 30, 2023 through December 17, 2023. For the purposes of enforcement, actual notification will be used from 5 p.m. on November 17, 2023, until November 30, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG-USCG–2023–0919 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander William Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@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 Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because an oil spill happened 2 days ago, and immediate action is needed to respond to the potential safety impacts associated with oil contamination. It is impracticable to publish NPRM because we must establish this safety zone immediately.

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

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with contamination due to oil spill which happened 2 days ago, will be a safety concern to all persons and critical infrastructure within the Captain of the Port Sector New Orleans area.

IV. Discussion of the Rule

This rule establishes a safety zone from 5 p.m. on November 17, 2023 through December 17, 2023. The safety zone will cover all navigable waters of Lower Mississippi River below Head of Passes. The duration of the zone is intended to protect persons and critical infrastructure from the potential contamination due to oil spill in the Gulf of Mexico. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on duration of rule.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–

888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves an emergency safety zone that will prohibit entry to Lower Mississippi River below Head of Passes. It is categorically excluded from further review under paragraph L60d of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination will be available in the docket after issuance or publication of this rule. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0919 to read as follows:

§ 165.T08–0919 Safety Zone; Gulf of Mexico, Lower Mississippi River below Head of Passes.

(a) *Location.* The following area is a safety zone: all navigable waters of Lower Mississippi River below Head of Passes.

(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 Sector New Orleans (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.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF–FM Channel 16 or 67 or by telephone at (504) 365–2545. 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) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

(e) *Enforcement period.* This section will be subject to enforcement from 5 p.m. on November 17, 2023, through December 17, 2023. It will be subject to enforcement this entire period unless the COTP determines it is no longer needed, in which case the Coast Guard will inform mariners via Notice to Mariners.

Dated: November 17, 2023.

K.K. Denning,

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

[FR Doc. 2023–26295 Filed 11–29–23; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 380

[Docket No. 19–CRB–0005–WR (2021–2025) COLA (2024)]

Cost of Living Adjustment to Royalty Rates for Webcaster Statutory License

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) in the royalty rates that commercial and noncommercial noninteractive webcasters pay for eligible transmissions pursuant to the statutory licenses for the public performance of and for the making of ephemeral reproductions of sound recordings.

DATES:

Effective date: November 30, 2023.

Applicability dates: These rates are applicable to the period January 1, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Anita Brown, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Sections 112(e) and 114(f) of the Copyright Act, title 17 of the United States Code, create statutory licenses for certain digital performances of sound recordings and the making of ephemeral reproductions to facilitate transmission of those sound recordings. On October 27, 2021, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under those licenses for the license period 2021–2025 for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. *See* 86 FR 59452.

Pursuant to those regulations, at least 25 days before January 1 of each year from 2022 to 2025, the Judges shall publish in the **Federal Register** notice of a cost of living adjustment (COLA) applicable to the royalty fees for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. 37 CFR 380.10.

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the Consumer Price Index for all Urban Consumers (CPI–U) from the CPI–U published in November 2020 (260.229), according to the formula: for subscription performances, $(1 + (C_y - 260.229)/260.229) \times \$0.0026$; for nonsubscription performances, $(1 + (C_y - 260.229)/260.229) \times \$0.0021$; for performances by a noncommercial webcaster in excess of 159,140 Aggregate Tuning Hours (ATH) per month, $(1 + (C_y - 260.229)/260.229) \times \$0.0021$; where C_y is the CPI–U published by the Secretary of Labor before December 1 of the preceding year. The adjusted rate shall be rounded to the nearest fourth decimal place. 37 CFR 380.10(c). The CPI–U published by the Secretary of Labor from the most recent index published before December 1, 2023, is 307.671.[1] Applying the formula in 37 CFR 380.10(c) and rounding to the nearest fourth decimal place results in an increase in the rates for 2024.

The 2024 rate for eligible transmissions of sound recordings by commercial webcasters is $0.0031 per subscription performance and $0.20025 per nonsubscription performance.

Application of the increase to rates for noncommercial webcasters results in a 2024 rate of $0.0025 per performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

As provided in 37 CFR 380.10(d), the royalty fee for making ephemeral recordings under section 112 of the Copyright Act to facilitate digital transmission of sound recordings under section 114 of the Copyright Act is included in the section 114 royalty fee and comprises 5% of the total fee.

List of Subjects in 37 CFR Part 380

Copyright, Sound recordings.

Final Regulations

In consideration of the foregoing, the Judges amend part 380 of title 37 of the Code of Federal Regulations as follows:

PART 380—RATES AND TERMS FOR TRANSMISSIONS BY ELIGIBLE NONSUBSCRIPTION SERVICES AND NEW SUBSCRIPTION SERVICES AND FOR THE MAKING OF EPHEMERAL REPRODUCTIONS TO FACILITATE THOSE TRANSMISSIONS

■ 1. The authority citation for part 380 continues to read as follows:

Authority: 17 U.S.C. 112(e), 114(f), 804(b)(3).

■ 2. Section 380.10 is amended by revising paragraph (a) to read as follows:

§ 380.10 Royalty fees for the public performance of sound recordings and the making of ephemeral recordings.

(a) *Royalty fees.* For the year 2024, Licensees must pay royalty fees for all Eligible Transmissions of sound recordings at the following rates:

(1) Commercial webcasters: $0.0031 per Performance for subscription services and $0.0025 per Performance for nonsubscription services.

(2) Noncommercial webcasters: $1,000 per year for each channel or station and $0.0025 per Performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

* * * * *

Dated: November 22, 2023.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2023–26221 Filed 11–29–23; 8:45 am]

BILLING CODE 1410–72–P

[1] This CPI–U was announced on November 14, 2023, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index,* available at *https://www.bls.gov/news.release/cpi.htm* at Table 1.

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 23–CRB–0011–PBR (2023–2027) COLA (2024)]

Cost of Living Adjustment to Public Broadcasters Compulsory License Royalty Rate

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) to the royalty rate that noncommercial radio stations at certain colleges, universities, and other educational institutions that are not affiliated with National Public Radio must pay for the use in 2024 of published nondramatic musical compositions in the SESAC Performing Rights, LLC (SESAC) and Global Music Rights, LLC (GMR) repertories pursuant to the statutory license under the Copyright Act for noncommercial broadcasting.

DATES:

Effective date: November 30, 2023.

Applicability dates: These rates are applicable to the period January 1, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Assistant, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Section 118 of the Copyright Act, title 17 of the United States Code, creates a statutory license for the use of published nondramatic musical works and published pictorial, graphic, and sculptural works in connection with noncommercial broadcasting.

On June 28, 2023, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under section 118 of the Copyright Act for the license period 2023–2027. *See* 88 FR 41827. Pursuant to these regulations, on or before December 1 of each year, the Judges shall publish in the **Federal Register** notice of the change in the cost of living and a revised schedule of the rates codified at § 381.5(c)(3) and (4) relating to compositions in the repertory of SESAC and GMR. The adjustment, fixed to the nearest dollar, shall be the greater of (1) the change in the cost of living as determined by the Consumer Price Index (all consumers, all items) (''CPI–U'') ''during the period from the most recent index published prior to the

previous notice to the most recent index published prior to December 1, of that year'' or (2) 1.5%. 37 CFR 381.10.

The change in the cost of living as determined by the CPI–U during the period from the most recent index published prior to the previous notice, *i.e.,* before December 1, 2022, to the most recent index published before December 1, 2023, is 3.2%.[1] In accordance with 37 CFR 381.10(b), the Judges announce that the COLA for calendar year 2024 shall be 3.2%. Application of the 3.2% COLA to the 2023 rates for the performance of published nondramatic musical compositions in the repertory of SESAC and GMR—$188 per station—results in an adjusted rate of $194 per station, rounded to the nearest dollar.

[1] On November 14, 2023, the Bureau of Labor Statistics announced that the CPI–U increased 3.2% over the last 12 months.

List of Subjects in 37 CFR Part 381

Copyright, Music, Radio, Rates, Television.

Final Regulations

In consideration of the foregoing, the Judges amend part 381 of title 37 of the Code of Federal Regulations as follows:

PART 381—USE OF CERTAIN COPYRIGHTED WORKS IN CONNECTION WITH NONCOMMERCIAL EDUCATIONAL BROADCASTING

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 17 U.S.C. 118, 801(b)(1) and 803.

■ 2. Section 381.5 is amended by revising paragraphs (c)(3)(i) and (ii) and (c)(4)(i) and (ii) to read as follows:

§ 381.5 Performance of musical compositions by public broadcasting entities licensed to colleges and universities.

* * * * *

(c) * * *

(3) * * *

(i) 2023: $188 per station.

(ii) 2024: $194 per station.

* * * * *

(4) * * *

(i) 2023: $188 per station.

(ii) 2024: $194 per station.

* * * * *

Dated: November 22, 2023.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2023–26223 Filed 11–29–23; 8:45 am]

BILLING CODE 1410–72–P

Proposed Rules

Federal Register
Vol. 88, No. 229
Thursday, November 30, 2023

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 STATE

22 CFR Part 62

[Public Notice: 12273]

RIN 1400–AF12

Exchange Visitor Program—Au Pairs; Extension of Comment Period

AGENCY: U.S. Department of State.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On October 30, 2023, the U.S. Department of State (Department of State) published a Notice of Proposed Rulemaking for the Exchange Visitor Program—Au pair category. The Notice of Proposed Rulemaking provided a deadline for submitting comments by December 29, 2023. The Department of State received a request from the Alliance for International Exchange seeking an extension of the public comment period. The Department of State has reviewed this request and is announcing an extension of the public comment period for 30 days to allow public comments to be submitted on or before January 28, 2024.

DATES: The comment period for the Notice of Proposed Rulemaking published in the **Federal Register** on October 30, 2023 (88 FR 74071) is extended. Written comments must be received by January 28, 2024.

ADDRESSES: Interested parties may submit comments to the Department of State by any of the following methods:

- *Visit the Regulations.gov website at: https://www.regulations.gov* and search for the docket number DOS–2023–0025.
- *Email: JExchanges@state.gov.* You must include RIN 1400–AF12 in the subject line of your message.
- All comments should include the commenter's name, the organization the commenter represents, if applicable, and the commenter's email address. If the Department of State is unable to read your comment for any reason, and cannot contact you for clarification, the Department of State may not be able to consider your comment.

FOR FURTHER INFORMATION CONTACT: Karen Ward, Director, Office of Private Sector Exchange Designation, Bureau of Educational and Cultural Affairs, U.S. Department of State, SA–5, 2200 C Street NW, Washington, DC 20522–0505. Telephone: 202–733–7852. Email: *DesignationAuPair@state.gov.*

SUPPLEMENTARY INFORMATION: On October 30, 2023, the Department of State published a Notice of Proposed Rulemaking for the Au pair category (88 FR 74071) (RIN 1400–AF12; Document ID DOS–2023–0025–0001). On November 6, 2023, the Department received a request from the Alliance for International Exchange (the Alliance), whose members represent a large percentage of Department of State-designated sponsors in the Au pair category, for a minimum 30-day extension of the public comment period of the Notice of Proposed Rulemaking. The Alliance requested a comment period extension given the many designated sponsors, exchange community host families, participants, and groups interested in filing comments and the number of issues addressed in the rule.

The Department of State has reviewed the request and has decided to extend the deadline. Therefore, the public comment period for the Notice of Proposed Rulemaking will now close on January 28, 2024.

Karen Ward,

Director, Office of Private Sector Exchange Designation, Bureau of Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 2023–26292 Filed 11–29–23; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0845]

RIN 1625–AA00

Safety Zone; Marina Del Rey, California

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to add two events to the table regarding ''Southern California Annual Firework Events for the Los Angeles Long Beach Captain of the Port zone.'' The proposed additions are temporary safety zones, one for the Marina Del Rey annual Boat Parade fireworks show and another for the Marina Del Rey New Year's Eve fireworks display. Entry into these safety zones would be prohibited during the annual events to provide for the safety of the waterway users and to keep them clear of potential harmful debris within the fallout zone.

DATES: Comments and related material must be received by the Coast Guard on or before December 15, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0845 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.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LCDR Kevin Kinsella, U.S. Coast Guard Sector Los Angeles-Long Beach; telephone (310) 521–3861, 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

On October 5, 2023, Los Angeles County notified the Coast Guard that it will be conducting its annual boat parade firework display on the second weekend in December, as well as its New Year's Eve fireworks display on December 31st each year. In both events, the fireworks will be launched from Marina Del Rey's South Jetty that runs between Ballona Creek and the entrance to Marina Del Rey, CA. Hazards from the fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector Los Angeles-Long Beach (COTP) has determined that potential

hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 1,000-foot radius of the pyrotechnics platform. The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 1,000-foot radius of the fireworks platform before, during, and after the scheduled annual event for this year and future years. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034. In addition, the Coast Guard is providing a shorter than usual comment period to obtain public input before the upcoming annual display for the 2023 season. The Coast Guard will use the input to determine if any changes are needed to the safety zones for these fireworks events.

III. Discussion of Proposed Rule

The COTP is proposing to amend the current Table 1 to 33 CFR 165.1125 for Southern California Annual Firework Events for the Los Angeles-Long Beach Captain of the Port zone. The proposed amendment adds two events to Table 1. The temporary safety zones will take place annually in the Marina Del Rey Harbor Channel Entrance for approximately two hours each on the second weekend in December and on New Year's Eve, December 31st. The temporary safety zones would cover all navigable waters within a 1,000-feet radius of the discharge area on the Marina Del Rey South Jetty located in position 33°57′45″ N/118°27′21″ W. The duration of the zones is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks displays. 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, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit around this safety zone before and after the Firework displays, which would impact the entrance of Marina Del Rey and Ballona Creek for less than a 2-hour window during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

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 two safety zones lasting two hours each that would prohibit entry within 1,000 feet of a fireworks display. Normally such actions are categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

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

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–2023–0845 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. In § 165.1125, amend Table 1 to § 165.1125 by adding an entry for items 14 and 15 to read as follows:

§ 165.1125 Southern California Annual Firework Events for the Los Angeles Long Beach Captain of the Port zone.

* * * * *

TABLE 1 TO § 165.1125

* * * * * * *

14. Holiday Fireworks, Los Angeles County	
Sponsor	Los Angeles County, CA.
Event Description	Fireworks Display.
Date	Second weekend in December.
Location	Marina Del Ray, CA.
Regulated Area	1,000-foot radius zone around the firework display located approximately: 33°57′45″ N, 118°27′21″ W on the Marina Del Rey South Jetty.

15. New Years Eve Fireworks, Los Angeles County	
Sponsor	Los Angeles County, CA.
Event Description	Fireworks Display.
Date	December 31.
Location	Marina Del Rey, CA.
Regulated Area	1,000-foot radius zone around the firework display located approximately: 33°57′45″ N, 118°27′21″ W on the Marina Del Rey South Jetty.

Dated: November 23, 2023.

R.D. Manning,

Captain, U.S. Coast Guard, Captain of the Port Sector Los Angeles-Long Beach.

[FR Doc. 2023–26341 Filed 11–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, and 173

[Docket No. PHMSA–2020–0103 (HM–257A)]

RIN 2137–AF50

Hazardous Materials: Streamlining Requirements for the Approval of Certain Energetic Materials

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: PHMSA proposes to amend the Hazardous Materials Regulations to revise the classification and approval process for certain low-hazard fireworks; to revise classification criteria for small arms cartridges to include tracer ammunition; to include the PHMSA portal as the method to submit applications for all explosives approvals; and to allow for voluntary termination of an explosive approval by the approval holder.

DATES: Comments must be submitted by February 28, 2024. PHMSA will consider late-filed comments to the extent possible.

ADDRESSES: You may submit comments by identification of the docket number (PHMSA–2020–0103 [HM–257A]) by any of the following methods:

Federal Rulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management System, U.S. Department of Transportation, Docket Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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FOR FURTHER INFORMATION CONTACT: Mr. Eugenio Cardez, Transportation Specialist, Standards and Rulemaking Division, Office of Hazardous Materials Safety, 202–366–8553, 1200 New Jersey Avenue SE, Washington, DC 20590.

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I. Background

The pyrotechnic industry is a global logistics supply chain comprised of mostly foreign fireworks manufacturers and domestic importers, retailers, distributors, carriers, and consumers. Fireworks are a Class 1 explosive material in accordance with the Hazardous Materials Regulations (HMR; 49 Code of Federal Regulations (CFR) parts 171–180). Class 1 explosives are divided into six divisions based on their explosion hazard: 1.1, 1.2, 1.3, 1.4, 1.5, and 1.6. PHMSA proposes to amend the classification and approval process of certain low-hazard fireworks of Division 1.4G. As defined in § 173.50 of the HMR, Division 1.4 consists of explosives that present a minor explosion hazard. Division 1.4 explosives have explosive effects that are largely confined to the package; no projection of fragments of appreciable size or range is to be expected; and an external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. Explosives are assigned compatibility codes used to specify the controls for the transportation, and storage related thereto, of explosives and to prevent an increase in hazard that might result if certain types of explosives were stored or transported together. Explosives assigned a ''G'' code are not limited to fireworks and may also be defined as pyrotechnic substances or articles containing a pyrotechnic substance, or articles containing both an explosive substance and an illuminating, incendiary, tear-producing or smoke-producing substance.

Subpart C of part 173 details requirements for the classification and packaging of Class 1 explosive materials and specifies that explosives, including fireworks, must be approved and assigned an explosives approval number —*i.e.,* an EX number—by PHMSA, based on actual testing and classification, prior to transportation to, from, and within the United States. Section 173.64 permits Division 1.3G and 1.4G fireworks to be approved without prior examination based on certain conditions, including compliance with the provisions of the 2018 American Pyrotechnic Association (APA) Standards 87–1A, 1B, and 1C,

which are incorporated by reference in § 171.7.[1] Further, § 173.65 permits—in lieu of an approval—Division 1.4G consumer fireworks (as defined in § 171.8) to be certified by a DOT-approved Fireworks Certification Agency (FCA). After the FCA reviews the consumer fireworks application and certifies it meets the requirements, the FCA assigns an FC number in place of an EX number for Division 1.4G consumer fireworks.

All fireworks transported to, from, and within the United States must be approved by PHMSA or certified by an FCA. The current approval process requires PHMSA personnel to conduct a multi-step review of each application, which includes accepting an application, entering application data into a database; reviewing the application for completeness and compliance with the APA standard; drafting the final action letter; conducting the final review; and signing and issuing the final approval. PHMSA estimates its review process takes about two hours per application, for an estimated 425 labor hours annually. PHMSA provides approvals free of charge as a public service to manufacturers. However, manufacturers have the option to use commercial FCAs for Division 1.4 consumer fireworks, which certify products for a fee, and may process approvals faster. See the preliminary regulatory impact analysis (PRIA) in the docket for this rulemaking for additional information.[2]

A. Low Hazard Fireworks

Low hazard fireworks refer to a group of explosive articles that are not designed to leave ground level, contain no aerial components, and contain less than 100 grams of chemical composition per tube. These devices have a minimal and well-understood hazard as explosives. Specifically, low hazard fireworks can only be manufactured using chemicals from the ''Permitted and Restricted Chemical Table for Consumer Fireworks and Novelties,'' [3] and reports [4] are restricted to 50 milligrams of report composition. The European community conducted extensive fireworks testing prior to the development of the United Nations (UN) default fireworks table. The devices proposed under this rulemaking for classification as Division 1.4G fireworks are consistent with the UN default table, as well as 30 years of classification experience under the APA standards.

Low hazard fireworks include ground and novelty firework devices, as currently listed in the 2018 APA Standard 87–1A.

Ground Devices

The 2018 APA Standard 87–1A defines ''ground device'' as a device designed to produce its effects at or near ground level. The following 17 individual ground devices are defined as low hazard fireworks and may be approved or certified for transportation in accordance with the HMR provided they meet the requirements for construction, formulation, and packaging: Chaser, Crackling Ball, Crackling Strip, Crackling Tube, Firecracker, Flasher/Strobe, Flitter Sparkler, Fountain Cone, Fountain Cylindrical, Fountain Nitrocellulose, Ground Spinner, Illuminating Torch, Smoke, Snake, Specialty Device, Wheel, and Wire Sparkler or Dipped Stick.

Ground devices meeting the provisions of the 2018 APA Standard 87–1A are classified and described as ''UN0336, Fireworks, Division 1.4G.'' Currently, ground devices are either approved by PHMSA personnel or certified by an FCA upon completion of a multi-step review of each application. PHMSA proposes streamlining the approval or certification process of these fireworks by allowing self-certification using an online application in the PHMSA portal with an automated process for review and issuance of a certification. This automated process may be used for the low hazard fireworks identified in this rule in lieu of the current process and would no longer require PHMSA or FCA personnel to conduct time-consuming reviews of each application or impose a cost on manufacturers who opt to use a FCA to certify these fireworks. Manufacturers of fireworks that meet the required criteria for the construction, formulation, and packaging of these ground devices—specifically discussed in Section II: Proposed Amendments—would certify compliance with specified conditions and limitations online and receive a certificate with a unique identifier number (*i.e.,* FW number) for each firework type. The online system will provide immediate comparison of the technical information provided against the criteria established for low hazard fireworks. Because of the low hazard associated with these fireworks, and because we maintain oversight through PHMSA's Quality Assurance and Quality Control (QA/QC) review program [5] of applications submitted through the PHMSA portal, PHMSA believes the current safety level for transport of these fireworks will be maintained when using this process for certification of eligible ground device fireworks.

Multi-tube devices, such as cake and combination fireworks devices, are excluded from this rulemaking. PHMSA is not proposing that multi-tube devices be allowed to be self-certified via the PHMSA portal at this time; however, manufacturers will still use the PHMSA portal for submitting an application for the standard explosive approval.

Novelty Devices

In 1995, PHMSA issued ''Guidance and Criteria for Fireworks Novelties,'' which sought to resolve confusion regarding novelty devices (*i.e.,* novelties) and PHMSA's explosives regulations. The guidance document was later reissued under the same name in 2005 and 2015, with only editorial changes. The current version [6] includes five novelties that—when shipped domestically by ground, rail, or vessel—may be transported as not regulated as explosives when manufactured in accordance with the provisions outlined for each type of device as specified in the 2001 APA Standard 87–1. The 2018 APA Standard 87–1A includes two additional novelties that may be excluded from HMR requirements—for a total of seven novelties for consideration for approval or certification for transportation as not subject to further regulation in accordance with proposed changes to the HMR, provided they meet the conditional requirements for construction, formulation, packaging, and transportation mode. The seven novelties are Booby Trap/Pull Apart, Novelty Flitter Sparkler, Party Popper, Novelty Snake, Snapper, Novelty Wire Sparkler or Novelty Dipped Stick, and Novelty Smoke Device. However, when these novelties are prepared for

[1] The 2018 APA Standards 87–1A, 1B, and 1C were incorporated by reference in the Hazardous Materials: Adoption of Miscellaneous Petitions To Reduce Regulatory Burdens Final Rule. 85 FR 75680 (Nov. 25, 2020). *See https://www.federalregister.gov/documents/2020/11/25/2020-23712/hazardous-materials-adoption-of-miscellaneous-petitions-to-reduce-regulatory-burdens.*

[2] The PRIA is available in the regulatory docket (Docket ID: PHMSA–2020–0103) at *www.regulations.gov.*

[3] *https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2021-09/2018%20APA%2087-1%20A.pdf.*

[4] Report: A concussive effect and flash of light produced by the ignition of a chemical composition.

[5] The PHMSA QA/QC Low Hazard Fireworks Review Program is currently under development while completing development of the electronic process, and when finalized will be similar to the PHMSA Fireworks FCA QA/QC Review Program.

[6] *See* ''Guidance and Criteria for Fireworks Novelties,'' available at: *https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/approvals-and-permits/hazmat/energetic-materials-approvals/57711/inalguidancefandcriteriaforfireworksnoveltydevices03192015.pdf.*

transportation by air, they must be classified and described as ''UN3178, Flammable solid, inorganic, n.o.s. (novelties)'' and shipped in accordance with requirements of the HMR.

A PHMSA approval or FCA certification is not required for novelties manufactured in accordance with the provisions outlined for each type specified in the APA standards when transported domestically by ground, rail, or vessel, but this exception is only applicable within the United States and its territories. PHMSA proposes to authorize the use of the automated self-certification process to enable the manufacturer to receive a certificate for use with international transportation. Manufacturers of novelties meeting the required criteria for the construction, formulation, and packaging of these devices would certify compliance with specified conditions and limitations online and receive a certificate with a unique identifier (defined as an ''FW number'') for each firework type, in the same manner proposed for ground devices.

There have been no systemic safety issues or safety concerns involving shipments of novelties that meet the requirements of both the APA standards and PHMSA's guidance memo. The history of safe shipments helps demonstrate that the proposed amendment will not have an adverse effect on safe transportation of these fireworks. Rather, the proposed changes ++in this NPRM will codify existing guidance to promote increased regulatory clarity and consistency, which will—at a minimum—maintain the current level of safety. Publication of a final rule will supersede previously issued guidance on this matter.

B. Tracer Ammunition

Section 173.56(h) authorizes self-classification of certain types of small arms cartridges into Division 1.4S, provided certain conditions are met. Explosives assigned an ''S'' code are defined as substances or articles so packed or designed that any hazardous effects arising from accidental functioning are limited to the extent that they do not significantly hinder or prohibit firefighting or other emergency response efforts in the immediate vicinity of the package. In particular, § 173.56(h)(3) specifies a condition that the ammunition has an inert projectile or is blank. However, the current criteria is silent on whether this ammunition includes tracer ammunition. Tracer ammunition utilizes a small amount of a pyrotechnic charges at the base or as coating of the projectile to make the trajectory of the projectile visible to the naked eye. As such, considering the § 173.56(h)(3) condition, affected entities have expressed uncertainty whether tracer ammunition is considered inert and, therefore, qualifies for the exception in paragraph (h). PHMSA considers the small amount of pyrotechnic charge as a negligible quantity of explosive material compared to the quantity of propelling charge contained within the cartridge itself, and this small amount of pyrotechnic charge at the base of or coated on the projectile does not increase the hazard in a bonfire test nor make unintentional initiation any more likely. In this rulemaking, PHMSA is considering allowing tracer ammunition to be eligible for self-classification as a Division 1.4S material provided all criteria outlined in § 173.56(h) are met.

C. Changes to the Approval Process

Currently, as part of the Hazardous Materials Program Procedures, in 49 CFR 107.705, the approval process for submitting applications includes mail, email, or fax. Although not explicitly stated, PHMSA also accepts applications for approvals submitted through the PHMSA portal.[7] PHMSA proposes to amend 49 CFR 107.705 to add the PHMSA portal to the current options to submit all types of approval applications, and to specify that use of the PHMSA portal will be the only option to submit explosives approval applications and to self-certify manufacture of low hazard fireworks. To be clear, PHMSA proposes that from the effective date of a published final rule, persons will no longer be able to submit explosives approval applications by mail, email, or fax and must use the PHMSA portal. PHMSA believes efficiencies will be gained by moving to an electronic only service. The PHMSA portal provides the public online access to PHMSA services, creating a single source for Hazardous Materials and Pipeline Safety applications and data. Persons need only to register to create an account to access and use the portal. Further discussion is provided in ''Section II.C.''

Furthermore, 49 CFR 107.713 describes the process for the modification, suspension, and termination of approvals. As currently prescribed in 49 CFR 107.713(c), before an approval is modified, suspended, or terminated, PHMSA must provide approval holders an opportunity to show cause why the proposed action should not be taken. PHMSA proposes to add a new paragraph (e) to allow approval holders to request termination of approvals, and to revise paragraph (c) to clarify that when an approval holder voluntarily seeks to terminate an approval, PHMSA is not required to issue a show cause letter.

II. Incorporation by Reference Discussion Under 1 CFR Part 51

According to the Office of Management and Budget (OMB), Circular A–119, ''*Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,*'' government agencies must use voluntary consensus standards wherever practical in the development of regulations.

PHMSA currently incorporates by reference into the HMR all or parts of numerous standards and specifications developed and published by standard development organizations (SDO). In general, SDOs update and revise their published standards every two to five years to reflect modern technology and best technical practices. The National Technology Transfer and Advancement Act of 1995 (NTTAA; Pub. L. 104–113) directs Federal agencies to use standards developed by voluntary consensus standards bodies in lieu of government-written standards whenever possible. Voluntary consensus standards bodies develop, establish, or coordinate technical standards using agreed-upon procedures. OMB issued Circular A–119 to implement section 12(d) of the NTTAA relative to the utilization of consensus technical standards by Federal agencies. This circular provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. Accordingly, PHMSA is responsible for determining which standards currently referenced in the HMR should be updated, revised, or removed, and which standards should be added to the HMR. Revisions to materials incorporated by reference in the HMR are handled via the rulemaking process, which allows for the public and regulated entities to provide input. During the rulemaking process, PHMSA must also obtain approval from the Office of the Federal Register to incorporate by reference any new materials. The Office of the Federal Register issued a rulemaking[8] that

[7] The PHMSA portal is available online at *https://portal.phmsa.dot.gov/phmsapub/faces/PHMSAHome;PHMSAPUB_SESSIONID=aHhG4dIf1U0E2nq599uvQ-RWl3nzKlgWsLSOcwxPNzx1te7cDD3R!883673165?req=-3710157719365173927&attempt=0&_afrLoop=1686827584595767&_afrWindowMode=0&_afrWindowId=null&_adf.ctrl-state=ns6jrdcpu_1.*

[8] 79 FR 66278 (Nov. 7, 2014).

revised 1 CFR 51.5 to require that an agency detail in the preamble of an NPRM the ways the materials it proposes to incorporate by reference are reasonably available to interested parties, or how the agency worked to make those materials reasonably available to interested parties.

The following standards appear in the regulatory text of this NPRM and have already been approved for the locations in which they appear: (1) APA 87–1A: Standard for the Construction, Classification, Approval and Transportation of Consumer Fireworks; (2) APA 87–1B: Standard for the Construction, Classification, Approval, and Transportation of Display Fireworks; and (3) APA 87–1C: Standard for the Construction, Classification, Approval, and Transportation of Entertainment Industry and Technical Pyrotechnics. No changes to these standards are proposed in this NPRM.

III. Proposed Amendments

To streamline procedural requirements for fireworks manufacturers and shippers, PHMSA proposes changes to the regulations relating to PHMSA's explosives approval program specific to fireworks. PHMSA also proposes changes to the HMR to address classification and packaging inconsistencies for tracer ammunition. PHMSA will continue to use the current approval process for Division 1.4G consumer fireworks in accordance with requirements specified in §§ 173.56(b), (f), or (i), and 173.65. However, instead of the current approval process, PHMSA proposes to permit manufacturers to self-certify classification of certain ground and novelty device fireworks using the PHMSA portal, as discussed previously and further below. Furthermore, PHMSA proposes to revise the self-classification of inert projectile cartridges in § 173.56(h) to include tracer ammunition; amend 49 CFR 107.705 to require use of the PHMSA portal as the only submittal option for explosives approval applications; and amend 49 CFR 107.713 to clarify that an approval holder may voluntarily terminate an approval and that a show cause letter from PHMSA is unnecessary when approval holders request to terminate approvals voluntarily.

In the PRIA supporting this rulemaking, PHMSA determined that the aggregate benefits of the amendments proposed justify their aggregate costs. If adopted in a final rule, the amendments proposed herein are expected to reduce the paperwork burden on the regulated community and PHMSA personnel since fewer paper-based explosives approval applications will be submitted and processed. The overall net benefits include a cost savings of 425 labor hours annually. See the PRIA for additional information. These cost savings will not have a material effect on the safety impact of PHMSA's explosives approval program.

A. Establishing Exceptions for Ground and Novelty Device Fireworks

PHMSA proposes to revise § 173.64 to outline the exceptions for ground and novelty device fireworks. Specifically, for certain low hazard fireworks of these types, the section would authorize exception from the standard explosive device approval process for classification of Division 1.4G fireworks. These exceptions would be implemented by establishing an automated process within the PHMSA portal for self-certification, review of the information provided, and issuance of a certificate with a unique identification (*i.e.,* FW number). This process may be used for the ground and novelty devices identified in this rulemaking in lieu of the current explosive approval process. PHMSA personnel would no longer be required to conduct a time-consuming review of each application. The automated review process will require the same information as currently required by the HMR. However, the diagram of the device and chemical formulation sheets will not require firsthand review by PHMSA personnel when compliance is certified by the applicant. PHMSA believes this proposed change is consistent with our Agency mission to protect the health and safety of the public and the environment, and consistent with Executive Order 12866 [9] that in part calls for agencies to examine existing regulations and identify and assess available alternatives to direct regulation. In this case, the current regulations to ensure the safe transport of explosives require explosives—such as fireworks—to be examined, classed, and approved by PHMSA; and further that certain fireworks manufactured according to APA 87–1A may be certified for transportation by a DOT-approved FCA instead. PHMSA believes that upon examination of the existing regulation and in consideration of the low safety hazard associated with certain ground and novelty devices, this proposal to streamline the process authorizing their manufacture and transport by self-certification benefits the public. PHMSA proposes that self-certification will introduce efficiencies and maintain the safety of transporting these fireworks under the HMR. To correspond to the changes proposed in this NPRM, PHMSA proposes to add a definition for ''low hazard firework'' to § 173.59.

[9] 58 FR 51735 (Oct. 4, 1993).

Ground Devices

PHMSA proposes that ground device fireworks certified using the PHMSA portal as conforming to the construction, formulation, and packaging requirements in revised § 173.64, will be authorized for transport as ''UN0336, Fireworks, 1.4G.'' Seventeen ground devices will be eligible for this new certification process: Chaser, Crackling Ball, Crackling Strip, Crackling Tube, Firecracker, Flasher/Strobe, Flitter Sparkler, Fountain Cone, Fountain Cylindrical, Fountain Nitrocellulose, Ground Spinner, Illuminating Torch, Smoke, Snake, Specialty Device, Wheel, and Wire Sparkler or Dipped Stick. Multi-tube devices,[10] such as cake and combination devices, are excluded from eligibility for certification using the automated process.

PHMSA proposes specific criteria for manufacturing (construction and formulation) and packaging of these ground devices. The fireworks would be subject to both general and specific requirements as presented below in the table of Proposed Criteria for Ground Devices. The proposed general requirements for ground devices are as follows:

- Devices must use chemicals in conformance with the permitted and restricted chemical table in the edition of APA Standard 87–1A, Appendix 1, incorporated by reference in § 173.64. The 2018 edition of the standard is currently incorporated by reference. Note that all chemical specifications in the table are maximum limits.
- All reports are limited to 50 mg (0.050 g) of composition per report.
- All devices are initiated by a safety fuse with the exception of firecrackers, flitter sparklers, nitrocellulose fountains, snakes, wire sparklers, or dipped sticks.
- All devices must be finished (they cannot be a component intended to be used in another device).
- All devices must successfully pass a thermal stability test as specified in § 173.64(a)(2).
- Each device must be marked with the alphanumeric PHMSA-assigned certification number (''FW number'') consisting of the letters FW, followed by

[10] Multi-tube devices are devices with more than one tube that contains fireworks (*i.e.,* pyrotechnic effects).

the year and month issued, and a sequential number based on order of issuance that year (*e.g.,* FWYYYYMMSSSS). If the device is too small, the package that contains the device must display the certification number.

The specific requirements for each of the 17 eligible ground device types are as follows:

PROPOSED CRITERIA FOR GROUND DEVICES

Device	Definition	Specification [11]	Special conditions
Chaser	Consists of a paper or cardboard tube, which vents out the fuse end of the tube.	20 total grams of chemical composition, with multiple reports permitted.	None.
Crackling Ball	Consists of a spherical ball that contains small granules of chemical composition that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Crackling Strip	Consists of small granules of chemical composition adhered to and encased in a paper or cardboard wrapping that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Crackling Tube	Consists of a tube that contains small granules of chemical composition that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Firecracker	Consists of a small paper-wrapped or cardboard tube that produces a single report.	50 milligrams of chemical composition per firecracker.	Multiple firecrackers can be fused together to form a string. There is no limit on number of firecrackers in a string.
Flasher/Strobe	Consists of a paper-wrapped or cardboard tube that produces a crackling/flashing/strobing light effect.	5 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 60 grams of composition.
Flitter Sparkler	Consists of a paper or cardboard tube attached to a stick or wire. Upon ignition, the device produces a shower of sparks, a colored flame and/or a crackling effect.	25 total grams of chemical composition, with no reports permitted.. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulations being chlorates.	None.
Fountain (Cone)	Consists of a conical paper or cardboard container that upon ignition produces a shower consisting of any combination of colored sparks, color flame, crackle, smoke, whistle and/or micro star effects.	50 total grams of chemical composition, with no reports permitted.	None.
Fountain (Cylindrical)	Consists of a paper or cardboard tube that upon ignition produces a shower consisting of any combination of colored sparks, color flame, crackle, smoke, and whistle or micro star effects.	100 total grams of chemical composition, with no reports permitted.	None.
Fountain (Nitrocellulose)	Consists of a paper or cardboard cone or tube device that produces a shower of small sparks, color, and flame as its primary effect using nitrocellulose as the major chemical component.	15 total grams of chemical composition, with no reports permitted.	None.
Ground Spinner	Consists of a paper or cardboard tube that upon ignition emits a shower of colored sparks that vents out of an orifice, causing the device to spin rapidly on the ground.	20 total grams of chemical composition, with reports permitted.	Multiple ground spinners can be fused together to form a string. Strings are limited to 20 grams of total composition.
Illuminating Torch	Consists of a paper or cardboard tube that upon ignition, emits a colored flame with or without crackles or sparks.	100 total grams of chemical composition, with no reports permitted.	None.

PROPOSED CRITERIA FOR GROUND DEVICES—Continued

Device	Definition	Specification [11]	Special conditions
Smoke	Consists of a paper or cardboard tube that upon ignition, emits smoke as the primary effect.	100 total grams of chemical composition. All mixtures containing a chlorate must contain an equal amount or greater amount of a carbonate or bicarbonate.	Multiple smoke devices can be fused together to form a string. Strings are limited to 100 grams of total composition.
Snake	Consists of pressed pellet of pyrotechnic composition that upon ignition, produces a snake-like ash that expands in length as the composition is consumed.	20 total grams of chemical composition, with no reports. Only formulations of nitrated asphalt, asphaltum, bitumen, pitch, and/or tar with an oxidizer (with or without a binder) are permitted.	None.
Specialty Device	Consists of a paper or cardboard tube(s), *e.g.,* in the shape of an animal or a small vehicle, that produces multiple effects.	20 total grams of chemical composition, with reports permitted.	No tube can contain more than 2 grams of composition; tubes cannot contain aerial components or internal shells.
Wheel	Consists of a paper or cardboard tube placed on the ground or attached to a post, by means of a nail, spike, or string. Upon ignition, the wheel rotates producing a shower of sparks, color, crackling, flame, or whistle effects.	200 total grams of chemical composition, with no reports. No tube can contain more than 60 total grams of composition, which includes a 20 gram propellant limit per tube. Tubes cannot contain aerial components. Handles are not permitted.	None.
Wire Sparkler or Dipped Stick	Consists of a metal wire or wood dowel coated with a chemical composition. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	100 total grams of chemical composition, with no reports permitted. Formulations containing chlorates are limited to four grams with no more than 15 percent of the formulations being chlorates.	Inner packaging cannot exceed 120 grams of composition.

Currently, manufacturers may submit low hazard fireworks approvals through the PHMSA portal, email, or mail, although all applications in the past several years have been through the PHMSA portal. A manufacturer follows a multi-step process to receive a certificate using PHMSA's automated process for review of low hazard fireworks. First, the applicant must register with PHMSA to create an account to use the PHMSA portal and provide the following contact information: company name, contact person, title, address, phone, and email address; manufacturing location; and U.S. agent (if applicable), address, phone, and email Address. A unique profile is created for each applicant based on their email address, which allows repeated access. If already registered with the PHMSA portal, persons must ensure all necessary information is provided to allow for self-certification. Applicants are required to create complex passwords in accordance with DOT's password requirements.

[11] This column describes the chemical composition weight limits per tube and whether reports are permitted.

Then, the applicant must provide specific information about a device and certify the construction, chemical composition, and packaging are in accordance with the HMR. This step requires the applicant to respond to the following questions:

- What is the name and/or product code of the device? (Must be unique.)
- What is the category of the ground device? (There will be a drop down menu with the 17 authorized ground devices.)
- What is the maximum weight in grams of chemical composition in the device?
- Does the device contain a report? (List how many reports.)
- What is the maximum weight in milligrams of any single report in the device?
- What is the total report weight in milligrams in the device?
- Did the device pass a thermal stability test?
- Does the device comply with the Permitted and Restricted Chemicals Table found in the APA Standard 87–1A, Appendix 1, currently incorporated by reference in § 173.64?
- Does the device use a safety fuse for ignition?
- Does the device meet one of the descriptions listed in § 173.64?
- Do you certify the device will be manufactured and transported in accordance with all the statements you attested to above?

Finally, the chemical composition and diagram of the ground device must be entered into and uploaded to the PHMSA portal. A certificate will be issued for each device following the successful completion of the process. The certificate will contain the unique alphanumeric certification number described above.

Novelty Devices

Similarly, PHMSA proposes that novelty devices (*i.e.,* novelties) certified using the PHMSA portal as conforming to the construction, formulation, and packaging requirements in revised § 173.64 will be authorized for transport and not subject to further regulation except for air transport. Although these novelty devices are considered Division 1.4 fireworks, consistent with the guidance discussed in Section I.A and as a condition for self-certification, novelty devices will be classed for transport as ''UN3178, Flammable solid, inorganic, n.o.s. (Novelties), 4.1, PG II,'' when transported internationally or by

air. Seven novelties will be eligible for this new certification process: Booby Trap/Pull Apart, Novelty Flitter Sparkler, Party Popper, Novelty Snake, Snapper, Novelty Wire Sparkler or Novelty Dipped Stick, and Novelty Smoke Device. Therefore, manufacturers may receive a certification for international transportation when it is required. Consistent with the 2015 guidance document, PHMSA considers certain novelties—identified in this NPRM as excepted from further regulation—as explosives under the HMR, subject to certain transportation conditions. However, PHMSA acknowledges that this exception is unique to the United States and complicates transportation of these fireworks into or out of the United States. Therefore, to facilitate international transportation of novelties, PHMSA proposes to issue a unique identifier number (FW number) as part of the automated self-certification process. This process facilitates the certification process and movement of novelty devices outside of the United States where they are classified the same way but not offered the same exceptions.

Novelties must comply with both the general and specific requirements for manufacture and packaging as provided in the table of Proposed Criteria for Novelties. The proposed general requirements for novelty devices are as follows:

- Devices that do not list specific chemical restrictions must use chemicals in conformance with the permitted and restricted chemical table in the APA Standard 87–1A, Appendix 1, incorporated by reference in § 173.64. The 2018 edition is currently incorporated by reference. Note that all chemical specifications in the table are maximum limits.
- No reports are permitted in novelties.
- Smoke devices must be initiated by a fuse.
- Devices must be finished and packaged in the inner packagings.
- All novelties must successfully pass a thermal stability test specified in § 173.64(a)(2).
- Each device must be marked with the alphanumeric PHMSA-assigned certification number (FW number), followed by the year and month issued, and a sequential number based on order of issuance that year (*e.g.,* FWYYYYMMSSSS). If the device is too small, the package that contains the device must display the certification number.

The specific requirements for each of the seven novelty types is as follows:

PROPOSED CRITERIA FOR NOVELTIES

Novelty	Definition	Specifications	Special conditions
Booby Trap/Pull Apart	Device that is actuated by means of friction. Pulling a string or strings apart activates the device, producing a noise effect.	0.016 total grams of chemical composition, which is limited to barium, potassium, and/or sodium chlorate with red phosphorus.	Inner packages must not contain more than 12 devices.
Novelty Flitter Sparkler	Consists of a paper or cardboard tube attached to a stick or wire. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	5 total grams of chemical composition, with no reports permitted. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulation being chlorates.	Inner packages must not contain more than 8 devices, and an ignition fuse is permitted.
Party Poppers	Device that is actuated by means of friction. Pulling a string or trigger activates the device, producing a noise effect and releasing paper streamers or confetti. Common examples resemble champagne bottles and toy pistols.	0.016 total grams of chemical composition, which is limited to barium, potassium, and/or sodium chlorate with red phosphorus.	Inner packages must not contain more than 72 devices.
Novelty Snakes and Glow-Worms	Consists of pressed pellet of pyrotechnic composition that upon ignition, produce a snake-like ash that expands in length as the composition is consumed.	2 total grams of chemical composition. Only formulations of nitrated asphalt, asphaltum, bitumen, pitch, and/or tar with an oxidizer (with or without a binder) are permitted.	Inner packaging must not contain more than 25 devices
Snappers	Consists of small, paper-wrapped items. When dropped, the device activates, producing a noise effect.	0.001 total grams of silver fulminate coated on small bits of sand or gravel.	Inner packages must not contain more than 50 devices with sawdust or other impact absorbing materials.
Novelty Wire Sparkler or Novelty Dipped Stick.	Consists of a metal wire or wood dowel coated with a chemical composition. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	25 total grams of chemical composition, with no reports permitted. Formulations containing perchlorates are limited to 5 grams. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulations being chlorates.	Inner packages must not contain more than 8 devices.

PROPOSED CRITERIA FOR NOVELTIES—Continued

Novelty	Definition	Specifications	Special conditions
Novelty Smoke Device	Consists of a paper or cardboard tube that upon ignition, emits smoke as the only effect.	5 total grams of chemical composition, with no reports permitted. All mixtures containing a chlorate must contain an equal amount or greater amount of a carbonate or bicarbonate (e.g. calcium carbonate, sodium bicarbonate).	Inner packages must not contain more than 72 devices.

Novelties must be in inner packagings that must be further packed in strong outer packagings. The packages must conform to the requirements of § 173.24. The maximum gross weight of a completed package may not exceed 30 kilograms (66 pounds). Additionally, each outer package, and an overpack if used, must be plainly marked with ''NOVELTIES, IN CONFORMANCE WITH § 173.64, NOT REGULATED, EXCEPT WHEN TRANSPORTED BY AIR.'' When novelties are transported by air, they must be classed and described as ''UN3178, Flammable solid, inorganic, n.o.s. (Novelties), 4.1, PG II,'' and packaged for transport accordingly.

Similar to ground devices, an applicant will follow a multi-step process to self-certify using PHMSA's automated process for review of low hazard fireworks. First, the applicant must register with PHMSA to create an account for use of the PHMSA portal and provide the following contact information: company name, contact person, title, address, phone, and email address; manufacturing location; and U.S. agent (if applicable), address, phone, and email address. A unique profile is created for each applicant based on their email address, which allows repeated access. If already registered with the PHMSA portal, persons must ensure all necessary information is provided to allow self-certification. Applicants are required to create complex passwords in accordance with DOT's password requirements.

Then, the applicant must provide the specific information about a novelty and certify that the construction, chemical composition, and packaging are in accordance with the HMR. This step requires the applicant to respond to the following questions:

- What is the name and/or product code of the device? (Must be unique.)
- What is the category of the novelty? (There will be a drop-down menu with the seven authorized novelties.)
- What is the maximum weight in grams of chemical composition in the device?
- Did the device pass the thermal stability test described in 49 CFR 173.64(a)(2)?
- Does the device comply with the Permitted and Restricted Chemicals Table found in the APA Standard 87–1A, Appendix 1, currently incorporated by reference in § 173.64?
- Does the novelty comply with the specific restrictions listed in the Table of Authorized Novelty Devices and Specifications?
- Does the device use a safety fuse for ignition?
- Does the novelty meet a device description listed in § 173.64?
- Do you certify the device will be manufactured and transported in accordance with all the statements attested to above?

Finally, the chemical composition and diagram must be entered into and uploaded to the PHMSA portal. A certificate will then be issued for each novelty following the successful completion of the process. The certificate will contain the unique alphanumeric certification number described above. The certificate will indicate the description and classification of the device as ''UN3178, Flammable solid, inorganic, n.o.s. (Novelties), 4.1, PG II'' for international transportation and domestic air transportation, and that it is not regulated as a Class 1 explosive when transported domestically by vessel, highway, or rail.

Fireworks Identification Scheme

As a baseline, fireworks must be approved and assigned an explosives approval number by PHMSA (EX number) based on actual testing and classification prior to transportation to, from, and within the United States. However, § 173.64 permits Division 1.3G and 1.4G fireworks to be approved without prior examination based on certain conditions, including compliance with the provisions of the 2018 APA Standards 87–1A, 1B, and 1C, which are incorporated by reference in § 171.7. Further, § 173.65 permits—in lieu of an approval—Division 1.4G consumer fireworks (as defined in § 171.8) to be certified by a DOT-approved FCA. After the FCA reviews the consumer fireworks application and certifies it meets the requirements, the FCA assigns an FC number.

However, in this NPRM, PHMSA is proposing to streamline the process for approval or certification of low hazard fireworks by allowing self-certification using an online application in the PHMSA portal with an automated process for review and issuance of a certification. This automated process may be used for the low hazard fireworks identified in this rulemaking in lieu of the current process and would no longer require PHMSA or FCA personnel to conduct time-consuming reviews of each application or impose a cost on manufacturers who opt to use an FCA to certify these fireworks. Manufacturers of fireworks that meet the required criteria for the construction, formulation, and packaging of these low hazard fireworks—specifically discussed in Section II. Proposed Amendments—would certify compliance with specified conditions and limitations online and receive a certificate with a unique identifier number (FW number) for each firework type. The FW number will identify a low hazard firework that has been certified through the newly proposed automated approval process as specified in § 173.64. An example of an FW number would be ''FW2023100001'' consisting of the letters FW, followed by the year and month issued, and a sequential number based on order of issuance that year.

Given the long history and wide recognition of the EX and FC numbering scheme, PHMSA seeks specific comments on the supply chain implications, the economic impact and safety concerns associated with the proposed FW numbering system, as well as comments on how to implement the changes if they are adopted. For example, will the use of different alpha designators (*i.e.,* EX, FC and FW) pose complications or confusion within the

transportation system? If so, please provide a suggested alternative to FW.

B. Authorizing the Self-Classification of Tracer Ammunition

Section 173.56(h) authorizes self-classification of certain types of small arms cartridges into Division 1.4S, provided certain conditions are met. In particular, § 173.56(h)(3) authorizes ammunition with inert projectile or blank ammunition. Tracer ammunition utilizes a small amount of pyrotechnic composition to provide visible light upon exit from a gun barrel. Due to the presence of the pyrotechnic composition, it is unclear whether tracer ammunition would qualify as an ''inert'' projectile. However, there is a negligible quantity of pyrotechnic composition in tracer ammunition compared to the quantities of pyrotechnic material contained within the projectile itself, and its presence neither increases the hazard in a bonfire test nor makes unintentional initiation any more likely.

The difference in hazard between inert projectile cartridges and the same cartridges with a small amount of pyrotechnic composition is negligible. Furthermore, there are no additional concerns related to tracer ammunition that justify exclusion from the self-classification provision of § 173.56(h)(3). Therefore, PHMSA proposes to amend § 173.56(h)(3) to also authorize self-classification of tracer ammunition that meets all other criteria outlined in § 173.56(h)(3).

C. Amending the Approvals Process

PHMSA currently provides several options for submittal of applications for approvals including mail, email, fax, and the PHMSA portal, although this latter method is not codified as an option. As such, PHMSA proposes to amend 49 CFR 107.705 to include the PHMSA portal as a submittal option for all approvals. Furthermore, PHMSA proposes to make the PHMSA portal the only method for submittal and acceptance of explosives approval applications, and to remove current options to submit those applications via mail, email, or fax. Transitioning to an all-electronic system will improve efficiency. Delays often occur when PHMSA personnel must transcribe application information into the portal database due to incomplete data, inability to read handwritten materials, and so forth. Where missing data or uncertainties are discovered, PHMSA personnel must follow up with the applicant or otherwise reject an application, which causes further delays. Electronic submissions will improve efficiency for the applicant on the front end (data entry) and for PHMSA on the back end (review and issuance of approval). The PHMSA portal provides online access to PHMSA services, creating a single source for all Hazardous Materials explosives applications and data. Persons need only to register to create an account and access the portal.

Finally, PHMSA proposes to add a new paragraph 49 CFR 107.705(e) to allow approval holders to request termination of approvals, and to amend 49 CFR 107.713(c) to clarify that when an approval holder voluntarily requests termination, PHMSA is not required to issue a show cause letter.

IV. Section-by-Section Review

The following is a section-by-section review of the proposed amendments to the HMR.

Part 107

Section 107.705

Section 107.705 prescribes the requirements for submitting registrations, reports, and applications for approval. PHMSA proposes revising paragraph (a)(1) to specify the PHMSA portal may also be used to file all approval applications with PHMSA and is the only authorized method for submitting explosives approval applications, and proposes removing options to submit those explosives applications via mail, email, or fax for all explosives approvals.

Section 107.713

Section 107.713 prescribes procedures for the issuance, modification, and termination of approvals required by the HMR. PHMSA proposes to revise 49 CFR 107.713(c) introductory text to indicate a PHMSA show cause letter is not necessary for voluntary termination of an approval; and add a new paragraph (e) to clarify approval holders may voluntarily request termination of an approval. PHMSA will then issue a termination letter, rather than a show cause letter.

Part 171

Section 171.8

Section 171.8 provides definitions and abbreviations. PHMSA proposes to define the term ''FW number'' as a number preceded by the prefix ''FW,'' assigned by PHMSA to a Division 1.4G Consumer firework device that has been certified under the provisions of § 173.64.

Part 173

Section 173.56

Section 173.56 prescribes the procedures for classification and approval of new explosives. Small arms cartridges meeting the criteria in paragraph (h) may be self-classified as Division 1.4S by the manufacturer. PHMSA proposes to modify § 173.56(h)(3) to provide clarity that tracer ammunition with inert projectiles is also eligible for self-classification as a Division 1.4S material provided all other criteria outlined in § 173.56(h) are met. This proposal will maintain the current level of safety with the HMR by ensuring proper understanding of what types of explosives may be classified or self-classified.

Section 173.59

Section 173.59 provides informational descriptions of terms for explosives. PHMSA is adding a separate term and description for ''low hazard fireworks.'' This proposal will maintain the current level of safety with the HMR by ensuring proper understanding of what explosives may qualify for the low hazard fireworks exceptions.

Section 173.64

Section 173.64 prescribes classification and approval exceptions from the standard explosives approval process for Division 1.3 and 1.4 fireworks. PHMSA proposes to revise § 173.64 to include further exceptions for low hazard consumer fireworks that qualify for self-certification. Specifically, paragraph (b) will outline criteria for self-certification of certain ground and novelty devices as Division 1.4 fireworks. Seven novelties will be eligible for self-certification and exception from the HMR, and 17 ground devices will be eligible for self-certification and classification as Division 1.4G fireworks. PHMSA also proposes to make some editorial changes to paragraph (a) consistent with revision to paragraph (b), such as adding a title to paragraph (a) and clarifying further the reference to § 173.65 for certification of Division 1.4G consumer fireworks by an FCA. This proposal will maintain the current level of safety with the HMR by ensuring proper understanding of which ground and novelty devices may qualify for this exception.

V. Regulatory Analyses and Notices

A. Statutory/Legal Authority

This NPRM is published under the authority of Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127). Section 5103(b)

of the HMTA authorizes the Secretary of Transportation to prescribe regulations for the safe transportation of hazardous materials (HAZMAT) in intrastate, interstate, and foreign commerce. The Secretary has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b).

B. Executive Orders 12866 and 14094; DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review''), as amended by Executive Order 14094 (''Modernizing Regulatory Review'' [12]), requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Similarly, DOT Order 2100.6A (''Policies and Procedures for Rulemakings'') requires PHMSA rulemaking actions include ''an assessment of the potential benefits, costs, and other important impacts of the regulatory action,'' and (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require PHMSA submit ''significant regulatory actions'' to the Office of Management and Budget (OMB) for review. This rulemaking is not considered a significant regulatory action under section 3(f) of Executive Order 12866 (as amended by Executive Order 14094) and therefore, was not formally reviewed by OMB. This rulemaking is also not considered a significant rule under DOT Order 2100.6A.

The following is a brief summary of costs, savings, and net benefits of some of the amendments proposed in this notice. PHMSA has developed a more detailed analysis of these costs and benefits in the PRIA, a copy of which has been placed in the docket. PHMSA seeks public comment on its proposed revisions to the HMR, and the preliminary cost and benefit analyses in the PRIA.

PHMSA estimates the costs associated with permitting self-certification of low-hazard fireworks are minimal. The actual standards required by the HMR for low-hazard fireworks are not affected by this rule change, merely allowing manufacturers to self-certify that the products meet those standards. PHMSA estimates the self-certifying application process for manufacturers will not add any additional time burdens as the approval information required for an approval will not be affected. PHMSA estimates approvals handled by PHMSA take approximately two hours per application. Of that time 30 minutes are required for data entry, 60 minutes for managerial review, and another 30 minutes for signature review and approval. Allowing self-classification, therefore, would save PHMSA 425 labor hours annually.

PHMSA emphasizes the proposed amendment for tracer ammunition is merely a formal codification and adoption of a policy in place since 2002. The proposed change would make the policy's definition into a formal regulation. Considering the long-standing nature of the 2002 policy, there would be minimal burdens to formally adopting the policy into the HMR.

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (Federalism) [13] and the Presidential Memorandum (Preemption).[14] Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in developing regulatory policies that may have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

The proposed rule would not have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The HMTA contains an express preemption provision at 49 U.S.C. 5125(a) that preempts State, local, and Tribal requirements if: (1) compliance with such requirement makes compliance with the DOT regulations issued under the authority of the HMTA not possible; or (2) compliance with such requirement is an obstacle to carrying out a regulation prescribed under the authority of the HMTA. The HMTA also contains an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following subjects:

- The designation, description, and classification of hazardous materials.
- The packing, repacking, handling, labeling, marking, and placarding of hazardous materials.
- The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents.
- The written notification, recording, and reporting of the unintentional release in transportation of hazardous material.
- The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This proposed rule addresses covered subject items (1) and (2) and would preempt state, local, and tribal requirements not meeting the ''substantively the same'' standard. Any preemption results directly from operation of 49 U.S.C. 5125. In addition, in this instance, the preemptive effect of the proposed rule is limited to the minimum level necessary to achieve the objectives of the HMTA under which the final rule is promulgated. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'') [15] and DOT Order 5301.1A (''Department of Transportation Tribal Consultation Policy and Procedures''). Executive Order 13175 and DOT Order 5301.1A require DOT Operating Administrations to assure meaningful and timely input from Native American tribal government representatives in developing rules that significantly or uniquely affect tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities, or the relationship and distribution of power between the Federal Government and Native American Tribes.

PHMSA assessed the impact of the rulemaking and determined that it would not significantly or uniquely affect Tribal communities or Native American Tribal governments. The changes to the hazardous materials program procedures and HMR proposed in this NPRM would have broad, national scope. PHMSA does not expect this rulemaking would significantly or uniquely affect Tribal communities,

[12] 88 FR 21879 (Apr. 11, 2023).

[13] 64 FR 43255 (Aug. 10, 1999).

[14] 74 FR 24693 (May 22, 2009).

[15] 65 FR 67249 (Nov. 9, 2000).

impose substantial compliance costs on Native American Tribal governments, or mandate Tribal action. And because PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect it would entail disproportionately high adverse risks for tribal communities. For these reasons, the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1A apply. However, PHMSA solicits comment from Native American tribal governments and communities on potential impacts of the proposed rulemaking.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider whether a rulemaking would have a ''significant economic impact on a substantial number of small entities'' to include small businesses; not-for-profit organizations that are independently owned and operated and are not dominant in their fields; and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') [16] requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rules on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated web page.[17]

This proposed rule has been developed in accordance with Executive Order 13272 and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts on small entities are considered properly. As explained above, this proposed rule facilitates the transportation of hazardous materials by streamlining the regulatory requirements for energetics manufacturers and shippers while maintaining the current level of safety for transportation of these items. Specifically, it proposes to amend the classification and approval process of certain low-hazard Class 1 explosive materials (*i.e.,* fireworks) and clarify classification eligibility for ammunition with inert projectile that has a pyrotechnic coating (*i.e.,* tracers). Finally, this rulemaking proposes to require use of the PHMSA portal, an online application, as the sole method to submit explosives approval applications.

Therefore, PHMSA expects that these amendments will not, if adopted, have a significant economic impact on a substantial number of small entities. However, PHMSA solicits comments on the anticipated economic impacts to small entities.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.8(d), PHMSA must provide interested members of the public and affected agencies an opportunity to comment on information and recordkeeping requests.

PHMSA has analyzed this NPRM in accordance with the Paperwork Reduction Act. PHMSA currently accounts for information collection and recordkeeping burdens under OMB Control Number 2137–0057 ''Approvals for Hazardous Materials.'' In this NPRM, PHMSA proposes to revise § 173.64 applicable to low hazard fireworks that may impact the burden accounted for in OMB Control Number 2137–0057. The proposed addition in § 173.64 would require manufacturers to provide information in association with pursuing allowance for the self-certification of certain ground and novelty device fireworks as low hazard fireworks for purposes of transportation. PHMSA analyzed this proposal and expects the impact to be negligible as the information is the same information currently required by the HMR, just in a different format.

PHMSA specifically requests comments on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these proposed requirements. Address written comments to the DOT Docket Operations Office as identified in the **ADDRESSES** section of this rulemaking. Comments regarding information collection burdens must be received prior to the close of the comment period identified in the **DATES** section of this rulemaking. In addition, you may submit comments specifically related to the information collection burden to the PHMSA Desk Officer, Office of Management and Budget, at fax number 202–395–674. Requests for a copy of this information collection should be directed to Steven Andrews, Standards and Rulemaking Division (PHH–10), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. If these proposed requirements are adopted in a final rule, PHMSA will submit the revised information collection and recordkeeping requirements to OMB for approval.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal Governments, and the private sector. For any NPRM or final rule that includes a Federal mandate that may result in the expenditure by State, local, or Tribal Governments, or by the private sector of $100 million or more in 1996 dollars in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

As explained in the PRIA, available for review in the docket, this proposed rule does not impose unfunded mandates under the UMRA. As explained in the PRIA, it is not expected to result in costs of $100 million or more in 1996 dollars to either State, local, or Tribal Governments, or to the private sector in any one year. Therefore, the analytical requirements of UMRA do not apply.

H. Draft Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4335),[18] requires Federal agencies to consider the environmental impacts of their actions in the decision-making process. The purpose and function of NEPA is satisfied if Federal agencies have considered relevant environmental information, and the public has been informed regarding the decision-making process. Agencies must prepare an environmental assessment (EA) for a proposed action that is not likely to have significant effects or when significance is unknown, and prepare a FONSI if, based on the EA, the agency determines not to prepare an EIS because the proposed action will not

[16] 67 FR 53461 (Aug. 16, 2002).

[17] DOT, ''Rulemaking Requirements Related to Small Entities,'' *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities* (last accessed June 17, 2021).

[18] Also at 40 CFR parts 1501 to 1508.

have significant effects. In accordance with these requirements, an agency's EA must discuss: (1) the need for the action; (2) the alternatives considered; (3) the environmental impacts of the proposed action and alternatives; and (4) a listing of the agencies and persons consulted before providing evidence for determining a FONSI. The draft EA (DEA) and proposed FONSI for the proposed action in this rulemaking are as follows. This DEA incorporates by reference the analysis included in the preamble text above.

1. Need for the Action

The changes in the explosives approval process, especially for classification and approval of low hazard fireworks, are needed to improve efficiency and provide regulatory clarification for offerors and carriers.

2. Alternatives Considered

No Action Alternative

Under the no action alternative, the current process for acquiring explosives approvals by hardcopy or email submission of application documents would continue. Additionally, stakeholders would continue to rely on previously issued guidance for classification and exception from regulation for certain low hazards fireworks. Finally, it would remain ambiguous whether tracer ammunition is eligible for self-classification as a Division 1.4S explosive (*i.e.,* the small arms cartridges exceptions).

Proposed Action Alternative—Explosives Approval Program and Exceptions for Divisions 1.3 and 1.4 Consumer Fireworks

Under this alternative, PHMSA would implement the proposed amendments of this rule as fully addressed in the preamble and regulatory text sections of this NPRM. However, a concise summary of the proposed amendments include the following:

(1) Establishing exceptions for ground and novelty firework devices.

(2) Authorizing the self-classification of tracer ammunition.

(3) Requiring electronic submittal of explosives approval applications to include reference to the PHMSA portal, and to authorize electronic submittal for all required approvals.

3. Environmental Impacts of Proposed Action and Alternatives

No Action Alternative

PHMSA expects the no action alternative to have no new impact on the environment as the status quo would remain in place. Explosives approval applications, including those for fireworks, would continue to be processed using all authorized filing formats currently in place, and manufacturers would continue to work within the scope of guidance issued by PHMSA for exceptions from regulation for low hazard fireworks. Additionally, classification of tracer ammunition as a Division 1.4S would remain the same but clarity on whether a manufacturer could self-classify would remain uncodified.

Proposed Action Alternative—Explosives Approval Program and Exceptions for Divisions 1.3 and 1.4 Consumer Fireworks

Under this alternative, PHMSA would implement the proposed amendments of this rule as fully addressed in the preamble and regulatory text sections of this NPRM. The proposed amended regulatory text would allow for a streamlining of procedural requirements for the transportation of low hazard ground and novelty firework devices. Specifically, PHMSA would allow an automated process within the PHMSA portal for self-certification, review of the information provided, and issuance of a certificate with a unique identification (*i.e.,* FW number). This process would eliminate the need for firsthand review by PHMSA personnel when compliance is certified by the applicant. The devices would still be subject to the same substantive testing and materials requirements, including construction, formulation, and packaging. Similarly, this NPRM proposes to clarify and codify existing guidance that self-certification is authorized for inert projectile cartridges coated with tracer composition and may be self-classified as a Division 1.4S material provided all other criteria outlined in § 173.56(h) are met. Although the proposal would reduce the hours PHMSA personnel spend reviewing documents, the automated process is designed to similarly ensure compliance. Furthermore, PHMSA will maintain oversight of the automated process for low hazard fireworks through PHMSA's QA/QC review program.

PHMSA also notes the difficulty in quantifying any environmental impact of requiring electronic processing of information; codifying approval and exception requirements for low hazard fireworks; and clarifying authorized self-classification of tracer ammunition. The changes proposed in this notice do not impact whether or not explosives are manufactured and transported, but rather how explosives approval applications are processed and how certain explosives may be classified. The process is already occurring and the changes proposed would primarily be about transitioning to an electronic format. For the above reasons, PHMSA expects the proposed action alternative to have no impact on the human environment, including public safety.

4. Agencies and Persons Consulted

PHMSA coordinated with the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the U.S. Coast Guard in the development of this proposed rule.

5. Environmental Justice

Executive Order 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') [19] directs Federal agencies to take appropriate and necessary steps to identify and address disproportionately high and adverse effects of Federal actions on the health or environment of minority and low-income populations to the greatest extent practicable and permitted by law. DOT Order 5610.2C (''Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') establishes departmental procedures for effectuating Executive Order 12898 promoting the principles of environmental justice through full consideration of environmental justice principles throughout planning and decision-making processes in the development of programs, policies, and activities—including PHMSA rulemaking.

PHMSA has evaluated this proposed rule under Executive Order 12898 and DOT Order 5610.2C and preliminarily determined that it would not cause disproportionately high and adverse human health and environmental effects on minority and low-income populations. The rulemaking is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And insofar as the rulemaking would not adversely affect the safe transportation of hazardous materials generally, the proposed revisions would not entail disproportionately high adverse risks for minority and low-income populations. This preliminary determination is consistent with the recent Executive Order 14096 (''Revitalizing Our Nation's Commitment to Environmental Justice for All''),[20] by achieving several goals,

[19] 59 FR 7629 (Feb. 16, 1994).

[20] 88 FR 25251 (Apr. 26, 2023).

including continuing to deepen the Administration's whole of government approach to environmental justice and to better protect overburdened communities from pollution and environmental harms.

6. Proposed Finding of No Significant Impact

As discussed in this DEA as well as Section II of the notice, the proposed actions of this rulemaking would introduce efficiencies to the explosives approval process and the way certain low hazard Class 1 explosive materials are authorized for transportation, and provide clarity on whether tracer ammunition for small arms cartridges may be classed as Division 1.4S material without the explosives approval process. The proposed actions would not cause environmental impact because the changes proposed are procedural and not substantive, and no reduction in compliance with HMR requirements are anticipated. There may be a negligible impact by changing from paper documents to reliance on electronic systems. Nothing is different between the approval and transport of explosives and low hazard fireworks under the current system and under the proposed system other than how applications are processed. Similarly, nothing is different between the current classification of tracer ammunition and the proposed action except how classification is determined (*i.e.,* either by formalized approval classification or by self-classification). Therefore, PHMSA proposes that, if adopted, this rulemaking will result in no significant impact to the human environment. PHMSA welcomes feedback related to environmental impacts that may result if the proposed requirements are adopted, as well possible alternatives and their environmental impacts.

I. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform any amendments to the hazardous materials program procedures and the HMR considered in this rulemaking. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS). DOT's complete Privacy Act Statement is in the **Federal Register**,[21] or on DOT's website at *https://www.dot.gov/privacy.*

J. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (''Promoting International Regulatory Cooperation'')[22] requires that agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

In developing requirements to allow manufacturers to self-certify certain fireworks as meeting criteria for transportation as low hazard fireworks in place of acquiring an explosives approval for transportation, PHMSA has made assurances that the process facilitates international transport. PHMSA realizes the absence of an approval and the associated approval number provides for domestic exception from regulation of certain low hazard novelty fireworks, and it has assessed the effects of the proposed rule to ensure it does not cause unnecessary obstacles to foreign trade. In fact, the proposed rule is expected to facilitate international trade by harmonizing U.S. and international requirements for the transportation of hazardous materials. The rule is expected to reduce regulatory burdens and minimize delays arising from having to comply with divergent regulatory requirements. This rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreements Act, as amended.

K. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) developed or adopted by voluntary consensus standard bodies. This NPRM involves voluntary consensus standards, which are discussed in Section I of this NPRM.

L. Severability

The purpose of this proposed rule is to operate holistically in addressing a panoply of issues related to safety hazards; the classification and approval process for certain low-hazard fireworks; permitting small arms cartridges to include tracer ammunition; and allowing for voluntary termination of an explosive approval by the approval holder. However, PHMSA recognizes that certain provisions focus on unique topics. Therefore, PHMSA preliminarily finds that the various provisions of this proposed rule are severable and able to function independently if severed from each other. Thus, in the event a court were to invalidate one or more of this proposed rule's unique provisions, the remaining provisions should stand and continue in effect. PHMSA seeks comment on which portions of this proposed rule should or should not be severable.

M. Cybersecurity and Executive Order 14028

Executive Order 14028 (''Improving the Nation's Cybersecurity'')[23] expressed the Biden-Harris Administration policy that ''the prevention, detection, assessment, and remediation of cyber incidents is a top priority and essential to national and economic security.'' Executive Order 14028 directed the Federal Government to improve its efforts to identify, deter, and respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' PHMSA has considered the effects of this NPRM and

[21] 65 FR 19477 (Apr. 11, 2000).

[22] 77 FR 26413 (May 4, 2012).

[23] 86 FR 26633 (May 17, 2021).

determined its regulatory amendments will not materially affect the cybersecurity risk profile for the classification and approval process for certain low-hazard fireworks, for small arms cartridges to include tracer ammunition, and the transportation of hazardous materials.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA proposes to amend 49 CFR chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 Section 4; Pub. L. 104–121 Sections 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.705, revise paragraph (a)(1) to read as follows:

§ 107.705 Registrations, reports, and applications for approval.

(a) * * *

(1) Filings. (i) Submission methods. The registration, report, or application may be filed with the Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Applications may be filed using the PHMSA portal at: *https://portal.phmsa.dot.gov/* or alternatively, may be filed with any attached supporting documentation in an appropriate format by facsimile (fax) to: (202) 366–3753 or (202) 366–3308, or by electronic mail (email) to: *approvals@dot.gov.*

(ii) Explosive approval applications. Filing of explosives approval and fireworks approval applications as well as certifications of low hazard fireworks must be submitted, and will only be accepted, using the PHMSA portal.

* * * * *

■ 3. In § 107.713, revise paragraph (c) introductory text and add paragraph (e) to read as follows:

§ 107.713 Approval modification, suspension or termination.

* * * * *

(c) Except as provided in paragraphs (d) and (e) of this section, before an approval is modified, suspended, or terminated, the Associate Administrator notifies the holder in writing of the proposed action and the reasons for it, and provides an opportunity to show cause why the proposed action should not be taken.

* * * * *

(e) The Associate Administrator may terminate an approval at the request of the approval holder based on the holder's determination that it is no longer needed. The approval holder must submit the request in writing to the Associate Administrator using the PHMSA portal at: *https://portal.phmsa.dot.gov/.*

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 4. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 5. In § 171.8, add a definition for ''FW number'' in appropriate alphabetical sequence to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

FW number means a number preceded by the prefix ''FW'', assigned by PHMSA to a Division 1.4G Consumer firework device that has been certified under the provisions of § 173.64 of this subchapter.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 6. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 7. In § 173.56, revise paragraph (h)(3) to read as follows:

§ 173.56 New explosives—definition and procedures for classification and approval.

* * * * *

(h) * * *

(3) Ammunition (including tracer ammunition) with inert projectile, or blank ammunition; and

* * * * *

■ 8. In § 173.59, add a definition for ''Low hazard firework'' in alphabetical order to read as follows:

§ 173.59 Description of terms for explosives.

* * * * *

Low hazard firework. As listed in § 173.64 of this subchapter, are pyrotechnic articles of certain chemical composition, design, and packaging that are not designed to leave ground level, contain no aerial components, present a low explosive hazard during transportation, and comply with any limits and requirements found therein. Low hazard fireworks include ground and novelty devices.

* * * * *

■ 9. Revise § 173.64 to read as follows:

§ 173.64 Exceptions for Division 1.3 and 1.4 fireworks.

(a) *Classification and approval.* Notwithstanding the requirements of § 173.56(b), Division 1.3 and 1.4 fireworks may be classed and approved by the Associate Administrator without prior examination and offered for transportation if the conditions of this paragraph (a) are met (see § 173.65 for an alternate method to approve Division 1.4G consumer fireworks using a DOT-approved Fireworks Certification Agency):

(1) Fireworks must be manufactured in accordance with the applicable requirements in APA 87–1A, 87–1B, and 87–1C (IBR, see § 171.7 of this subchapter).

(2) The firework device must pass a thermal stability test conducted by a third-party laboratory or the manufacturer. The test must be performed by maintaining the device, or a representative prototype of a large device such as a display shell, at a temperature of 75 °C (167 °F) for 48 consecutive hours. When a device contains more than one component, those components that could be in physical contact with each other in the finished device must be placed in contact with each other during the thermal stability test.

(3) The manufacturer applies in writing to the Associate Administrator following the applicable requirements in APA 87–1A, 87–1B, and 87–1C and is notified in writing by the Associate Administrator that the fireworks have

been classed, approved, and assigned an EX number. Each application must be complete and include all relevant background data and copies of all applicable drawings, test results, and any other pertinent information on each device for which approval is being requested. The manufacturer must sign the application and certify that the device for which approval is requested conforms to the appropriate APA Standard, that the descriptions and technical information contained in the application are complete and accurate, and, with respect to APA 87–1A, that no duplicate application has been submitted to a fireworks certification agency. If the application is denied, the manufacturer will be notified in writing of the reasons for the denial. The Associate Administrator may require that the fireworks be examined by an agency listed in § 173.56(b)(1) of this part.

(b) *Additional exceptions for low hazard Division 1.4 consumer fireworks.* Low hazard fireworks are pyrotechnic articles of certain chemical composition, design, and packaging such that they present a low explosive hazard during transportation. Low hazard ground device fireworks listed in the table to paragraph (b)(2) of this section and meeting the specified conditions and limitations are eligible for self-classification and transport as UN0336, Fireworks, Division 1.4G. Further, certain low hazard novelty fireworks listed in the table to paragraph (b)(3) of this section meeting the specified conditions and limitations may be excepted from the requirements of this subchapter as a Class 1 explosive material. Low hazard fireworks are not subject to the explosives approval requirements of § 173.56 or the DOT-approved Fireworks Certification Agency requirements of § 173.65.

(1) *General requirements.* No person may manufacture and offer for transport a low hazard firework unless compliance with requirements of this paragraph (b) has been certified with the Associate Administrator. No person may accept for transport a low hazard firework that has not been certified as specified in this section. If the person certifying compliance is not a resident of the United States, the person must designate an agent for service in accordance with § 105.40 of this chapter. Additionally, low hazard fireworks:

(i) Must successfully pass a thermal stability test as specified in paragraph (a)(2) of this section;

(ii) May not be transported as a component part for another firework or explosive; and

(iii) Must be marked with an FW number issued by the Associate Administrator. If the firework is too small for the marking, the outer package of the fireworks must be marked with the FW number.

(2) *Requirements specific to ground firework devices.* (i) Ground devices must use chemicals in conformance with the permitted and restricted chemical list in APA 87–1A, Appendix 1.

(ii) When permitted, all reports are limited to 50 mg of composition per report.

(iii) Ground devices must be initiated by a fuse; however, a fuse is not required for the following types: flitter sparklers, wire or dipped sparklers, fountain (nitrocellulose), and snakes (glow worms).

(iv) Authorized ground devices, and their descriptions, specifications, and special conditions for transport are set forth as follows:

TABLE 1 TO PARAGRAPH (b)(2)—AUTHORIZED GROUND DEVICES AND SPECIFICATIONS

Type	Description	Specification	Special conditions
Chaser	Consists of a paper or cardboard tube, which vents out its fuse hole.	20 grams total of chemical composition, with multiple reports permitted (each report limited to 50 milligrams).	None.
Crackling Ball	Consists of a spherical ball that contains small granules of chemical composition that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Crackling Strip	Consists of small granules of chemical composition adhered to and encased in a paper or cardboard wrapping that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Crackling Tube	Consists of a tube that contains small granules of chemical composition that upon ignition produce sparks and/or a crackling effect.	20 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 72 grams of composition.
Firecracker	Consists of a small paper-wrapped or cardboard tube that produces a single report.	50 milligrams of chemical composition per firecracker.	Multiple firecrackers can be fused together to form a string. There is no limit on number of firecrackers in a string.
Flasher/Strobe	Consists of a small paper-wrapped or cardboard tube that produces a crackling/flashing/strobe light effect.	5 total grams of chemical composition, with no reports permitted.	Inner packaging cannot exceed 60 grams of composition.
Flitter Sparkler	Consists of a paper or cardboard tube attached to a stick or wire. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	25 total grams of chemical composition, with no reports permitted. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulation being chlorates.	None.
Fountain (Cone)	Consists of a paper or cardboard tube that upon ignition produces a shower consisting of any combination of colored sparks, color flame, crackle, smoke, whistle, or micro star effects.	50 total grams of chemical composition, with no reports permitted.	None.

TABLE 1 TO PARAGRAPH (b)(2)—AUTHORIZED GROUND DEVICES AND SPECIFICATIONS—Continued

Type	Description	Specification	Special conditions
Fountain (Cylindrical)	Consists of a paper or cardboard tube that upon ignition produces a shower consisting of any combination of colored sparks, color flame, crackle, smoke, whistle, or micro star effects.	100 total grams of chemical composition, with no reports permitted.	None.
Fountain (Nitrocellulose)	Consists of a cone or tube device that produces a shower of small sparks, color, and flame as its primary effect using nitrocellulose as the major chemical component.	15 total grams of chemical composition, with no reports permitted.	None.
Ground Spinner	Consists of a paper or cardboard tube that upon ignition emits a shower of sparks that vent out of an orifice causing the device to spin rapidly on the ground.	20 total grams of chemical composition, with reports permitted (each report limited to 50 milligrams).	Multiple ground spinners can be fused together to form a string. Strings are limited to 20 grams of total composition.
Illuminating Torch	Consists of a paper or cardboard tube that upon ignition, emits a colored flame with or without crackles or sparks.	100 total grams of chemical composition, with no reports permitted.	None.
Smoke	Consists of a paper or cardboard tube that upon ignition emits smoke as the primary effect.	100 total grams of chemical composition. All mixtures containing a chlorate must contain an equal amount or greater amount of a carbonate or bicarbonate (*e.g.,* calcium carbonate, sodium bicarbonate).	Multiple smoke devices can be fused together to form a string. Strings are limited to 100 grams of total composition.
Snake	Consists of pressed pellet of pyrotechnic composition that upon ignition produce a snake-like ash that expands in length as the composition is consumed.	20 total grams of chemical composition, with no reports. Only formulations of nitrated asphalt, asphaltum, bitumen, pitch, and/or tar with an oxidizer (with or without a binder) are permitted.	None.
Specialty Device	Consists of a paper or cardboard tube(s), *e.g.,* in the shape of an animal or a small vehicle, that produces multiple effects.	20 total grams of chemical composition, with reports permitted (each report limited to 50 milligrams). No tube can contain more than 2 grams of composition; tubes cannot contain aerial components or internal shells.	None.
Wheel	Consists of a paper or cardboard tube(s) placed on the ground or attached to a post, by means of a nail, spike or string. Upon ignition the wheel rotates, producing a shower of sparks, color, crackling, flame, or whistle effects.	200 total grams of chemical composition, with no reports. No tube can contain more than 60 total grams of composition, which includes a 20 gram propellant limit per tube. Tubes cannot contain aerial components Handles are not permitted.	None.
Wire Sparkler or Dipped Stick.	Consists of a metal wire or wood dowel coated with a chemical composition. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	100 total grams of chemical composition, with no reports permitted. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulations being chlorates.	Composition weight per inner packaging cannot exceed 120 grams.

(3) *Requirements specific to novelty firework devices.* Except for transportation by air, novelty fireworks conforming to the requirements of this paragraph (b)(3) are not subject to this subchapter. For air transportation, novelty devices must be transported as required by this subchapter for ''UN3178, Flammable solid, inorganic, n.o.s. (Novelties), 4.1, PG II''.

(i) Novelty devices must use chemicals in conformance with the permitted and restricted chemical list in APA Standard 87–1A, Appendix 1 (IBR, see § 171.7 of this subchapter).

(ii) Inner packagings of novelty devices must be packaged in strong outer packagings. The packages must conform to the requirements of § 173.24. The maximum gross weight of a completed package may not exceed 30 kg (66 pounds).

(iii) Each outer package, and overpack if used, containing novelty devices must be plainly marked ''NOVELTIES, IN CONFORMANCE WITH § 173.64, NOT REGULATED, EXCEPT WHEN TRANSPORTED BY AIR''.

(iv) Authorized novelty devices, and their descriptions, specifications, and special conditions for transport are set forth as follows:

TABLE 2 TO PARAGRAPH (b)(3)—AUTHORIZED NOVELTY DEVICES AND SPECIFICATIONS

Type	Description	Specifications	Special conditions
Booby Trap/Pull Apart	Is a device that is actuated by means of friction. Pulling a string or strings apart activate the device producing a noise effect.	0.016 total grams of chemical composition, which is limited to barium, potassium, and/or sodium chlorate with red phosphorus.	Inner packages must not contain more than 12 devices.
Novelty Flitter Sparkler	Consists of a paper or cardboard tube attached to a stick or wire. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	5 total grams of chemical composition, with no reports permitted. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulation being chlorates.	
Party Poppers	Is a device that is actuated by means of friction. Pulling a string or trigger activates the device producing a noise effect and releasing paper streamers or confetti. Common examples resemble champagne bottles and toy pistols.	0.016 total grams of chemical composition, which is limited to barium, potassium, and/or sodium chlorate with red phosphorus.	Inner packages must not contain more than 72 devices.
Novelty Snakes and Glow-Worms.	Consists of pressed pellet of pyrotechnic composition that upon ignition, produce a snake-like ash that expands in length as the composition is consumed.	2 total grams of chemical composition. Only formulations of nitrated asphalt, asphaltum, bitumen, pitch, and/or tar with an oxidizer (with or without a binder) are permitted.	Inner packaging must not contain more than 25 devices.
Snappers	Consists of small, paper-wrapped items. When dropped, the device activates, producing a noise effect.	0.001 total grams of silver fulminate coated on small bits of sand or gravel.	Inner packages must not contain more than 50 devices with sawdust or other impact absorbing materials.
Novelty Wire Sparkler or Novelty Dipped Stick.	Consists of a metal wire or wood dowel coated with a chemical composition. Upon ignition, the device produces a shower of sparks, a colored flame, and/or a crackling effect.	25 total grams of chemical composition, with no reports permitted. Formulations containing perchlorates are limited to 5 grams. Formulations containing chlorates are limited to 4 grams with no more than 15 percent of the formulations being chlorates.	Inner packages must not contain more than 8 devices.
Novelty Smoke Device	Consists of a paper or cardboard tube that upon ignition, emits smoke as the only effect.	5 total grams of chemical composition, with no reports permitted. All mixtures containing a chlorate must contain an equal amount or greater amount of a carbonate or bicarbonate (e.g., calcium carbonate, sodium bicarbonate).	Inner packages must not contain more than 72 devices.

(4) *Recordkeeping requirements.* In addition to the certification of each low hazard firework in accordance with this section, the manufacturer must maintain a record of the documents demonstrating compliance with this section. Each record must clearly provide the FW number assigned to the device certified. The record must contain the following information at minimum: FW certification document, category of device, drawing, chemical composition list, gram quantities, and if applicable, U.S. agent of service information. The record must be accessible at or through the principal place of business for five years after the device is manufactured and must be made available, upon request, to an authorized official of a Federal, State, or local government agency at a reasonable time and location, not to exceed five (5) business days.

Issued in Washington, DC, on November 17, 2023, under authority delegated in 49 CFR 1.97.

William S. Schoonover,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2023–25887 Filed 11–29–23; 8:45 am]

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Notices

Federal Register

Vol. 88, No. 229

Thursday, November 30, 2023

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

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–47–2023]

Foreign-Trade Zone (FTZ) 183; Authorization of Production Activity; Flextronics America, LLC; (Automatic Data Processing Machines); Austin, Texas

On July 28, 2023, Flextronics America, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 183C, in Austin, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 50833, August 2, 2023). On November 27, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: November 27, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–26335 Filed 11–29–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon 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 certain activated carbon (activated carbon) from the People's Republic of China (China) would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of this AD order.

DATES: Applicable November 24, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Palmer, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2007, Commerce published in the **Federal Register** the AD order on activated carbon from China.[1] On June 1, 2023, the ITC instituted,[2] and Commerce initiated,[3] the third 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 *Order* would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the order be revoked.[4]

On November 24, 2023, 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 a 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* is certain activated carbon. Certain activated carbon is a powdered, granular, or pelletized carbon product obtained by ''activating'' with heat and steam various materials containing carbon, including but not limited to coal (including bituminous, lignite, and anthracite), wood, coconut shells, olive stones, and peat. The thermal and steam treatments remove organic materials and create an internal pore structure in the carbon material. The producer can also use carbon dioxide gas (CO_2) in place of steam in this process. The vast majority of the internal porosity developed during the high temperature steam (or CO_2 gas) activated process is a direct result of oxidation of a portion of the solid carbon atoms in the raw material, converting them into a gaseous form of carbon.

The scope of the *Order* covers all forms of activated carbon that are activated by steam or CO_2, regardless of the raw material, grade, mixture, additives, further washing or post-activation chemical treatment (chemical or water washing, chemical impregnation or other treatment), or product form. Unless specifically excluded, the scope of the *Order* covers all physical forms of certain activated carbon, including powdered activated carbon (PAC), granular activated carbon (GAC), and pelletized activated carbon.

Excluded from the scope of the *Order* are chemically activated carbons. The carbon-based raw material used in the chemical activation process is treated with a strong chemical agent, including but not limited to phosphoric acid, zinc chloride, sulfuric acid, or potassium hydroxide that dehydrates molecules in the raw material, and results in the formation of water that is removed from the raw material by moderate heat treatment. The activated carbon created by chemical activation has internal porosity developed primarily due to the action of the chemical dehydration agent. Chemically activated carbons are typically used to activate raw materials with a lignocellulosic component such as cellulose, including wood, sawdust, paper mill waste and peat.

To the extent that an imported activated carbon product is a blend of steam and chemically activated carbons, products containing 50 percent or more steam (or CO_2 gas) activated carbons are

[1] *See Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China,* 72 FR 20988 (April 27, 2007) (*Order*).

[2] *See Certain Activated Carbon from China; Institution of a Five-Year Review,* 88 FR 35926 (July 3, 2023).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 35832 (June 1, 2023).

[4] *See Certain Activated Carbon from the People's Republic of China: Final Results of Expedited Third Sunset Review of the Antidumping Duty Order,* 88 FR 66810 (September 28, 2023).

[5] *See Certain Activated Carbon from China,* 88 FR 82397 (November 24, 2023) (*ITC Final Determination*); *see also Certain Activated Carbon from China,* Inv. No. 731–TA–1143 (Third Review), USITC Publication 5035 (November 2023).

within the scope, and those containing more than 50 percent chemically activated carbons are outside the scope. This exclusion language regarding blended material applies only to mixtures of steam and chemically activated carbons.

Also excluded from the scope are reactivated carbons. Reactivated carbons are previously used activated carbons that have had adsorbed materials removed from their pore structure after use through the application of heat, steam and/or chemicals.

Also excluded from the scope is activated carbon cloth. Activated carbon cloth is a woven textile fabric made of or containing activated carbon fibers. It is used in masks and filters and clothing of various types where a woven format is required.

Any activated carbon meeting the physical description of subject merchandise provided above that is not expressly excluded from the scope is included within the scope. The products subject to the *Order* are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3802.10.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, 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 November 24, 2023.[6] Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Order* not later than 30 days prior to the fifth anniversary of the date of the last determination by the ITC.

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

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 published pursuant to section 777(i) of the Act and 19 CFR 351.218(f)(4).

Dated: November 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–26296 Filed 11–29–23; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See ITC Final Determination.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–866]

Certain Folding Gift Boxes From the People's Republic of China: Continuation of the Antidumping Duty Order

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

SUMMARY: As a result of 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 certain folding gift boxes (gift boxes) from the People's Republic of China (China) would be likely to 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 this AD order.

DATES: Applicable November 8, 2023.

FOR FURTHER INFORMATION CONTACT: Alex Cipolla, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4956.

SUPPLEMENTARY INFORMATION:

Background

On January 8, 2002, Commerce published the AD order on certain folding gift boxes from China.[1] On June 1, 2023, 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 *Order* would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of margins of dumping likely to prevail should the *Order* be revoked.[4]

On November 8, 2023, 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 products covered by the *Order* are certain folding gift boxes. Folding gift boxes are a type of folding or knock-down carton manufactured from paper or paperboard. Folding gift boxes are produced from a variety of recycled and virgin paper or paperboard materials, including, but not limited to, clay-coated paper or paperboard and kraft (bleached or unbleached) paper or paperboard. The scope of the *Order* excludes gift boxes manufactured from paper or paperboard of a thickness of more than 0.8 millimeters, corrugated paperboard, or paper mache. The scope also excludes those gift boxes for which no side of the box, when assembled, is at least nine inches in length.

Folding gift boxes included in the scope are typically decorated with a holiday motif using various processes, including printing, embossing, debossing, and foil stamping, but may also be plain white or printed with a single color. The subject merchandise includes folding gift boxes, with or without handles, whether finished or unfinished, and whether in one-piece or multi-piece configuration. One-piece gift boxes are die-cut or otherwise formed so that the top, bottom, and sides form a single, contiguous unit. Two-piece gift boxes are those with a folded bottom and a folded top as

[1] *See Notice of Antidumping Duty Order: Certain Folding Gift Boxes from the People's Republic of China,* 67 FR 864 (January 8, 2002) (*Order*).

[2] *See Folding Gift Boxes from China; Institution of a Five-Year Review,* 88 FR 35917 (June 1, 2023).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 35832 (June 1, 2023).

[4] *See Certain Folding Gift Boxes from the People's Republic of China: Final Results of Expedited Sunset Review of the Antidumping Duty Order,* 88 FR 69133 (October 5, 2023), and accompanying Issues and Decision Memorandum.

[5] *See Folding Gift Boxes from China; Determination,* 88 FR 77107 (November 8, 2023) (*ITC Final Determination*); and *Folding Gift Boxes from China,* Inv. No. 731–TA–921 (Fourth Review), USITC Pub. 5471 (November 2023).

separate pieces. Folding gift boxes are generally packaged in shrink-wrap, cellophane, or other packaging materials, in single or multi-box packs for sale to the retail customer. The scope excludes folding gift boxes that have a retailer's name, logo, trademark or similar company information printed prominently on the box's top exterior (such folding gift boxes are often known as ''not-for-resale'' gift boxes or ''give-away'' gift boxes and may be provided by department and specialty stores at no charge to their retail customers). The scope of the *Order* also excludes folding gift boxes where both the outside of the box is a single color and the box is not packaged in shrink-wrap, cellophane, other resin-based packaging films, or paperboard.

Imports of the subject merchandise are classified under Harmonized Tariff Schedules of the United States (HTSUS) subheadings 4819.20.0040 and 4819.50.4060. These subheadings also cover products that are outside the scope of the *Order*. Furthermore, although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the *Order* is dispositive.

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to a 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 November 8, 2023.[6] Pursuant to section 751(c)(2) of the Act, Commerce intends to initiate the next five-year review of this order not later than 30 days prior to the fifth anniversary of the effective date of the last determination by the ITC.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

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 published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: November 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–26336 Filed 11–29–23; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See ITC Final Determination.*

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, December 5, 2023—10:00 a.m.

PLACE: Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD.

STATUS: Commission Meeting—Closed to the Public.

MATTERS TO BE CONSIDERED:

Meeting Matter

Briefing Matter

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: November 28, 2023.

Sarah Bock,

Paralegal Specialist.

[FR Doc. 2023–26485 Filed 11–28–23; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 2023–0031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigation of Smart Toys and Additional Toys Through Child Observations

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Pursuant to the Paperwork Reduction Act of 1995 (PRA), this is the Consumer Product Safety Commission's (CPSC or Commission) second notice inviting public comment about a request for approval from the Office of Management and Budget (OMB) for a new information collection. The proposed collection is associated with CPSC's investigation, through child observations and caregiver questionnaires, of smart toys and additional toys (take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives) to consider children's ability to interact with toys as the manufacturer intended and assist in updating CPSC's age determination guidelines. We received one comment on the first notice, which we address in this notice, and again describe the proposed collection of information. By publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for approval of the collection of information, as proposed.

DATES: Submit written or electronic comments on the collection of information by January 2, 2024.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. In addition, written comments that are sent to OMB, also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2023–0031, by any of the following methods:

Electronic Submissions: CPSC encourages you to submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal

identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov;* insert the docket number, CPSC–2023–0031, into the ''Search'' box; and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301)504–7791, or by email to: *CGillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning the proposed collection of information. CPSC published notice of this collection on August 7, 2023, and received one comment. 88 FR 52142. CPSC has not made any changes in the study based on that comment.

I. Burden Description

Under the PRA, CPSC is publishing the following information: [1]

- A title for the collection of information;
- A summary of the collection of information;
- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of response to the collection of information;
- An estimate of the burden that will result from the collection of information; and
- Notice that comments may be submitted to the agency and OMB.

44 U.S.C. 3507(a)(1)(D). Specifically, the Commission provides the following information:

Title: Investigation of Smart Toys and Additional Toys Through Child Observations.

OMB Control Number: New.

Type of Request: New information collection requirement.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 1 year from date of approval.

Summary of the Collection of Information: CPSC proposes to conduct individual in-person data collection sessions with up to 60 children aged 2 to 4 years old and their caregivers, for a total of 120 participants. Caregivers will answer a series of screening questions to determine if the caregiver and child meet the criteria for enrollment in the study. CPSC will enroll in the data collection study children and caregivers who meet the screening criteria and are willing to participate.

Over 2 in-person sessions, researchers will collect data primarily through direct human observations of children's interactions with toys and caregivers' responses to questionnaires. In each session, researchers will introduce children to 4 or 5 toys chosen from 6 toy categories (smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives). The researcher will demonstrate for the child how to use each toy and then document the child's play patterns with the toy, noting the child's ability to interact with each toy consistent with the manufacturer's instructions. Researchers will use coding checklists to document real-time observations of the child's interactions with the toys, in the form of concrete behaviors across different modalities, such as gross motor (*e.g.,* turns figurines head), fine motor (*e.g.,* slides switch on/off), and behavioral (*e.g.,* feeds an animal, engages in pretend play with one or multiple figurines), which demonstrate the child's ability to use the toy as intended.

Caregivers will respond to researcher questions about the caregiver's perception of their child's ability to interact with the selected toys as intended, potential purchasing decisions for the specific toys, and whether the caregiver would demonstrate how to play with the toys or some of the components as the manufacturer intends. Researchers will record on paper forms their observations of children's interactions and caregiver's responses to questions about the toys.

Researchers will randomize the presentation order of the toys for each caregiver/child pair to preclude any effects of sequence and control for learning or fatigue that might take place. Also, researchers will use video cameras to record each child's interaction with a toy. Researchers will use the video as a backup reference for real time coding.

Researchers will separate out all personally identifiable information from data collected. Also, researchers will separate out from collected information all identifying information from the initial screening, as well as scheduling. This information will be kept on a secure server in password protected files and discarded by researchers when no longer needed. At the end of each session, researchers will save the video data onto a secure server. Researchers will enter data recorded on the paper forms into a secure database, which also will be kept on a secure server. Researchers will limit access to this information and will summarize all information collected during the sessions using generic categories and summary statistics.

Description of the Need for the Information and Proposed Use of the Information: Created in 1972, the CPSC is an independent federal regulatory agency with a public health and safety mission to protect the public from unreasonable risks of injury and death from consumer products used in and around the home, in recreation, and in schools. As part of this statutory mandate, CPSC is authorized to conduct research on consumer products and behavior to identify and address product safety hazards, as well as to develop efficient and effective means of bringing about safety improvements. This information collection supports the Commission's strategic goal of safety.

Age-appropriate toys are important for the physical, intellectual, and socioemotional development of children. Age-appropriate toys can help children learn, develop imaginative capacities, and refine motor coordination. However, interacting with toys intended for older children poses a potential risk for a child to be seriously or fatally injured. In 2021, an estimated 206,400 toy-related injuries were treated in U.S. hospital emergency rooms.[2] Of the 206,400 toy-related injuries, an estimated 74% happened to children 14 years of age or younger; 69% occurred to children 12 years of age or younger; and 37% happened to children 4 years of age or younger.

To identify a toy's safety hazards, the CPSC Division of Human Factors first determines the intended age group of potential users. CPSC considers age determinations for toys to be of

[1] On November 21, 2023, the Commission voted (4–0) to publish this notice.

[2] Consumer Product Safety Commission: Toy-Related Deaths and Injuries, Calendar Year 2021. November, 2022: Toy-Related Deaths and Injuries, Calendar Year 2021; available at: *https://www.cpsc.gov/Research--Statistics/Toys-and-Childrens-Products.*

paramount importance because age-grading and labeling can be used to assist consumers in making purchasing decisions, and also serve as the basis for the toy's regulatory requirements and the associated testing parameters. For example, toys intended for children under 8 years of age are required to undergo use and abuse tests based on actual use and misuse by children of that age. Test specifications vary for different age groups (*i.e.,* children 18 months and younger, 19–36 months, and 37–95 months). Toys intended for children younger than 3 years old cannot contain small parts. Additionally, since 2008, CPSC regulations establish lead and phthalates limitations for many products intended for children 12 years of age.

CPSC staff consider numerous toy characteristics when determining the intended age, including the physical characteristics of the toy (*e.g.,* size and weight of the toy and its components), the cognitive requirements for using the toy as intended, the fine motor or other physical skills required to use the toy as the manufacturer intended, and the toy's theme and appearance. The CPSC's *Age Determination Guidelines: Relating Consumer Product Characteristics to the Skills, Play Behaviors, and Interests of Children (Guidelines),* available at *https://www.cpsc.gov/content/2020-Age-Determination-Guidelines,* provide details and examples for each of these characteristics for different age groups. Manufacturers can use the *Guidelines* to generate an intended age during a toy's design phase. Manufacturers can also use the *Guidelines* to accurately age label a product, which promotes safety by informing consumer purchasing and toy-safety decisions (meaning which toys are appropriate to allow a child to play with).

Although the *Guidelines* include extensive information about a large variety of toys, some toy categories are not well covered in the *Guidelines* because they include toys that are new to the U.S. market since the research that went into the 2020 version of the *Guidelines.* While smart toys are discussed in the *Guidelines,* this category of toys evolves rapidly, so the *Guidelines* may not represent what is currently in the market. Other toys such as figurines, interlocking building sets, and musical toys are discussed in the *Guidelines,* though not extensively. This data collection will add to the information about selected toys in six toy categories (smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives), and enrich CPSC's understanding regarding the ages of children who are interested in these toys and who possess the skills and cognitive ability to use them as intended. This data collection will provide information to help CPSC determine the developmentally appropriate ages for selected toys. Ultimately, the data collection will inform the various stakeholders who use the information contained in the *Guidelines.*

Affected Public: Children between 2 and 4 years of age and their caregivers.

Estimated Number of Respondents: 60 children and 60 caregivers, totaling 120 individuals.

Frequency: One-time data collection that will take place over 2 in-person sessions. The first session will last up to 80 minutes, and the second session will last up to 80 minutes.

Estimated Total Annual Burden Hours: CPSC plans to pilot test the study with 4 participants (2 caregivers and 2 children) with a maximum time burden of 2.67 hours per person (10.68 hours). CPSC also assumes a 15-minute completion time for the recruitment screener questionnaire to be filled out by a maximum of 100 people, to select 60 adult participants (25 hours).

CPSC estimates that the total time for each selected respondent pair (caregiver/child) to participate in the data collection will likely not be more than 160 minutes. Therefore, each participant has a maximum time burden of 2.67 hours. Data collection duration for each respondent will be 2.67 hours, or a total of 160 hours for 60 respondent pairs. Respondent pairs will not incur any reporting costs from the information collection. The pairs also will not incur a record keeping burden or record keeping costs from this information collection. We will assume an hourly wage rate of $31.54 for each respondent pair (caregiver and child).[3]

Accordingly, the total burden hours to recruit participants and for selected respondents to participate is 356 hours (recruitment screening time (25 hours), pilot study (10.68 hours), and the main study (2.67 hours × 120 participants)).

The total cost of this collection to the federal government is $93,345 annually. This represents 6 months of staff time. This amount includes federal employee salaries and benefits. No travel costs are associated with the collection. This estimate uses an annual salary of $126,949 (the equivalent of a GS–13, Step 5 employee, in the Washington DC area in 2023)[4] which represents 68.0 percent of the employer costs for employee compensation. The remaining 32.0 percent of employer costs are added for benefits (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2023, percentage of wages and salaries for all civilian management, professional, and related employees),[5] for a total annual compensation per FTE of $186,690.

Estimated Total Annual Burden Cost: $104,573.24 (Respondents: $11,228.24 (31.54/hr. × 356 hours) + Federal Government: $93,345).

II. Comment Response

Comment Summary: The National Center for Health Research submitted a comment on the proposal, supporting CPSC's research but concerned that the study design will not provide the needed information. The commenter suggests that CPSC may need at least twice as many as the 60 children and 60 caregivers in the study to determine products appropriate for children ages 2 to 4. The commenter believes that the study should include more children to represent the diversity of U.S. children in the 3-year age group for cognitive and social development, socio-economic status, and social and cultural differences, because these differences could influence the ability to use toys safely and effectively. The commenter states that even 120 children may not be an adequate sample size because each child would only be evaluated regarding 4 of the 6 different toy categories, opining that more children are necessary to study appropriate labeling for children under 3 years old, and that increasing the number and diversity of children and caregivers that engage with each toy category is essential to provide information that will be reliable and generalizable for families across the country.

CPSC's Response: The proposed data collection is not intended to provide nationally representative data; this research is exploratory. Further, as this is largely a descriptive study, CPSC does not plan on conducting inferential statistics and doing hypothesis testing. Researchers will gather information by documenting children's play patterns with selected toys from each of six toy categories that are not addressed in CPSC's *Guidelines* (*i.e.,* smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives). Given

[3] Average hourly wage across all occupations from *https://www.bls.gov/oes/current/oes_va.htm#00-0000.* CPSC uses occupational wage estimates for Virginia because the study will be conducted in the area.

[4] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB.pdf.*

[5] *https://www.bls.gov/news.release/archives/ecec_06162023.pdf.*

that children's play behaviors with these toy categories have not been thoroughly examined, this research is an initial exploration of the types of play behaviors children of different age groups exhibit when interacting with the selected toys. Researchers will gather information by observing children's play patterns in a laboratory setting and noting how they interact with selected toys. The controlled laboratory setting will allow researchers to explore developmental differences in play patterns among the age groups.

Additionally, the duration of each session provides the researchers an opportunity to observe naturalistic play behaviors without rushing the child through interacting with the toy. Researchers will code and summarize observation data while the child is interacting with the toy. Researchers will tabulate descriptive statistics to identify the universe of behaviors for each age group and toy, and, when possible, compare children's play with toys that are intended for their age, versus toys that are intended for children either older or younger. Collecting this data will add to the available information about toys in six toy categories and inform potential next steps in the age-grading process.

Because pilot testing per pair could be up to a maximum of 80 minutes for each session, CPSC is calculating the overall possible information collection participant burden based upon a 160-minute maximum burden. Researchers determined the duration of sessions to balance adequate time for observation, needed breaks for the child, and not overburdening the child.

The commenter expressed concern that ''Each child would only be evaluated regarding 4 of the 6 different toy categories.'' In fact, the researchers will introduce children to selected toys from 6 toy categories (smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives) in each of the sessions. During the first session they will be introduced to 4 toys and during the second session they will be introduced to 5 toys, for a total of 9 toys. The order in which the toys are presented will be randomized to preclude the effects of fatigue and learning from one toy to the next.

Elina Lingappa,

Paralegal Specialist, Consumer Product Safety Commission.

[FR Doc. 2023–26364 Filed 11–29–23; 8:45 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; Disaster Response Cooperative Agreement Application

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 29, 2024.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through *www.regulations.gov* (preferred method).

(2) By mail sent to: AmeriCorps, Attention: Rita Pratte, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, 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. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Rita Pratte, 202–815–5719, or by email at *rpratte@americorps.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Disaster Response Cooperative Agreement Application.

OMB Control Number: 3045–0133.

Type of Review: Renewal.

Respondents/Affected Public: Businesses and Organizations.

Total Estimated Number of Annual Responses: 100.

Total Estimated Number of Annual Burden Hours: 3,960.

Abstract: AmeriCorps seeks renewal of the current information collection pursuant to the Domestic Volunteer Service Act of 1973 (42 U.S.C. 4950 *et seq.*) and the National and Community Service Act of 1990, (42 U.S.C. 12501 *et seq.*) The information collected is used to help AmeriCorps more effectively use its deployable resources to meet the needs of communities affected by disaster. An understanding of the participating programs allows AmeriCorps to match the capabilities of the programs to the needs of the communities and will allow better asset mapping and resource typing. Additionally, the information collected will allow AmeriCorps to conduct better outreach to interested programs by providing them with more information about the Agency's disaster procedures, reimbursement requirements, and support services offered. This information collection ensures interested programs meet the appropriate programmatic and fiscal requirements to successfully execute disaster response activities. It also helps AmeriCorps identify and deploy programs effectively and efficiently, matching the capabilities of the programs to the needs of the communities asking for assistance. The forms under the DRCA allow for effective information collection during a disaster event as well as assess the capacity of all DRCA programs throughout the year. Information is collected electronically through completion of the forms and emailed to AmeriCorps. The current application is due to expire on March 31, 2024.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. 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. All written comments will be available for public inspection on *regulations.gov.*

Walter Goodson,

Director, AmeriCorps NCCC.

[FR Doc. 2023–26266 Filed 11–29–23; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF EDUCATION

President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics

AGENCY: U.S. Department of Education, President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics.

ACTION: Announcement of an open meeting.

SUMMARY: This notice sets forth the agenda for the December 19, 2023, virtual meeting of the President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics (Commission), and how members of the public may attend the meeting and submit written comments pertaining to the work of the Commission.

DATES: The meeting of the Commission will be held on Tuesday, December 19, 2023, from 12 p.m. to 5 p.m. Eastern Standard Time.

ADDRESSES: The meeting will be conducted virtually.

FOR FURTHER INFORMATION CONTACT: Emmanuel Caudillo, Designated Federal Official, President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics, U.S. Department of Education, 400 Maryland Avenue SW, Room 7E220, Washington, DC 20202, telephone: (202) 453–5529, or email: *Emmanuel.Caudillo@ed.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is required by Section 1009(a)(2) of 5 U.S.C. Chapter 10 (Federal Advisory Committees).

The Commission's Statutory Authority and Function: The Commission is established by Executive Order 14045 (September 13, 2021) and continued by Executive Order 14109 (September 29, 2023). The Commission is also governed by the provisions of 5 U.S.C. Chapter 10 (Federal Advisory Committees), which sets forth standards for the formation and use of advisory committees. The Commission's duties are to advise the President, through the Secretary of Education, on matters pertaining to educational equity and economic opportunity for the Hispanic and Latino community in the following areas: (i) what is needed for the development, implementation, and coordination of educational programs and initiatives at the U.S. Department of Education (Department) and other agencies to improve educational opportunities and outcomes for Hispanics and Latinos; (ii) how to promote career pathways for in-demand jobs for Hispanic and Latino students, including registered apprenticeships, internships, fellowships, mentorships, and work-based learning initiatives; (iii) ways to strengthen the capacity of institutions, such as Hispanic-serving Institutions, to equitably serve Hispanic and Latino students and increase the participation of Hispanic and Latino students, Hispanic-serving school districts, and the Hispanic community in the programs of the Department and other agencies; (iv) how to increase public awareness of and generate solutions for the educational and training challenges and equity disparities that Hispanic and Latino students face and the causes of these challenges; and (v) approaches to establish local and national partnerships with public, private, philanthropic, and nonprofit stakeholders to advance the mission and objectives of this order, consistent with applicable law.

Meeting Agenda: The agenda for the Commission meeting builds upon conversations and information shared in the Commission's three prior meetings. It includes: (1) a discussion and vote on recommendations presented by the Commission's four subcommittees: Advancing PreK–12 Educational Equity; Advancing Higher Education and Hispanic Serving Institutions (HSIs); Strengthening Economic Opportunity & Workforce Development; and Strengthening Public Partnerships and Public Awareness; (2) presentations from federal and community leaders on topics related to Executive Order 14045; and (3) and discussion around next steps towards advancing duties of the Commission, as outlined by Executive Order 14045.

Access to the Meeting: Members of the public may register to virtually attend the meeting by accessing the link at *https://www.ed.gov/hispanicinitiative* or emailing *WhiteHouseHispanicInitiative@ed.gov* by 5 p.m. EST on Monday, December 18, 2023. Instructions on how to access the meeting will be emailed to members of the public that register to attend and will be posted to *https://www.ed.gov/hispanicinitiative* by Monday, December 18, 2023 by 6 p.m. EST.

Public Comment: Written comments pertaining to the work of the Commission may be submitted electronically to *WhiteHouseHispanicInitiative@ed.gov* by 5 p.m. EST on Monday, December 18, 2023. Include in the subject line: ''Written Comments: Public Comment.'' The email must include the name(s), title, organizations/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to the electronic mail message (email) or provided in the body of an email message. Please do not send material directly to members of the Commission.

Reasonable Accommodations: The meeting platform and access code are accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least one week before the meeting date. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Commission's website, at *https://sites.ed.gov/hispanic-initiative/presidential-advisory-commission* no later than 90 days after the meeting. Pursuant to 5 U.S.C. 1009(b), the public may request to inspect records of the meeting, and other Commission records, at 400 Maryland Avenue SW, Washington, DC, by emailing *Emmanuel.Caudillo@ed.gov* or by calling (202) 453–5529 to schedule an appointment.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the

official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department 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.

Authority: Executive Order 14045 (September 13, 2021) and continued by Executive Order 14109 (September 29, 2023).

Alexis Barrett,

Chief of Staff, Office of the Secretary.

[FR Doc. 2023–26368 Filed 11–29–23; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0070; FRL–10841–08–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients (August 2023)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before January 2, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0070, and the specific case number for the chemical substance related to your comment, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Anne Overstreet, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–2425, email address: *BPPDFRNotices@epa.gov.* The mailing address is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions*).

The *New Active Ingredient* listed in this notice was incorrectly identified as a *New Use* in the **Federal Register** on September 20, 2023 (88 FR 64909) (FRL–10578–08–OCSPP).

Notice of Receipt—New Active Ingredient

File Symbol: 524–AAL. *Docket ID number:* EPA–HQ–OPP–2023–0379. *Applicant:* Bayer CropScience LP, 700 Chesterfield Parkway West, Chesterfield, MO 63017. *Active ingredient:* GA20ox_SUP miRNA. *Product type:* Plant-incorporated Protectant. *Proposed use:* Plant Growth Regulator. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 16, 2023.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2023–26333 Filed 11–29–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1255; FR ID 186656]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as

required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 29, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1255.

Title: Rules and Policies Regarding Calling Number Identification Service—Caller ID, CC Docket No. 91–281.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 46,291 respondents; 1,705 responses.

Estimated Time per Response: .083 hours (5 minutes).

Frequency of Response: Monthly and on-going reporting requirements.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority for the information collection requirements is found at section 201(b) of the Communications Act of 1934, as amended, 47 U.S.C. 201(b), and section 222, 47 U.S.C. 222. The Commission's implementing rules are codified at 47 CFR 64.1600–01.

Total Annual Burden: 142 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission amended rules requiring that carriers honor privacy requests to state that § 64.1601(b) of the Commission's rules shall not apply when calling party number (CPN) delivery is made in connection with a threatening call. Upon report of such a threatening call by law enforcement on behalf of the threatened party, the carrier will provide any CPN of the calling party to law enforcement and, as directed by law enforcement, to security personnel for the called party for the purpose of identifying the party responsible for the threatening call. Carriers now have a recordkeeping requirement in order to quickly provide law enforcement with information relating to threatening calls.

The Commission also amended rules to allow non-public emergency services to receive the CPN of all incoming calls from blocked numbers requesting assistance. The Commission believes amending its rules to allow non-public emergency services access to blocked Caller ID promotes the public interest by ensuring timely provision of emergency services without undermining any countervailing privacy interests. Carriers now have a recordkeeping requirement in order to provide emergency serve providers with the information they need to assist callers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–26339 Filed 11–29–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than December 15, 2023.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Patriot Financial Partners GP III, LLC, Patriot Financial Partners GP III, L.P., Patriot Financial Partners III, L.P., Patriot Financial Advisors, LLC, Patriot Financial Advisors, L.P., W. Kirk Wycoff, and James F. Deutsch, all of Radnor, Pennsylvania;* as a group acting in concert, to acquire voting shares of Fortis Bancorp and thereby indirectly acquire voting shares of Fortis Bank, both of Denver, Colorado.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–26345 Filed 11–29–23; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Survey of Household Economics and Decisionmaking (FR 3077; OMB No. 7100–0374).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of

Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Survey of Household Economics and Decisionmaking.

Collection identifier: FR 3077.

OMB control number: 7100–0374.

Effective Date: November 30, 2023.

General description of collection: The Survey of Household Economics and Decisionmaking (SHED) is an ad hoc voluntary survey covering topics such as individuals' overall financial well-being, employment experiences, income and ability to pay bills, economic preparedness, banking and access to credit, housing and living arrangement decisions, education and human capital, student loans, and retirement planning. The overall content of the SHED depends on changing economic, regulatory, or legislative developments as well as changes in the financial services industry. The Board uses the SHED to monitor usage of emerging financial products and understand how macroeconomic conditions are affecting households.

Frequency: Annually.

Respondents: Non-institutionalized individuals who are 18 years of age and older.

Total estimated number of respondents: 20,500.

Total estimated change in burden: 495.

Total estimated annual burden hours: 8,200.[1]

Current actions: On August 18, 2023, the Board published a notice in the **Federal Register** (88 FR 56626) requesting public comment for 60 days on the extension, with revision, of the FR 3077. The Board proposed to revise the FR 3077 by removing the qualitative ad-hoc surveys, effective November 30, 2023 (however, the annual SHED may still include qualitative components). This revision is to reduce duplication across information collections.

The Board also proposed adding two minutes to the quantitative survey time per response and slightly reducing the potential number of respondents, also effective November 30, 2023. The increase in survey length reflects two adjustments. First, it is intended to provide additional flexibility for new topics related to financial well-being that are covered in the survey. For example, in recent years the survey has included questions on inflation, cryptocurrency, and buy now pay later products which are valuable for understanding financial well-being, and this additional minute will allow the Board to cover these and other emerging issues more thoroughly. Second, because the burden is calculated for all contacted respondents, and response rates have increased in recent years, the computed time per respondent has increased. The slight reduction in potential respondents similarly reflects that the final stage response rate for the survey has exceeded expectations in recent years, thereby requiring fewer contacted respondents.

The comment period for this notice expired on October 17, 2023. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, November 27, 2023.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–26326 Filed 11–29–23; 8:45 am]

BILLING CODE 6210–01–P

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 3077.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Ad Hoc Clearance for Surveys of Consumer and Community Affairs Publications and Resources (FR 1378; OMB No. 7100–0358).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Ad Hoc Clearance for Surveys of Consumer and Community Affairs Publications and Resources.

Collection identifier: FR 1378.

OMB control number: 7100–0358.

General description of collection: The Board uses this collection to seek input from users or potential users of the Board's publications, resources, and conference materials to understand their interests and needs; to inform decisions concerning content, design, and dissemination strategies; to gauge public awareness of the Board's publications, resources, and conferences; and to assess the effectiveness of the Board's communications with various respondents.

The surveys in this collection are used to gather qualitative and quantitative information directly from users or potential users of Board publications, resources, and conference materials, such as consumers (consumer surveys) and stakeholders (stakeholder surveys). The content of survey questions and the type of consumer or stakeholder respondents vary from survey to survey. Survey respondents include individuals, businesses, non-profit institutions, government entities, and other Board stakeholders.

Frequency: Event-generated.

Respondents: Individuals, businesses, non-profit institutions, government entities, and other Board stakeholders.

Total estimated number of respondents: 1,900.

Total estimated annual burden hours: 2,300.[1]

Current actions: On August 18, 2023, the Board published a notice in the **Federal Register** (88 FR 56623) requesting public comment for 60 days on the extension, without revision, of the FR 1378. The comment period for this notice expired on October 17, 2023. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, November 27, 2023.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–26329 Filed 11–29–23; 8:45 am]

BILLING CODE 6210–01–P

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 1378.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Consumer and Stakeholder Surveys (FR 3073; OMB No. 7100–0359).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Consumer and Stakeholder Surveys.

Collection identifier: FR 3073.

OMB control number: 7100–0359.

General description of collection: The Board uses this collection to inform consumer-focused research, implement statutory requirements, and facilitate community development. The surveys in this collection inform the Board's work by identifying emerging risks and providing additional data on the issues that affect the well-being of consumers and communities and how the financial services marketplace functions. The surveys in this collection gather quantitative and qualitative information directly from individual consumers or households (consumer surveys) on consumer finance topics. This collection also gathers quantitative and qualitative information on current and emerging community economic issues from stakeholders (stakeholder surveys).

Frequency: Event-generated.

Respondents: Individuals and Board stakeholders.

Total estimated number of respondents: 10,600.

Total estimated annual burden hours: 12,000.[1]

Current actions: On August 18, 2023, the Board published a notice in the **Federal Register** (88 FR 56621) requesting public comment for 60 days on the extension, without revision, of the FR 3073. The comment period for this notice expired on October 17, 2023. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, November 27, 2023.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–26328 Filed 11–29–23; 8:45 am]

BILLING CODE 6210–01–P

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 3073.

GENERAL SERVICES ADMINISTRATION

[Notice–AD–2023–01; Docket No. 2023–0002; Sequence No. 39]

Notice of 2024 Presidential Transition Directory

AGENCY: Presidential Transition; General Services Administration (GSA).

ACTION: Notice of availability of the GSA 2024 Presidential Transition Directory.

SUMMARY: The Presidential Transition Directory: The website is designed to help candidates in the 2024 Presidential election get quick and easy access to key resources about the Federal Government structure and key policies related to Presidential Transition. The creation of the Presidential Transition Directory is mandated by the Presidential Transition Act of 1963, as amended.

DATES: *Applicable:* November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Jonathan Foye at (202) 219–1493 or *presidentialtransition2024@gsa.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Transition Directory

(*presidentialtransition.gsa.gov*) website is designed to help candidates in the 2024 Presidential election get quick and easy access to key resources about the Federal Government structure and key policies related to Presidential Transition. The creation of the Presidential Transition Directory is mandated by the Presidential Transition Act of 1963, as amended (3 U.S.C. 102 Note). Connecting resources from the Office of Personnel Management, National Archives and Records Administration, U.S. Office of Government Ethics and others, the site will also help future political appointees better understand important aspects of their roles and some of the key policies and elements of Federal service.

The site will be continuously updated as new information becomes available to help ensure candidates and their staff have access to the best information possible.

Aimee Whiteman,

Federal Transition Coordinator, U.S. General Services Administration.

[FR Doc. 2023–26337 Filed 11–29–23; 8:45 am]

BILLING CODE 6820–AZ–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2023–09; Docket No. BSC–RPM–2023–0005; Sequence No. 1]

Business Standards Council Review of Real Property Management Federal Integrated Business Framework Annual Update: Request for Public Comment

AGENCY: Office of Government-wide Policy; General Services Administration, (GSA).

ACTION: Request for public comment.

SUMMARY: This notice informs the public of the opportunity to provide input on the annual update to the real property management business standards in support of Federal shared services.

DATES: Interested parties should submit comments by the method outlined in the **ADDRESSES** section immediately below on or before January 2, 2024.

ADDRESSES: Submit comments in response to Notice–MA–2023–09 via *http://www.regulations.gov.* Submit comments using the Federal eRulemaking portal by searching for ''Notice Notice–MA–2023–09.'' Select the link ''Comment Now'' that corresponds with ''Notice–MA–2023–09.'' Follow the instructions provided at the screen. Please include your name, company name (if any), and ''Notice BSC–RPM–2023–0005'' on your attached document.

• *Instructions:* Please submit comments only and cite ''Notice–MA–2023–09'' in all correspondence related to this notice. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal or business confidential information, or both, provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov* approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Chris Coneeney, Director, Real Property Policy Division, at 202–208–2956, or by email at *chris.coneeney@gsa.gov.*

SUPPLEMENTARY INFORMATION: On April 26, 2019, the Office of Management and Budget (OMB) published OMB memorandum M–19–16, ''Centralized Mission Support Capabilities for the Federal Government'' (available at *https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-16.pdf*). Mission support business standards, established and agreed to by the Chief Financial Officer (CFO) Act agencies, using the Federal Integrated Business Framework website at *https://ussm.gsa.gov/fibf/,* enable the Federal Government to better coordinate on the decision-making needed to determine what mission support services can be adopted and commonly shared. These business standards are an essential first step towards agreement on outcomes, data, and cross-functional end-to-end processes that will drive economies of scale and leverage the government's buying power. The business standards will be used as the foundation for common mission support services shared by the CFO Act agencies.

GSA serves as the real property management business standards lead on the Business Standards Council. The goal of the real property management business standards is to drive real estate management consistency, equity and standardization across the Federal Government.

This year's updates reflect changes as a result of the business information exchange with the Financial Management shared service functional area and as a result of the environmental scan of recent laws, executive orders and other policy changes. The data elements, scenarios, use cases, and functions, activities and business capabilities artifacts were all updated.

GSA is seeking public feedback on the annual update to the business standards, including comments on the understandability of the standards, suggested changes and usefulness of the draft standards to industry and agencies.

Guiding questions in the standards development include:

• Do the draft business standards appropriately document the business processes covered?

• Are the draft business standards easy to understand?

• Will your organization be able to show how your solutions or services, or both, can meet these draft business standards?

• What would you change about the draft business standards? Is there anything missing?

Comments will be used in the formulation of the final real property management business standards.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy, U.S. General Services Administration.

[FR Doc. 2023–26370 Filed 11–29–23; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of the re-establishment of a matching program between CMS and the Peace Corps for ''Verification of Eligibility for Minimum Essential Coverage Under the Patient Protection and Affordable Care Act through a Peace Corps Health Benefit Plan.''

DATES: The deadline for comments on this notice is January 2, 2024. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately January 1, 2024 to June 30, 2025) and within 3 months of expiration may be renewed for up to one additional year if the parties make no change to the matching program and certify that the program has been conducted in

compliance with the matching agreement.

ADDRESSES: Interested parties may submit comments on this notice to the CMS Privacy Act Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850 or by email at *Barbara.Demopulos@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact Anne Pesto, Senior Advisor, Marketplace Eligibility and Enrollment Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, at 443–955–9966, by email at *anne.pesto@cms.hhs.gov,* or by mail at 7500 Security Blvd., Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving Federal benefits. The law governs the use of computer matching by Federal agencies when records in a system of records (meaning, Federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other Federal or non-Federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient Federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o)(2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos,

Privacy Act Officer, Division of Security, Privacy Policy and Governance, Office of Information Technology, Centers for Medicare & Medicaid Services.

PARTICIPATING AGENCIES:

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Peace Corps is the source agency.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

The principal authority for the matching program is 42 U.S.C. 18001, *et seq.*

PURPOSE(S):

The purpose of the matching program is to assist CMS in determining individuals' eligibility for financial assistance in paying for private health insurance coverage. In this matching program, the Peace Corps provides CMS with daily files, identifying all Peace Corps volunteers and the dates when each volunteer was eligible for coverage under a Peace Corps health benefit plan, which CMS makes available to state administering entities (AEs) through a data services hub, under a separate matching agreement. CMS and AEs use the Peace Corps data to verify whether an individual who is applying for or is enrolled in private health insurance coverage under a qualified health plan through a federally-facilitated or state-based health insurance exchange is eligible for coverage under a Peace Corps health benefit plan, for the purpose of determining the individual's eligibility for financial assistance (including an advance tax credit and cost sharing reduction, which are types of insurance affordability programs) in paying for private health insurance coverage. Peace Corps health benefit plans provide minimum essential coverage, and eligibility for such plans precludes eligibility for financial assistance in paying for private coverage. The data provided by the Peace Corps under this matching program will be used by CMS and AEs to authenticate identity, determine eligibility for financial assistance, and determine the amount of any financial assistance.

CATEGORIES OF INDIVIDUALS:

The categories of individuals whose information is involved in the matching program are: (1) active and recently separated Peace Corps volunteers, identified in data CMS receives from the Peace Corps, and (2) consumers who apply for or are enrolled in private insurance coverage under a qualified health plan through a federally-facilitated or state-based health insurance exchange (and other relevant individuals, such as applicants' and enrollees' household members), whose records are matched against the data CMS receives from the Peace Corps.

CATEGORIES OF RECORDS:

The categories of records which will be provided by the Peace Corps to CMS in this matching program are identity records and minimum essential coverage period records, consisting of these data elements: last name, middle initial, first name, and date of birth. CMS will not send any data about individual applicants/enrollees to the Peace Corps in order to receive this data about Peace Corps volunteers.

SYSTEM(S) OF RECORDS:

A. System of Records Maintained by CMS

The applicable CMS system of records is CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018).

B. System of Records Maintained by the Peace Corps

The applicable Peace Corps system of records is PC–17 Peace Corps, Volunteer Applicant and Service Records System, last published in full at 50 FR 1950 (Jan. 14, 1985) and partially amended at 65 FR 63641 (Oct. 24, 2000), 72 FR 44878 (Aug. 9, 2007), 75 FR 53000 (Aug. 30, 2010), and 79 FR 41599 (July 16, 2014). Routine use (i) published at 50 FR 1950 (Jan. 14, 1985), which permits disclosures ''to verify active or former volunteer service,'' authorizes the Peace Corps' disclosures to CMS.

[FR Doc. 2023–26330 Filed 11–29–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Early Childhood Facilities Combined Application Guide (New Collection)

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Early Childhood Development (ECD), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting Office of Management and Budget (OMB) approval of the Tribal Early Childhood Facilities Combined Application Guide for joint applications for construction and major renovation projects using both Head Start and Child Care and Development Fund (CCDF) resources.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Funding for facilities under the CCDF is authorized by section 658O(c)(6) of the Child Care and Development Block Grant (CCDBG) Act, 42 U.S.C. 9858(c)(6), and is managed by the Office of Child Care (OCC). Funding for Head Start facilities projects is authorized by 45 CFR part 1303 (subpart E) Head Start Program Performance Standards and is managed by the Office of Head Start (OHS). The guide streamlines the process for Tribal CCDF Lead Agencies and American Indian and Alaska Native (AI/AN) Head Start programs submitting collaborative, joint applications to use federal CCDF and Head Start funds for facilities projects where funds can be used for reasonable costs and fees related to planning for a facilities project and to support the application development in tribal communities. Both funds aim to construct or improve early childhood facilities, often serving the same children, but application submission and review processes are currently unique to each respective funding stream. The proposed information collection will provide instructions to Tribal CCDF Lead Agencies and AI/AN Head Start programs on submitting joint plans for how proposed facilities projects will enable the programs to better serve current AI/AN families or increase enrollment currently limited by inadequate facilities. The guide will provide critical information and resources, so recipients understand the requirements of each program and develop plans that reflect the needs of their communities. Reducing and streamlining administrative burdens for tribal constituents follows policy priorities laid out in the 2022 HHS Equity Action Plan and is in alignment with Executive Order 14095—Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers.

Respondents: AI/AN Head Start Facilities and Tribal CCDF Lead Agencies (information collection does not include direct interaction with individuals or families that receive the services).

Annual Burden Estimates: We estimate at most 10 applications per year and have estimated burden based on this maximum number.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal Early Childhood Facilities Application Guide	10	1	100	1,000

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9858(c)(6); 45 CFR part 1303 subpart E.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–26307 Filed 11–29–23; 8:45 am]

BILLING CODE 4184–87–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Survey of Staff Recruitment, Training, and Professional Development in Early Head Start (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children & Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a nationally representative survey of Early Head Start (EHS) grant recipients regarding their recruitment, hiring, and professional development practices.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, the ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The *Survey of Staff Recruitment, Training, and Professional Development in EHS* is a nationally representative survey that will describe how EHS programs ensure staff have the qualifications and competencies to deliver high-quality services to infants, toddlers, and their families. The information collection will examine how EHS grant recipients search for and hire qualified teaching and home visiting staff and support staff in their ongoing professional development and career advancement. The information collection aims to identify successful strategies or approaches as well as challenges faced as EHS programs search for, hire, and train teaching and home visiting staff. Findings are intended to inform program planning, training and technical assistance, and research.

Respondents: EHS program directors or their designee.

Annual Burden Estimates:

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Survey instrument for center-based programs only	232	1	.5	116
Survey instrument for home-based programs only	56	1	.5	28
Survey instrument for programs with center-based and home-based options	312	1	.75	234

Estimated Total Annual Burden Hours: 378.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Head Start Act section 640 [42 U.S.C. 9835].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–26297 Filed 11–29–23; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–0656; FDA–2022–E–0657; FDA–2022–E–0658; FDA–2022–E–0659; FDA–2022–E–0660; and FDA–2022–E–0680]

Determination of Regulatory Review Period for Purposes of Patent Extension; Amondys 45

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Amondys 45 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. 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 Nos. FDA–2022–E–0656; FDA–2022–E–0657; FDA–2022–E–0658; FDA–2022–E–0659; FDA–2022–E–0660; FDA–2022–E–0680 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AMONDYS 45.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Amondys 45 (casimersen), which is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Amondys 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for Amondys 45 (U.S. Patent Nos. 8,524,880; 9,228,187; 9,447,415; 9,758,783; 10,287,586; and 10,781,450) from The University of Western Australia, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 14, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Amondys 45 represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Amondys 45 is 2,412 days. Of this time, 2,166 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 22, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 22, 2014.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 25, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Amondys 45 (NDA 213026) was initially submitted on June 25, 2020.

3. *The date the application was approved:* February 25, 2021. FDA has verified the applicant's claim that NDA 213026 was approved on February 25, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 157 days, 450 days, 755 days, 933 days, 1,063 days, or 1,329 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26299 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–0676]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZEGALOGUE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZEGALOGUE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. 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:

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

Instructions: All submissions received must include the Docket No. FDA–2022–E–0676 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZEGALOGUE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for

example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ZEGALOGUE (dasiglucagon), which is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and older. Subsequent to this approval, the USPTO received a patent term restoration application for ZEGALOGUE (U.S. Patent No. 10,442,847) from Zealand Pharma A/S, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 28, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZEGALOGUE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZEGALOGUE is 1,734 days. Of this time, 1,373 days occurred during the testing phase of the regulatory review period, while 361 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 24, 2016. The applicant claims February 22, 2017, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 24, 2016, which was the first date after receipt of the first IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* March 27, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for ZEGALOGUE (NDA 214231) was initially submitted on March 27, 2020.

3. *The date the application was approved:* March 22, 2021. FDA has verified the applicant's claim that NDA 214231 was approved on March 22, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 47 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26260 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2026; FDA–2022–E–2027; FDA–2022–E–2028]

Determination of Regulatory Review Period for Purposes of Patent Extension; Qelbree

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Qelbree and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2022–E–2026; FDA–2022–E–2027; FDA–2022–E–2028 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QELBREE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Qelbree (viloxazine) indicated for the treatment of Attention Deficit Hyperactivity Disorder in pediatric patients 6 to 17 years of age. Subsequent to this approval, the USPTO received patent term restoration applications for Qelbree (U.S. Patent Nos. 9,358,204; 9,603,853; 9,662,338) from Supernus Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 13, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Qelbree represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Qelbree is 4,328 days. Of this time, 3,816 days occurred during the testing phase of the regulatory review period, while 512 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 29, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 8, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for Qelbree (NDA 211964) was initially submitted on November 8, 2019.

3. *The date the application was approved:* April 2, 2021. FDA has verified the applicant's claim that NDA 211964 was approved on April 2, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 785 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To

meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26301 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5262]

Determination of Regulatory Review Period for Purposes of Patent Extension; Nuzyra Injection (New Drug Application 209817)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) has determined the regulatory review period for Nuzyra Injection (new drug application (NDA) 209817) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. 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–2019–E–5262 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; Nuzyra Injection (NDA 209817). '' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic

Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Nuzyra Injection (NDA 209817) (omadacycline). Nuzyra Injection (NDA 209817) is indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia, and
- Acute bacterial skin and skin structure infections.

Subsequent to this approval, the USPTO received a patent term restoration application for Nuzyra Injection (NDA 209817) (U.S. Patent No. 7,553,828) from Paratek Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Nuzyra Injection (NDA 209817) and Nuzyra Tablets (NDA 209816) represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the products' regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Nuzyra Injection (NDA 209817) is 4,361 days. Of this time, 4,118 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 26, 2006. The applicant claims September 26, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 26, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* February 2, 2018. FDA has verified the applicant's claim that the NDA for Nuzyra Injection (NDA 209817) was initially submitted on February 2, 2018.

3. *The date the application was approved:* October 2, 2018. FDA has verified the applicant's claim that NDA 209817 was approved on October 2, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,812 days of patent term extension.

Note: We have determined that the regulatory review period for the human drug product, NUZYRA, approved under NDA 209817 is the same as the regulatory review period determined for the human drug product, NUZYRA, approved under NDA 209816.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26363 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2562]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 2, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0133. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i)

OMB Control Number 0910–0133—Extension

This information collection request supports FDA regulations found in 21 CFR 130.17 (section 130.17). Section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity (SOIs) for food. Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and SOI prescribed by regulation is misbranded if it does not conform to such definition and SOI. Section 130.17 provides for the issuance by FDA of temporary marketing permits (TMPs) that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and SOIs. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and SOIs. The information so obtained can be used in support of a petition to establish or amend the applicable definition or SOI to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a TMP. To assist respondents with the TMP process, we have developed guidance entitled ''Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity: Guidance for Industry'' (November 2021). This resource can be found on our website *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-permits-interstate-shipment-experimental-packs-food-varying-requirements.*

Description of Respondents: Respondents to this collection of information include private sector businesses including institutional and/or industrial customers and food industry members such as manufacturers, packers, or distributors desiring to apply for a TMP or TMP extension.

In the **Federal Register** of July 17, 2023 (88 FR 45431), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c); Request for TMP	13	2	26	25	650
130.17(i); Request for TMP extension	1	2	2	2	4
Total					654

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26300 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4095]

Using Relative Supersaturation To Support ''Urinary Tract Health'' Claims for Adult Maintenance Cat Food; 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 guidance for industry #284 entitled ''Using Relative Supersaturation to Support ''Urinary Tract Health'' Claims for Adult Maintenance Cat Food.'' FDA's Center for Veterinary Medicine (CVM) has evaluated the use of relative supersaturation (RSS) methodology to support urinary tract health claims for certain adult maintenance cat food. RSS is a measurement that estimates the potential for crystal formation and bladder stone growth, which is a common affliction in cats. This draft guidance provides recommendations for how pet food manufacturers can use RSS methodology to substantiate general structure or function claims that an adult maintenance cat food supports urinary tract health by promoting a healthy mineral content in the urinary tract.

DATES: Submit either electronic or written comments on the draft guidance by February 28, 2024 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–2023–D–4095 for ''Using Relative Supersaturation to Support ''Urinary Tract Health'' Claims for Adult Maintenance Cat Food.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Donnelly, Center for Veterinary Medicine (HFV–227), Food and Drug Administration, 12225 Wilkins Avenue, Rockville, MD 20852, 240–402–9802, *karen.donnelly2@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #284 entitled ''Using Relative Supersaturation to Support ''Urinary Tract Health'' Claims for Adult Maintenance Cat Food.'' RSS methodology is a measurement that estimates the potential for crystal formation and bladder stone (urolith) growth, which is a common affliction in cats. One of the primary conditions for urolith formation in any species is oversaturation of the urine with dissolved substances (solutes) that have the potential to precipitate out of solution and form crystals. These crystals can eventually grow into uroliths. The two most common types of uroliths in cats are magnesium ammonium phosphate (struvite) and calcium oxalate (CaOx).

Based on concerns about uroliths, pet food manufacturers use various formulation strategies to make adult maintenance cat food, with general structure or function claims, that support urinary tract health (UTH cat food). Historically, manufacturers of UTH cat food restricted the magnesium content and/or formulated their cat food to produce slightly acidic urine (pH of 5.9 to 6.4). The slight acidity and low magnesium content create a urinary environment that is unfavorable for struvite crystallization and urolith growth but may be favorable for CaOx urolith growth in predisposed cats. Formulating cat food based on RSS methodology is a more recent dietary strategy that some pet food manufacturers use to create UTH cat food. RSS provides a numerical measurement of the degree of saturation of a specific urolith-forming substance, and thus a quantitative method to evaluate the risk of urolith formation. The principles of RSS apply to all urolith types, so UTH cat food based on RSS methodology has the potential to help protect cats from both struvite and CaOx uroliths.

In response to requests from pet food manufacturers, CVM has evaluated the use of RSS methodology to support urinary tract health claims for certain adult maintenance cat food. This draft guidance provides recommendations for how a cat food manufacturer can use RSS methodology to substantiate general structure or function claims that an adult maintenance cat food supports urinary tract health by promoting a healthy mineral content in the urinary tract. This draft guidance also includes information we recommend the manufacturer submits to us to ensure the urinary tract health claim is substantiated.

This level 1 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 ''Using Relative Supersaturation to Support ''Urinary Tract Health'' Claims for Adult Maintenance Cat Food.'' 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26306 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2459]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 2, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction and Combination Products—21 CFR Parts 3 and 4

OMB Control Number 0910–0523—Extension

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb–2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a web page that includes contact and resource information pertaining to the RFDs process at *https://www.fda.gov/combination-products/jurisdictional-information.* As communicated on our web page, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at *combination@fda.hhs.gov.*

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

- The guidance document entitled, ''How to Write a Request for Designation'' (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.*
- The guidance document entitled ''How to Prepare a Pre-Request for Designation,'' (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd.*
- This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, ''Requesting FDA Feedback on Combination Products,'' (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.*

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

In the **Federal Register** of July 31, 2023 (88 FR 49467), we published a 60-day notice soliciting comment on the proposed collection of information. One comment was received expressing interest in combination product

submissions, but was not responsive to the four information collection topics solicited in our notice and therefore we do not discuss the comment here.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3.7; request for designation (RFD)	55	1	55	24	1,320
Pre-RFD submissions	77	1	77	24	1,848
CPAM requests	3	1	3	25	75
Total					3,243

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden reflects a decrease in the number of respondents (four respondents) and a corresponding decrease in total hours (96 hours). Based on a recent evaluation of CPAM requests received from each product center in fiscal years 2020, 2021, and 2022, our estimated annual burden for CPAM requests remains unchanged.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26262 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2198; FDA–2022–E–2202; FDA–2022–E–2203; and FDA–2022–E–2204]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ukoniq

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Ukoniq and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. 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 Nos. FDA–2022–E–2198; FDA–2022–E–2202; FDA–2022–E–2203; and FDA–2022–E–2204 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; UKONIQ.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Ukoniq (umbralisib tosylate) indicated for the treatment of adult patients with:

- Relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen.
- Relapsed or refractory follicular lymphoma who have received at least three prior lines of systemic therapy.

Subsequent to this approval, the USPTO received patent term restoration applications for Ukoniq (U.S. Patent Nos. 9,150,579; 9,669,033; 10,072,013; and 10,570,142) from Rhizen Pharmaceuticals SA, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Ukoniq represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Ukoniq is 2,963 days. Of this time, 2,727 days occurred during the testing phase of the regulatory review period, while 236 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 28, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 28, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 15, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Ukoniq (NDA 213176) was initially submitted on June 15, 2020.

3. *The date the application was approved:* February 5, 2021. FDA has verified the applicant's claim that NDA 213176 was approved on February 5, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 291 days, 577 days, or 583 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26303 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2212; FDA–2022–E–2215; and FDA–2022–E–2216]

Determination of Regulatory Review Period for Purposes of Patent Extension; Koselugo

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Koselugo and is publishing this notice of that determination as required by law. FDA has made the determination because of the

submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. 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 Nos. FDA–2022–E–2212; FDA–2022–E–2215; and FDA–2022–E–2216 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; KOSELUGO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Koselugo (selumetinib) indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. Subsequent to this approval, the USPTO received patent term restoration applications for Koselugo (U.S. Patent Nos. 7,425,637; 8,178,693; 9,156,795) from AstraZeneca AB and Array BioPharma Inc. and the

USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Koselugo represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Koselugo is 5,100 days. Of this time, 4,889 days occurred during the testing phase of the regulatory review period, while 211 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* April 26, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 26, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 13, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for Koselugo (NDA 213756) was initially submitted on September 13, 2019.

3. *The date the application was approved:* April 10, 2020. FDA has verified the applicant's claim that NDA 213756 was approved on April 10, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 927 days, 1,550 days, or 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26324 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2089]

Determination of Regulatory Review Period for Purposes of Patent Extension; Rezurock

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Rezurock and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 28, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–E–2089 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; REZUROCK.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the

Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product Rezurock (belumosudil mesylate). Rezurock is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy. Subsequent to this approval, the USPTO received a patent term restoration application for Rezurock (U.S. Patent No. 8,357,693) from Kadmon Pharmaceuticals, LLC (agent for Surface Logix, LLC), and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 13, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Rezurock represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Rezurock is 4,327 days. Of this time, 4,037 days occurred during the testing phase of the regulatory review period, while 290 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 12, 2009. The applicant claims January 8, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 12, 2009, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 30, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Rezurock (NDA 214783) was initially submitted on September 30, 2020.

3. *The date the application was approved:* July 16, 2021. FDA has verified the applicant's claim that NDA 214783 was approved on July 16, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,154 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26358 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a virtual meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public and will be streamed live on *hhs.gov/live.* A pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to present their comments live during the virtual meeting. Individuals who wish to provide written public comment should send an email to *CARB@hhs.gov* that includes their written comments. Registration information is available on the website *http://www.hhs.gov/paccarb* and should be completed by December 18, 2023 for the December 20, 2023 virtual Public Meeting. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Upcoming Meetings page. HHS is also giving notice of the appointment of 16 new PACCARB councilmembers that will be sworn-in in preparation of the December 20, 2023 virtual public meeting.

DATES: The meeting is scheduled to be held on December 20, 2023, from 9 a.m. to 4 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting is strongly suggested and should be completed no later than December 18, 2023.

ADDRESSES: The virtual meeting can be accessed through a live webcast on the day of the meeting. Additional instructions regarding attending this meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Rockville, MD 20852. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The Advisory Council is authorized to consist of at least 30 members, including the voting and non-voting members and the Chair and Vice Chair. The current composition of the Advisory Council consists of 15 voting members, including the Chair and Vice Chair, eight non-voting liaison representative members, and 12 non-voting ex-officio members. In March of 2023, the terms of 16 councilmembers ended, and an announcement was published August 1, 2022 and closed on September 19, 2022 to solicit nominations to fill the open PACCARB positions, nine of which were in the voting member category, including the Chair and Vice-Chair positions, while the remaining seven were in the non-voting liaison member category. These positions have been filled and the new PACCARB members will be sworn-in in preparation for the December 20, 2023, virtual public meeting. Newly appointed voting members were selected to serve four-year terms, and non-voting liaison members were appointed to serve for two-year terms. The full roster of councilmembers, including the 16 new members, can be found on the Membership page at *http://www.hhs.gov/paccarb.*

The December 20, 2023, virtual public meeting will be dedicated to current global U.S. federal efforts to combat antimicrobial resistance in response to a task from the Secretary given to the PACCARB in 2023. The signed task letter from the Secretary can be found at *http://www.hhs.gov/paccarb.* The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items and times are tentative and subject to change. Instructions regarding attending the meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments during the December meeting by pre-registering online at *http://www.hhs.gov/paccarb.* Pre-registration is required for participation in this session with limited spots available. Written public comments can also be emailed to *CARB@hhs.gov* by midnight December 18, 2023 and should be limited to no more than one page. All public comments received prior to December 18, 2023, will be provided to the PACCARB members. Additionally, companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the

PACCARB live during an Innovation Spotlight. Pre-registration is required for participation, with limited spots available. All information regarding this session can also be found online at *http://www.hhs.gov/paccarb.*

Dated: November 9, 2023.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2023–26320 Filed 11–29–23; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Instrumentation, Assay Development and Cellular Biology.

Date: December 15, 2023.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joonil Seog, SCD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9791, *joonil.seog@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–26264 Filed 11–29–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Review.

Date: December 18, 2023.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–26361 Filed 11–29–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket Number: USCG–2023–0825]

Designation of the Coast Guard Academy Athletics Corporation as a Qualified Organization and Appointment of Dr. Daniel Rose as a Member of the Board of Directors of the Corporation

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice.

SUMMARY: The Coast Guard announces the designation of the Coast Guard Academy Athletics Corporation (CGAAC) as a qualified non-Federal entity that can receive support from the Federal Government. Dr. Daniel Rose, Athletics Director of the Coast Guard Academy, has been appointed to serve as a member on the Board of Directors of the CGAAC. Dr. Rose will provide oversight of, advice to, and coordination with, the CGAAC. Dr. Rose will not participate in the day-to-day operations of the CGAAC.

DATES: The appointment was made October 19, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0825 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Commander Jeffrey G. Janaro, Coast Guard Academy, telephone 860–444–8255, email *jeff.g.janaro@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard announces the designation of the Coast Guard Academy Athletics Corporation (CGAAC) as a ''qualified organization'' under 14 U.S.C. 953. Section 953 allows the Coast Guard Academy Alumni Association to establish a ''qualified organization'' solely for the purpose of supporting Coast Guard athletics.

A ''qualified organization'' means an organization (1) that operates as an organization under subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and exempt from taxation under subsection (a) of that section; (2) for which authorization under sections 1033(a) and 1589(a) of Title 10 may be provided; and (3) established by the Coast Guard Academy Alumni Association solely for the purpose of supporting Coast Guard athletics.

The Coast Guard also announces the appointment of Dr. Daniel Rose, the Coast Guard Academy Athletics Director, to serve on the CGAAC Board of Directors in accordance with 10 U.S.C. 1033. Under 10 U.S.C. 1033 the Secretary of the Department of the Homeland Security is authorized to appoint, without compensation, an officer to provide oversight of, advice to, and coordination with, a designated entity, such as CGAAC, and participation of the member in the activities of the designated entity, which would not extend to participation in the day-to-day operations of the entity. This authority of the Secretary is delegated to the Commandant of the Coast Guard through the Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3 (paragraph II.14).

The effective date of Dr. Rose's appointment is October 19, 2023. Dr. Rose will serve in his official capacity as the Coast Guard Academy Athletics Director, without additional compensation, providing oversight and advice to the CGAAC. Dr. Rose's participation will not extend to participation in the day-to-day operations of the CGAAC.

M.W. Hammond,

Captain, U.S. Coast Guard, Acting Assistant Superintendent, U.S. Coast Guard Academy.

[FR Doc. 2023–26304 Filed 11–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4743–DR; Docket ID FEMA–2023–0001]

La Jolla Band of Luiseño Indians; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the La Jolla Band of Luiseño Indians (FEMA–4743–DR), dated September 27, 2023, and related determinations.

DATES: The declaration was issued September 27, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 27, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the La Jolla Band of Luiseño Indians resulting from Tropical Storm Hilary during the period of August 19 to August 21, 2023, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the La Jolla Band of Luiseño Indians.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the La Jolla Band of Luiseño Indians. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Andrew F. Grant, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

La Jolla Band of Luiseño Indians for Public Assistance.

The La Jolla Band of Luiseño Indians are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26285 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3602–EM; Docket ID FEMA–2023–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the Commonwealth of the Northern Mariana Islands (FEMA–3602–EM), dated October 8, 2023, and related determinations.

DATES: This change occurred on October 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Teresa Y. Serata, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Benigno B. Ruiz as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26270 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4726–DR; Docket ID FEMA–2023–0001]

Montana; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Montana (FEMA–4726–DR), dated August 12, 2023, and related determinations.

DATES: This change occurred on October 25, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth G. Clark, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Alana B. Kuhn as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26279 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4724–DR; Docket ID FEMA–2023–0001]

Hawaii; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Hawaii (FEMA–4724–DR), dated August 10, 2023, and related determinations.

DATES: This amendment was issued September 22, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 22, 2023, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Deanne Criswell, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in certain areas of the State of Hawaii resulting from wildfires beginning on August 8, 2023, and continuing, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend my declarations of August 10, 2023, August 18, 2023, and September 8, 2023, to authorize Federal funds for debris removal, including direct Federal assistance, at 100 percent of the total eligible costs for a continuous 180-day period of the State's choosing within the first nine months from the start of the incident period. I further authorize Federal funds for emergency protective measures, including direct Federal assistance, at 100 percent of the total eligible costs for a continuous 90-day period of the State's choosing within the first six months from the start of the incident period.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26276 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4728–DR; Docket ID FEMA–2023–0001]

Illinois; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–4728–DR), dated August 15, 2023, and related determinations.

DATES: This amendment was issued October 23, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 15, 2023.

Calhoun and Logan Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030,

Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26280 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4744–DR; Docket ID FEMA–2023–0001]

Vermont; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA–4744–DR), dated October 6, 2023, and related determinations.

DATES: The declaration was issued October 6, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 6, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Vermont resulting from severe storms and flooding during the period of August 3 to August 5, 2023, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Vermont.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William F. Roy, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Vermont have been designated as adversely affected by this major disaster:

Addison County for Public Assistance.

All areas within the State of Vermont are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26287 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4724–DR; Docket ID FEMA–2022–0001]

Hawaii; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Hawaii (FEMA–4724–DR), dated August 10, 2023, and related determinations.

DATES: This amendment was issued October 13, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective September 30, 2023.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26277 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3602–EM; Docket ID FEMA–2023–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 2 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the Commonwealth of the Northern Mariana Islands (FEMA–3602–EM), dated October 8, 2023, and related determinations.

DATES: This amendment was issued October 30, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective October 16, 2023.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26271 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4724–DR; Docket ID FEMA–2023–0001]

Hawaii; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Hawaii (FEMA–4724–DR), dated August 10, 2023, and related determinations.

DATES: This change occurred on October 13, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Thomas J. Dargan, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Timothy B. Manner as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26278 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3601–EM; Docket ID FEMA–2023–0001]

Guam; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the territory of Guam (FEMA–3601–EM), dated October 8, 2023, and related determinations.

DATES: This amendment was issued October 30, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective October 16, 2023.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26268 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4673–DR; Docket ID FEMA–2023–0001]

Florida; Amendment No. 15 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–4673–DR), dated September 29, 2022, and related determinations.

DATES: This amendment was issued October 25, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 25, 2023, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Deanne Criswell, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in certain areas of the State of Florida resulting from Hurricane Ian during the period of September 23 to November 4, 2022, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend my declarations of September 29, 2022, October 4, 2022, and November 28, 2022, to authorize Federal

funds for all categories of Public Assistance at 90 percent of total eligible costs, except assistance previously approved at 100 percent.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26272 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4745–DR; Docket ID FEMA–2023–0001]

Montana; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Montana (FEMA–4745–DR), dated October 11, 2023, and related determinations.

DATES: This change occurred on October 25, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth G. Clark, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Alana B. Kuhn as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26289 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4699–DR; Docket ID FEMA–2023–0001]

California; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–4699–DR), dated April 3, 2023, and related determinations.

DATES: This amendment was issued November 1, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 3, 2023.

Mariposa and Tuolumne Counties for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate the incident period (already designated for Individual Assistance and Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26273 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3600–EM; Docket ID FEMA–2023–0001]

Louisiana; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Louisiana (FEMA–3600–EM), dated September 27, 2023, and related determinations.

DATES: The declaration was issued September 27, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 27, 2023, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Louisiana resulting from seawater intrusion beginning on September 20, 2023, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Louisiana.

You are authorized to provide appropriate assistance for required emergency measures,

authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program limited to temporary measures that address reduced water treatment capability due to saltwater intrusion resulting from low water levels of the Mississippi River for no more than 90 days from the date of declaration.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Benjamin Abbott, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Louisiana have been designated as adversely affected by this declared emergency:

Jefferson, Orleans, Plaquemines, and St. Bernard Parishes for emergency protective measures, including direct federal assistance, under the Public Assistance program limited to temporary measures that address reduced water treatment capability due to saltwater intrusion resulting from low water levels of the Mississippi River for no more than 90 days from the date of declaration.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26286 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4746–DR; Docket ID FEMA–2023–0001]

Agua Caliente Band of Cahuilla Indians; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Agua Caliente Band of Cahuilla Indians (FEMA–4746–DR), dated October 18, 2023, and related determinations.

DATES: The declaration was issued October 18, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 18, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Agua Caliente Band of Cahuilla Indians resulting from Tropical Storm Hilary during the period of August 19 to August 21, 2023, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Agua Caliente Band of Cahuilla Indians.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Agua Caliente Band of Cahuilla Indians. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Andrew F. Grant, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

Agua Caliente Band of Cahuilla Indians for Public Assistance.

The Agua Caliente Band of Cahuilla Indians is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26290 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3602–EM; Docket ID FEMA–2023–0001]

Commonwealth of the Northern Mariana Islands; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of the Northern Mariana Islands (FEMA–3602–EM), dated October 8, 2023, and related determinations.

DATES: The declaration was issued October 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 8, 2023, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the Commonwealth of the Northern Mariana Islands resulting from Tropical Storm Bolaven beginning on October 9, 2023, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the Commonwealth of the Northern Mariana Islands.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Benigno B. Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of the Northern Mariana Islands have been designated as adversely affected by this declared emergency:

The islands of Agrihan, Alamagan, Pagan, Rota, Saipan, and Tinian for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26269 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4740–DR; Docket ID FEMA–2023–0001]

New Hampshire; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Hampshire (FEMA–4740–DR), dated September 14, 2023, and related determinations.

DATES: This amendment was issued October 24, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Hampshire is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 14, 2023.

Grafton and Rockingham Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26284 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3601–EM; Docket ID FEMA–2023–0001]

Guam; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the territory of Guam (FEMA–3601–EM), dated October 8, 2023, and related determinations.

DATES: The declaration was issued October 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 8, 2023, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the territory of Guam resulting from Tropical Storm Bolaven beginning on October 8, 2023, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the territory of Guam.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or

avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Benigno B. Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the territory of Guam have been designated as adversely affected by this declared emergency:

The territory of Guam for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26267 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4724–DR; Docket ID FEMA–2023–0001]

Hawaii; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Hawaii (FEMA–4724–DR), dated August 10, 2023, and related determinations.

DATES: This amendment was issued September 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 8, 2023, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Deanne Criswell, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in certain areas of the State of Hawaii resulting from wildfires beginning on August 8, 2023, and continuing, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend my declarations of August 10, 2023, and August 18, 2023, to authorize Federal funds for all categories of Public Assistance at 90 percent of total eligible costs, except assistance previously approved at 100 percent.

This adjustment to state and local cost sharing applies only to Public Assistance costs and direct Federal assistance eligible for such adjustments under the law. The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided for Other Needs Assistance (Section 408) and the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26275 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4728–DR; Docket ID FEMA–2023–0001]

Illinois; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–4728–DR), dated August 15, 2023, and related determinations.

DATES: This change occurred on November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended Waddy Gonzalez, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Andrew D. Friend as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant;

97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26281 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4745–DR; Docket ID FEMA–2023–0001]

Montana; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Montana (FEMA–4745–DR), dated October 11, 2023, and related determinations.

DATES: The declaration was issued October 11, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 11, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Montana resulting from flooding during the period of June 1 to June 8, 2023, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Montana.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Alana B. Kuhn, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Montana have been designated as adversely affected by this major disaster:

Carbon, Daniels, Fergus, Garfield, Golden Valley, Musselshell, Petroleum, Phillips, Stillwater, and Treasure Counties for Public Assistance.

All areas within the State of Montana are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26288 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4730–DR; Docket ID FEMA–2023–0001]

Alaska; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Alaska (FEMA–4730–DR), dated August 23, 2023, and related determinations.

DATES: This amendment was issued October 30, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Alaska is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 23, 2023.

The Kusilvak Census Area and Yupiit Regional Educational Attendance Area for Individual Assistance.

The Iditarod Regional Educational Attendance Area and Yukon-Koyukuk Census Area for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26282 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4724–DR; Docket ID FEMA–2023–0001]

Hawaii; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Hawaii (FEMA–4724–DR), dated August 10, 2023, and related determinations.

DATES: The amendment was issued October 11, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident for this disaster has been expanded to include high winds.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26274 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4731–DR; Docket ID FEMA–2023–0001]

Colorado; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Colorado (FEMA–4731–DR), dated August 25, 2023, and related determinations.

DATES: This amendment was issued November 1, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Colorado is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 25, 2023.

Jefferson County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–26283 Filed 11–29–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6432–N–01]

Notice of Certain Operating Cost Adjustment Factors for 2024

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice establishes operating cost adjustment factors (OCAFs) for project-based assistance contracts issued under Section 8 of the United States Housing Act of 1937 and renewed under the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) for eligible multifamily housing projects having an anniversary date on or after February 11, 2024. OCAFs are annual factors used to adjust Section 8 rents renewed under section 515 or section 524 of MAHRA.

DATES: Applicability Date: February 11, 2024.

FOR FURTHER INFORMATION CONTACT: Jennifer Lavorel, Director, Program Administration Office, Office of Asset Management and Portfolio Oversight, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone number 202–402–2515 (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:

I. Background

Section 514(e)(2) and section 524(c)(1) of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) (42 U.S.C. 1437f note), as amended, require HUD to establish guidelines for the development of operating cost adjustment factors (OCAFs) for rent adjustments. Similar language is found in sections 524(a)(4)(C)(i), 524(b)(1)(A), and 524(b)(3)(A) of MAHRA, all of which prescribe the use of the OCAF in the calculation of renewal rents. MAHRA gives HUD broad discretion in setting OCAFs. For example, sections 524(a)(4)(C)(i), 524(b)(1)(A), 524(b)(3)(A), and 524(c)(1), simply refer to ''an operating cost adjustment factor established by the Secretary.'' HUD uses a single methodology for establishing OCAFs. The sole limitation to this grant of authority is a specific requirement in each of the foregoing provisions that application of an OCAF ''shall not result in a negative adjustment.''

OCAFs vary among states and territories. Contract rents are adjusted by applying the OCAF for the state or territory in which the subject project is located to that portion of the rent attributable to operating expenses exclusive of debt service.

The OCAFs provided in this notice are applicable to eligible projects having a contract anniversary date on or after February 11, 2024.

II. OCAF Data Sources

OCAFs are calculated as the sum of weighted component cost changes for electricity, employee benefits/employee wages, fuel oil, goods/supplies/equipment, insurance, natural gas, property taxes, and water/sewer/trash using publicly available indices. The weights used in the OCAF calculations for each of the nine cost component groupings are set using current percentages attributable to each of the nine expense categories. The nine cost component weights are calculated at the state level, which is the lowest level of geographical aggregation with enough projects to permit statistical analysis. These data are not available for the Western Pacific Islands, so data for Hawaii are used as the best available indicator of OCAFs for these areas. HUD calculates weights using three years of audited Annual Financial Statements from projects covered by OCAFs. The

expenditure percentages for these nine categories have been found to be stable over time, and using three years of data increases their stability.

HUD uses the best current price data sources for the nine cost categories in calculating annual change factors. State-level data for electricity, fuel oil, and natural gas from Department of Energy surveys are relatively current and continue to be used. Data on changes in employee benefits/employee wages, goods/supplies/equipment, insurance, property taxes, and water/sewer/trash costs are available only at the national level.

The data sources used for the selected nine cost indicators are as follows:

• *Electricity:* Energy Information Agency (EIA), May 2023 ''Electric Power Monthly'' report, Table 5.6.B. HUD compares the January 2023 to May 2023 estimate with the January 2022 to May 2022 estimate. *https://www.eia.gov/electricity/monthly/epm_table_grapher.php?t=epmt_5_06_b.*

• *Employee benefits/employee wages:* Bureau of Labor Statistics (BLS) ECI, Private Industry Benefits, All Workers (Series ID CIU2030000000000I), at the national level and Private Industry Wages and Salaries, All Workers (Series ID CIU2020000000000I), at the national level. HUD compares the second quarter of 2023 to the second quarter of 2022.

• *Fuel Oil:* EIA U.S. Weekly Heating Oil and Propane Prices report. Average weekly residential heating oil prices in cents per gallon excluding taxes for the period from October 5, 2022, through the week of March 29, 2023 are compared to the average from October 5, 2021, through the week of March 29, 2022. For the States with insufficient fuel oil consumption to have separate estimates, the relevant regional Petroleum Administration for Defense Districts (PADD) change between these two periods is used; if there is no regional PADD estimate, the U.S. change between these two periods is used. *https://www.eia.gov/dnav/pet/pet_pri_wfr_a_EPD2F_PRS_dpgal_w.htm.*

• *Goods/Supplies/Equipment:* Bureau of Labor Statistics (BLS) Consumer Price Index, All Items Less Food, Energy and Shelter (Series ID CUUR0000SA0L12E) at the national level. HUD compares the July 2023 estimate to the estimate for July 2022.

• *Insurance:* Bureau of Labor Statistics (BLS) Producer Price Index, Industry Data for Direct Property and Casualty Insurers: Commercial Multiple Peril Insurance (Series ID PCU5241265241265) at the national level. HUD compares the estimate for July 2023 to the estimate for July 2022.

• *Natural Gas:* Energy Information Agency, Natural Gas, Residential Energy Price, June 2022–May 2023 monthly prices in dollars per 1,000 cubic feet at the state level. Due to EIA data quality standards, several states were missing data for one or two months in 2022 and 2023; in these cases, data for these missing months were estimated using data from the surrounding months in that year and the relationship between that same month and the surrounding months in 2021. *http://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_a.htm.*

• *Property Taxes:* Census Quarterly Summary of State and Local Government Tax Revenue—Table 1: *https://www.census.gov/econ/currentdata/dbsearch?program=QTAX&startYear=2019&endYear=2021&categories=QTAXCAT1&dataType=T01&geoLevel=US&notAdjusted=1&submit=GET+DATA&releaseScheduleId=.* Twelve-month property taxes are computed as the total of four quarters of tax receipts for the period from April through March. Total 12-month taxes are then divided by the number of occupied housing units to arrive at average 12-month tax per housing unit. The number of occupied housing units is taken from U.S. Census Bureau's Current Population Survey/Housing Vacancy Survey (CPS/HVS) housing inventory estimates, Table 8: *https://www.census.gov/housing/hvs/data/histtab8.xlsx.*

• *Water/Sewer/Trash:* Consumer Price Index, All Urban Consumers, Water and Sewer and Trash Collection Services (Series ID CUUR00 00SEHG) at the national level. HUD compares the estimate for July 2023 to the estimate for July 2022.

The sum of the nine cost component percentage weights equals 100 percent of operating costs for purposes of OCAF calculations. To calculate the OCAFs, state-level cost component weights developed from AFS data are multiplied by the selected inflation factors. For instance, if wages in Virginia comprised 50 percent of total operating cost expenses and increased by 4 percent from 2022 to 2023, the wage increase component of the Virginia OCAF for 2024 would be 2.0 percent (50% * 4%). This 2.0 percent would then be added to the increases for the other eight expense categories to calculate the 2024 OCAF for Virginia. For states where the calculated OCAF is less than zero, the OCAF is floored at zero. The OCAFs for 2024 are included as an Appendix to this notice.

III. Findings and Certifications Environmental Impact

This notice sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 Code of Federal Regulations 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

IV. Paperwork Reduction Act

This notice does not impact the information collection requirements already submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

V. Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 14.195.

Julia R. Gordon,

Assistant Secretary for Housing—FHA Commissioner.

Appendix

OPERATING COST ADJUSTMENT FACTORS FOR 2024

	2023	2024	Percent change in OCAF
Alabama	5.8	5.1	−12.1
Alaska	6	4.9	−18.3
Arizona	5.7	4.7	−17.5
Arkansas	5.9	5.3	−10.2

OPERATING COST ADJUSTMENT FACTORS FOR 2024—Continued

	2023	2024	Percent change in OCAF
California	7.1	5.4	−23.9
Colorado	5.9	5.2	−11.9
Connecticut	6.1	7.1	16.4
Delaware	5.8	5.3	−8.6
District of Columbia	5.8	5.4	−6.9
Florida	6.1	5.2	−14.8
Georgia	5.6	4.8	−14.3
Hawaii	7.3	5.4	−26.0
Idaho	5.1	4.8	−5.9
Illinois	7.3	5.6	−23.3
Indiana	6.4	5	−21.9
Iowa	5	4.5	−10.0
Kansas	5.5	5.1	−7.3
Kentucky	6.4	4.8	−25.0
Louisiana	5.9	5	−15.3
Maine	8.3	8	−3.6
Maryland	6.6	5.4	−18.2
Massachusetts	6.1	6.6	8.2
Michigan	5.5	5.2	−5.5
Minnesota	7.3	5.3	−27.4
Mississippi	6.2	5.3	−14.5
Missouri	5.2	5.2	0.0
Montana	5.4	5.3	−1.9
Nebraska	5.9	4.9	−16.9
Nevada	6.2	5.4	−12.9
New Hampshire	5.7	7	22.8
New Jersey	5.3	5.6	5.7
New Mexico	6	4.9	−18.3
New York	7.6	5.4	−28.9
North Carolina	5.7	4.9	−14.0
North Dakota	6	4.7	−21.7
Ohio	6.2	5.6	−9.7
Oklahoma	4.9	5.2	6.1
Oregon	5.6	4.9	−12.5
Pacific Islands	7.3	5.4	−26.0
Pennsylvania	5.8	6.1	5.2
Puerto Rico	6.3	5	−20.6
Rhode Island	5.3	6.4	20.8
South Carolina	5.6	4.8	−14.3
South Dakota	4.8	4.3	−10.4
Tennessee	5.7	4.9	−14.0
Texas	5.7	5.3	−7.0
Utah	5.6	4.8	−14.3
Vermont	6	5.2	−13.3
Virgin Islands	5.8	5.7	−1.7
Virginia	6	5.2	−13.3
Washington	5.9	4.9	−16.9
West Virginia	6.6	5.3	−19.7
Wisconsin	6.6	5.1	−22.7
Wyoming	5.6	4.9	−12.5
United States	6.1	5.3	−13.1

[FR Doc. 2023–26331 Filed 11–29–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–NWRS–2023–N061; FVRS31100600000–XXX–FF06R05000; OMB Control Number 1018–New]

Agency Information Collection Activities; Submission to the Office of Management and Budget; U.S. Fish and Wildlife Service Grassland Easements

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection in use without Office of Management and Budget (OMB) approval.

DATES: Interested persons are invited to submit comments on or before January 2, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice 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. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference ''1018–New Grassland Easements'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

On March 20, 2023, we published in the **Federal Register** (88 FR 16651) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on May 19, 2023. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests (ICRs), the Service also published the **Federal Register** notice on *Regulations.gov* (Docket No. FWS–R6–NWRS–2023–0036) to provide the public with an additional method to submit comments (in addition to the typical *Info_Coll@fws.gov* email and U.S. mail submission methods). We received three comments in response to that notice:

Comment 1: Email comment from Jean Public, received on March 20, 2023. The commenter did not address the information collection requirements.

Agency Response to Comment 1: No response required.

Comment 2: Anonymous comment received via *Regulations.gov* (FWS–R6–NWRS–2023–0036–0002) on March 29, 2023. The commenter supports the grassland easement program, stating it is a great step towards restoring and conserving America's land and wildlife. They further opined that the program creates a beneficial relationship between ranchers and the Service, and easements balance both economic gains and environmental protection.

Agency Response to Comment 2: The commenter did not address the information collections; therefore, no response required.

Comment 3: Anonymous comment received via *Regulations.gov* (FWS–R6–NWRS–2023–0036–0003) on May 14, 2023. The commenter requested that the Service prohibit hunting, fishing, and trapping.

Agency Response to Comment 3: The commenter did not address the information collections; therefore, no response required.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Vast grasslands once covered much of North America. Settlement, agriculture, and development have reduced prairie habitats to a patchwork of isolated grasslands surrounded by croplands, roads, and cities. Loss of grasslands is detrimental to people as well as to wildlife. Grasslands help reduce soil erosion caused by wind and water. They also filter chemicals, thus protecting our water supplies. Vegetation such as grass, forbs, and shrubs helps trap snow and rain. This allows a more regulated flow of precipitation to seep into the ground, recharging water supplies. Grasslands also provide season-long forage for livestock. Many wildlife species depend on grasslands for food, cover, and nesting sites. Protecting grasslands ensures that wildlife will be there for future generations to enjoy.

In the United States, the Prairie Pothole Region is located within the northern Great Plains, in parts of Iowa, Minnesota, Montana, North Dakota, and South Dakota. Characterized by thousands of shallow, glacially formed wetlands known as potholes, the Prairie Pothole Region provides habitat for globally significant populations of breeding waterfowl. In addition, the Prairie Pothole Region is important breeding and migratory habitat for many species of grassland and wetland-dependent birds. The Migratory Bird Hunting and Conservation Stamp Act (16 U.S.C. 718d(b)(3)) and the Safe, Accountable, Flexible, Efficient Transportation Equity Act (P.L. 109–59, section 1119) authorize the U.S. Fish and Wildlife Service (Service) to enter into grassland easements with private landowners. The Service acquires easements from willing sellers only. Once approved, the easements are a permanent (perpetual) easement between the Service and all present and future landowners.

A grassland easement is a legal agreement signed with the United States of America, through the Service, that pays the landowner to permanently keep their land in grass. Eligible property must lie within an approved

county and have potential value to wildlife. Highest priority lands are large tracts of grassland with high wetland densities, and native prairie or soils most likely to be converted to cropland. Landowners retain the right to open or close their lands to hunting and trapping, as they have in the past. In addition, subsurface rights such as oil, gas, and minerals are not affected. However, the easement may limit enrollment or participation in U.S. Department of Agriculture programs where base acres of cropland are used to determine program eligibility, such as the Conservation Reserve Program. Landowners should contact their local Farm Service Agency for information regarding eligibility. Property subject to a grassland easement remains on local tax rolls. By selling easements, landowners receive funds to pay down debt, reinvest in capital improvements, or buy other lands to maintain and/or expand working lands.

Landowners who sell a grassland easement to the Service agree to maintain permanent vegetative cover such as forbs, grasses, and low shrubs. The value the Service pays is affected by the easement type and the permitted uses. Land encumbered by a grassland easement may not be cultivated. If the landowner retains grazing rights, grazing is allowed anytime during the year. However, mowing, haying, and grass seed harvesting are restricted, and may be delayed until after July 15 each year. This specific restriction is designed to help grassland nesting species, such as ducks and pheasants, complete their nesting before the grass is disturbed.

The Service collects the following information in conjunction with the administration of grassland easements:

Application Process

To apply for the Grassland Easement Program, landowners must contact the Service to speak to a realty specialist or field biologist, who can explain the program and answer questions from the landowner. If the landowner decides they would like to participate in the program, they complete Form 3–2573, ''Easement Acquisition—Initial Landowner Inquiry Form'' and a site inspection will be scheduled.

A Service realty specialist estimates the value of the easement based on the assessed value of the proposed land. In situations where a landowner is purchasing the land under a contract for deed, in order for an easement to be placed on the property, both the purchaser and the contract seller, who holds the legal title, must sign the easement agreement. When the Service accepts the easement, the landowner will receive a letter, sent via certified mail, notifying them of the acceptance of the easement being recorded at the county courthouse. A copy of the easement will be included with the certified letter.

Typically, within 8–12 months after the easement is signed, the Service makes one single lump-sum payment to the landowner, in the form of an electronic funds transfer (EFT) from the U.S. Treasury, for the full amount specified in the easement. The Interior Business Center will issue an IRS Form 1099–S at the end of the calendar year. The payment may not be taxable; however, it should be reported on the landowner's Federal income tax return.

The Service is required to monitor easements annually. It is the responsibility of the refuge manager to monitor and inspect easements for compliance, maintain communications with landowners, and ensure habitat values lost or damaged as a result of easement violations are restored. To avoid easement violations, landowners must contact their local Service representative before performing any alterations that may impact vegetation or wetlands within the easement boundary. Violation of easement terms may result in legal prosecution, fines, and restitution.

Should the quality of the grassland easement deteriorate, the landowner may obtain a Special Use Permit (FWS Form 3–1383–G) to replant or rejuvenate tame (non-native) grassland habitat. The Service encourages grasses suitable to the landowner's needs and also to the long-term benefit of wildlife. Cost-sharing or donated seed may be available through Federal, State, or private organizations. Form 3–1383–G is currently approved under OMB Control No. 1018–0102.

Correction of Title Defects

The Service obtains title information from the abstracter at no cost to the landowner. The title is checked to determine that all owners of record have signed the easement. Service attorneys review the case and furnish an opinion of title. If the opinion indicates any title defects, Service personnel assist the landowner in correcting the defects before the Service accepts the easement. The process usually takes 6 to 9 months.

Subordination Agreements

Usually, mortgages do not affect easement transactions. If the mortgage holder needs to consent to the easement, we will ask the mortgage holder for a signed statement known as a subordination agreement, which subordinates the rights of the mortgage to those of the easement. Payment of easements where there is a mortgage or contract for deed is dependent on the mortgage holder or the contract seller and the terms of the landowner's agreement with them. They may require that all or part of the money be applied to the mortgage or contract balance, or they may allow the entire payment to go to the landowner.

Requests for Approval—Other Improvements/Alterations

Existing farm sites and other permanent structures are excluded from grassland easements. Planning for future improvements or expansions of existing farm sites or structures is important and should be considered at the time the easement is executed, when practical. Requests for improvements may be allowed and will require prior Service approval. To avoid easement violations, landowners must contact their local Service representative before manipulating permanent vegetative cover on easement lands.

Requests for Approval—Mowing Before July 15th

Mowing before July 15 to control weeds is prohibited without prior written approval by the Service.

Notification Requirement—Sale or Transfer of Lands

Easements, and the associated covenants and agreements, run with the land and are binding on all persons and entities who come into ownership or possession of the lands subject to the easement. The landowner must notify the Regional Director in writing of any sale or transfer at least 30 days following the sale or transfer of any portion of the lands subject to this easement.

Recordkeeping Requirements

Landowners may be required to maintain and/or furnish documentation such as records of ownership, sales, property characteristics, and corresponding assessed values of record, upon request, as part of the application process or associated information collections.

Non-Hour Cost Burdens on Landowners

Landowners are responsible for the management of and costs associated with noxious weed and pest control, and must also pay any fees associated with subordination agreements. They may file a claim for reimbursement from the Government.

Title of Collection: U.S. Fish and Wildlife Service Grassland Easements.

OMB Control Number: 1018-New.

Form Number: 3–2573.

Type of Review: New information collection in use without OMB approval.

Respondents/Affected Public: Individuals/households and private sector.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Non-Hour Burden Cost: $ 2,115,000 (associated with noxious and pest control requirements, and subordination agreements).

Requirement	Average number of annual respondents	Average number of responses each	Average number of annual responses	Average completion time per response (hours)	Estimated annual burden hours
Application Process (Form 3–2573)					
Individuals	525	1	525	2	1,050
Private Sector	525	1	525	4	2,100
Correction of Title Defects					
Individuals	525	1	525	3	1,575
Private Sector	525	1	525	5	2,625
Subordination Agreements					
Individuals	500	1	500	2	1,000
Private Sector	500	1	500	5	2,500
Request for Approval—Other Improvements/Alterations					
Individuals	175	1	175	3	525
Private Sector	200	1	200	2	400
Request for Approval—Mowing Before July 15th					
Individuals	50	1	50	1	50
Private Sector	50	1	50	1	50
Notification Requirement—Sale or Transfer of Lands					
Individuals	20	1	20	2	40
Private Sector	20	1	20	2	40
Totals	3,615		3,615		11,955

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2023–26294 Filed 11–29–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/A0A501010.999900]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Between Redding Rancheria, California and the State of California

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Tribal-State Compact between the Redding Rancheria, California and the State of California.

DATES: The Compact takes effect on November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, *IndianGaming@bia.gov;* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Compact permits the Tribe to offer certain forms of Class III gaming. The Compact is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2023–26376 Filed 11–29–23; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–NPS0036715 PPWONRADE1 PPMRSNR1Y:NM0000 211P103601; OMB Control Number 1024–NEW]

Agency Information Collection Activities; NPS Preservation Values for Individual Animals

AGENCY: National Park Service, Interior.

ACTION: Notice of Information Collections; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 we, the National Park Service (NPS), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 2, 2024.

ADDRESSES: Written comments and suggestions on the information collection requirements should be submitted by the date specified above in **DATES** to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Phadrea Ponds, NPS Information Collection Clearance Officer (ADIR–ICCO), National Park Service, 13461 Sunrise Valley Drive, Mail Stop 244 Reston, VA 20192 (mail); or *phadrea_ponds@nps.gov* (email). Please include 1024–NEW (PVIA) in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Leslie Richardson, Economist, NPS Social Science Branch at *leslie_a_richardson@nps.gov* (email) or at 970–821–5352 (telephone), or contact Chris Neher by email at *bioecon@montana.com.* Please reference OMB Control Number 1024–NEW (PVIA) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published (87 FR 43054) on July 19, 2022. No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The National Park Service (NPS) is authorized by the System Unit Resource Protection Act (54 U.S.C. 100721) to collect information that can be used to assess the economic value of lost resources that cannot be restored or replaced. The NPS Environmental Quality Division will request approval to conduct a survey to determine the economic value associated with the preservation (avoided loss) of individual members of a wildlife species population. The survey will provide estimates of the full value of protecting individual animals from intentional or accidental loss. These value estimates are not currently available to the NPS and are necessary for park management decisions.

Title of Collection: NPS Preservation Values for Individual Animals.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: General Public.

Total Estimated Number of Annual Respondents: 8,876 (On-site Survey: 5,600; Non-response Survey: 1,260; Mail back Survey: 2,016).

Estimated Completion Time per Response: On-site Survey: 5 minutes; Non-response Survey: 2 minutes; Mail back Survey: 15 minutes.

Total Estimated Number of Annual Burden Hours: 1,014.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct, or sponsor nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collections Clearance Officer, National Park Service.

[FR Doc. 2023–26308 Filed 11–29–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1299]

Bulk Manufacturer of Controlled Substances Application: Pharmaron Manufacturing Services (US) LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Pharmaron Manufacturing Services (US) LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 29, 2024. Such persons may also file a written request for a hearing on the application on or before January 29, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on October 23, 2023, Pharmaron Manufacturing Services (US) LLC, 498 Washington Street, Coventry, Rhode Island 02816, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I

The company plans to bulk manufacture the listed controlled substance for the purpose of producing material for clinical trials. No other activities for this drug code are authorized for this registration.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–26343 Filed 11–29–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1298]

Importer of Controlled Substances Application: Pharmaron Manufacturing Services (US) LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Pharmaron Manufacturing Services (US) LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 2, 2024. Such persons may also file a written request for a hearing on the application on or before January 2, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 30, 2023, Pharmaron Manufacturing Services (US) LLC, 498 Washington Street, Conventry, Rhode Island 02816, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I

The company purpose of importing Dimethyltryptamine (7435) is to conduct process and analytical technology transfer, further process, and analytical development as needed and subsequently manufacture/produce an Active Pharmaceutical Ingredient under Good Manufacturing Practices at the US Pharmaron site (Pharmaron Manufacturing Services (US) LLC in Coventry, Rhode Island. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–26342 Filed 11–29–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0057]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Uniform Crime Reporting (UCR) Instrument Pretesting and Burden Estimation Generic Clearance

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Department of Justice (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. The proposed information collection was previously published in the **Federal Register** on September 15, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until January 2, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Edward L. Abraham, Crime and Law Enforcement Statistics Unit Chief, FBI, CJIS Division, Module D–1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; telephone number: 304–625–4830, email: *elabraham@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 agency, 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;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1110–0057. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ 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 DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* UCR Instrument Pretesting and Burden Estimation Generic Clearance.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number is 1110–0057. The applicable component within DOJ is the CJIS Division, FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract*: Abstract: This clearance provides the FBI's UCR Program the ability to conduct pretests which evaluate the validity and reliability of information collection instruments and determine the level of burden state and local agencies have in reporting crime data to the FBI. The PRA only allows for nine or fewer respondents in the collection of information, such as pretesting activities. This clearance request expands the pretesting sample to 350 people for each of the information collections administered by the UCR Program. Further, the clearance will allow for a brief five-minute cost and burden assessment for the 18,000 law enforcement agencies participating in the UCR Program.

5. *Obligation to Respond:* the obligation to respond is voluntary.

6. *Total Estimated Number of Respondents:* 18,000 law enforcement respondents.

7. *Estimated Time per Respondent:* five minutes per submission.

8. *Frequency:* 1/annually.

9. *Total Estimated Annual Time Burden:* 1,850 hours annual burden.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 9, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–26372 Filed 11–29–23; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

National Institute of Justice

[OJP (NIJ) Docket No. 1819]

Publication of NIJ Standard 0101.07, Ballistic Resistance of Body Armor, and NIJ Standard 0123.00, Specification for NIJ Ballistic Protection Levels and Associated Test Threats, and Information About the NIJ Compliance Testing Program

AGENCY: National Institute of Justice, Office of Justice Programs, U.S. Department of Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) announces publication of NIJ Standard 0101.07, *Ballistic Resistance of Body Armor* and NIJ Standard 0123.00, *Specification for NIJ Ballistic Protection Levels and Associated Test Threats.* The NIJ Compliance Testing Program (CTP) will be transitioning program operations to focus on implementing NIJ Standard 0101.07 as described below.

FOR FURTHER INFORMATION CONTACT: Mark Greene, Office Director, Office of Technology and Standards, National Institute of Justice, 810 7th Street NW, Washington, DC 20531, by telephone at (202) 598–9481 [Note: this is not a toll-free telephone number], or by email at *mark.greene2@usdoj.gov*.

SUPPLEMENTARY INFORMATION: The National Institute of Justice (NIJ) announces publication of NIJ Standard 0101.07, *Ballistic Resistance of Body Armor.* The document can be found here: *https://www.ojp.gov/pdffiles1/nij/307346.pdf.* It specifies minimum performance requirements and test methods for the ballistic resistance of body armor used by U.S. law enforcement that is intended to protect the torso against handgun and rifle ammunition. This revised standard supersedes NIJ Standard 0101.06, *Ballistic Resistance of Body Armor,* effective immediately. The primary purpose of this standard will be for use by the NIJ Compliance Testing Program (CTP) for testing, evaluation, and certification of ballistic-resistant body armor. It will also be used by NIJ-approved ballistic testing laboratories and body armor suppliers participating in the NIJ CTP. More information on this standard can be found here: *https://nij.ojp.gov/standard-0101-07.*

NIJ also announces publication of NIJ Standard 0123.00, *Specification for NIJ Ballistic Protection Levels and Associated Test Threats.* The document can be found here: *https://www.ojp.gov/pdffiles1/nij/307347.pdf.* It specifies the NIJ ballistic protection levels and associated test threats identified by U.S. law enforcement as representative of current prevalent threats in the United States. This standard should be used in conjunction with other standards to test and evaluate specific ballistic-resistant equipment, such as ballistic-resistant body armor, against contemporary ballistic threats that pose a life-threatening safety hazard to U.S. law enforcement officers. The NIJ CTP will use this standard for testing, evaluation, and certification of ballistic-resistant body armor using NIJ Standard 0101.07 and other types of ballistic-resistant equipment that may be added to the

scope of the NIJ CTP's conformity assessment activities in the future. More information on this standard can be found here: *https://nij.ojp.gov/standard-0123-00.*

The NIJ CTP is a body armor certification program that provides personnel working in U.S. law enforcement and correctional agencies confidence that the body armor they purchase and use performs according to minimum performance requirements to protect against common handgun and rifle threats as well as stab threats. The NIJ CTP produces a Compliant Products List (CPL) of armor models that meet program requirements, which includes compliance with NIJ Standard 0101.06. Currently, there are over 400 models of ballistic-resistant body armor listed on NIJ's CPL for armor compliant with NIJ Standard 0101.06 (''06'' CPL). The CPL for ballistic-resistant body armor can be found here: *https://nij.ojp.gov/topics/equipment-and-technology/body-armor/ballistic-resistant-armor.*

With the publication of NIJ Standard 0101.07, the NIJ CTP will begin an orderly transition from testing new body armor models for compliance with NIJ Standard 0101.06 to testing for compliance with NIJ Standard 0101.07. Given the large number of fielded ballistic-resistant armor models currently worn by law enforcement officers, the NIJ CTP anticipates maintaining the ''06'' CPL through at least the end of calendar year 2027. The NIJ CTP may opt to continue support of the ''06'' CPL for longer should the need arise.

The NIJ CTP will stop accepting applications for new body armor models for testing for compliance with NIJ Standard 0101.06 on January 5, 2024, at 5:00 p.m. Eastern time. New body armor models submitted on or before this date that meet program requirements will be added to the ''06'' CPL, however, no new models of armor will be added to the ''06'' CPL after the last models submitted are adjudicated through the NIJ CTP process. Furthermore, any actively listed armor models that are removed or withdrawn from the ''06'' CPL will not be reinstated to active status, effective immediately. All armor models listed on the ''06'' CPL will be subject to Follow-up Inspection Testing (FIT) for as long as the ''06'' CPL is published.

The NIJ CTP will begin accepting applications for new body armor models for testing for compliance with NIJ Standard 0101.07 in 2024. Commercial entities interested in participating in the NIJ CTP must first register in the Testing Information Management System (TIMS) and complete an Applicant Agreement. TIMS can be accessed through the following web page: *https://cjtec.org/compliance-testing-program/testing-information-management-system/.*

The NIJ CTP will host an informational online webinar that will offer a guided tour of TIMS prior to opening the system for registration. The date and time of the webinar, as well as instructions on how to attend, will be published on the TIMS web page above. Commercial entities interested in participating in the NIJ CTP are strongly encouraged to attend the webinar. NIJ anticipates that commercial entities may begin registering in TIMS after the webinar is held. The exact date that commercial entities can register in TIMS, as well as instructions on how to use TIMS, will be displayed on the TIMS web page above.

The NIJ CTP anticipates allowing commercial entities that have registered in TIMS and completed an Applicant Agreement to submit new body armor models for testing for compliance with NIJ Standard 0101.07 in the middle of April 2024. The exact date that new armor models can be submitted will be displayed on the TIMS homepage on April 1, 2024. The NIJ CTP anticipates that it will take several months for the first wave of body armor models to be certified to the new program requirements, with a new CPL for armor models compliant with NIJ Standard 0101.07 (''07'' CPL) subsequently published.

Ballistics laboratories interested in participating in the NIJ CTP to test armor in accordance with NIJ Standard 0101.07 must communicate their interest by email to the contact listed above as soon as possible so that appropriate program requirements can be met in a timely manner. Information on program requirements for laboratory participation in the NIJ CTP can be found here: *https://cjtec.org/compliance-testing-program/nij-approved-test-laboratories/.* NIJ encourages ballistics laboratories to check the above web page regularly for updates.

NIJ plans to hold an in-person workshop for body armor manufacturers to discuss implementation of NIJ Standard 0101.07 and NIJ Standard 0123.00 through the NIJ CTP. Information about this workshop will be published separately in the **Federal Register**.

More information about standards and conformity assessment at NIJ can be found here: *https://nij.ojp.gov/equipment-standards-and-conformity-assessment.* More information on the NIJ CTP can be found here: *https://cjtec.org/compliance-testing-program/.*

NIJ publishes this notice pursuant to its authority at 34 U.S.C. 10122(c) and 6 U.S.C. 161–165.

Nancy La Vigne,

Director, National Institute of Justice.

[FR Doc. 2023–26327 Filed 11–29–23; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

National Institute of Justice

[OJP (NIJ) Docket No. 1818]

Body Armor Manufacturer In-Person Workshop

AGENCY: National Institute of Justice, Office of Justice Programs, U.S. Department of Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) will hold an in-person workshop for body armor manufacturers to provide an overview of NIJ Standard 0101.07, *Ballistic Resistance of Body Armor,* and NIJ Standard 0123.00, *Specification for NIJ Ballistic Protection Levels and Associated Test Threats.* The NIJ Compliance Testing Program (CTP) will outline how it will begin to phase out use of NIJ Standard 0101.06 and phase in the use of NIJ Standard 0101.07 in the administration of the program over the next year. The impact of the transition to NIJ Standard 0101.07 on the Compliant Products List (CPL) and Follow-up Inspection Testing (FIT) of currently listed body armor models compliant with NIJ Standard 0101.06 will also be discussed.

DATES: The in-person workshop will be held on Thursday, February 15, 2024, from 9 a.m. to 3 p.m. eastern time.

ADDRESSES: The in-person workshop will be held at RTI International's William M. Moore, Jr. Collaboration Center, located in the Holden Building on RTI's main campus at 3040 E Cornwallis Road, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Mark Greene, Office Director, Office of Technology and Standards, National Institute of Justice, 810 7th Street NW, Washington, DC 20531 by telephone at (202) 598–9481 [Note: this is not a toll-free telephone number], or by email at *mark.greene2@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The in-person workshop will be an open forum and there will opportunities for attendees to ask questions. Space is limited at this workshop, and as a result, NIJ requests that each

manufacturer limit their representatives to no more than two per organization. Exceptions to this limit may occur, should space allow. Participants planning to attend are responsible for their own travel arrangements. To register for the in-person workshop, please send an email to *askctp@nijctp.org* by 5 p.m. eastern time on Friday, February 2, 2024, and provide the name of your company and the names of the representatives who will attend. Please put ''Body Armor Manufacturer In-person Workshop'' in the subject line of the email. A preliminary agenda will be sent to registered attendees approximately one week prior to the workshop.

Attendees should note that the workshop will be held at RTI International's main campus in Research Triangle Park, NC, where the NIJ CTP is administered. A map of the campus can be found on the RTI website at *https://www.rti.org/sites/default/files/rtp_campus_map_9_2022.pdf.* Please note that visitor access to the RTI campus is controlled. Please see *https://www.rti.org/sites/default/files/visitor_management_system_visitor_process_guide_map.pdf* for more information on the RTI visitor management process.

More information about standards and conformity assessment at NIJ can be found here: *https://nij.ojp.gov/equipment-standards-and-conformity-assessment.* More information on the NIJ CTP can be found here: *https://cjtec.org/compliance-testing-program/.*

NIJ publishes this notice pursuant to its authority at 34 U.S.C. 10122(c) and 6 U.S.C. 161–165.

Nancy La Vigne,

Director, National Institute of Justice.

[FR Doc. 2023–26325 Filed 11–29–23; 8:45 am]

BILLING CODE 4410–18–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 23–120]

Privacy Act of 1974; System of Records

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the National Aeronautics and Space Administration is providing public notice of a modification to a previously announced system of records, Astronaut Candidate Selection Records, NASA 10ACSR. This notice incorporates locations and NASA standard routine uses previously published separately from, and cited by reference in, this and other NASA systems of records notices. Other modifications are described in the Supplementary Information section below.

DATES: Submit comments within 30 calendar days from the date of this publication. The changes will take effect at the end of that period, if no adverse comments are received.

ADDRESSES: Bill Edwards-Bodmer, Privacy Act Officer, Office of the Chief Information Officer, National Aeronautics and Space Administration Headquarters, Washington, DC 20546–0001, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

FOR FURTHER INFORMATION CONTACT: NASA Privacy Act Officer, Bill Edwards-Bodmer, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

SUPPLEMENTARY INFORMATION: This system notice includes minor revisions to NASA's existing system of records notice to bring its format into compliance with OMB guidance and to update records access, notification, and contesting procedures consistent with NASA Privacy Act regulations. It incorporates in whole, as appropriate, information formerly published separately in the **Federal Register** as Appendix A, Location Numbers and Mailing Addresses of NASA Installations at which Records are Located, and Appendix B, Standard Routine Uses—NASA, and removes references to ''Appendix A'' and ''Appendix B.'' This notice also updates Administrative, Technical, and Physical Safeguards to reflect current information technology security protocols. Finally, this notice is also modified to make minor editorial changes.

William Edwards-Bodmer,

NASA Privacy Act Officer.

SYSTEM NAME:

Astronaut Candidate Selection Records, NASA 10ACSR.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Lyndon B. Johnson Space Center, National Aeronautics and Space Administration (NASA), Houston, TX 77058–3696.

SYSTEM MANAGER(S):

Astronaut Candidate Program Manager, Lyndon B. Johnson Space Center, National Aeronautics and Space Administration (NASA), Houston, TX 77058–3696.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

51 U.S.C. 20113(a); 44 U.S.C. 3101; 5 U.S.C. 3301 *et seq.*

PURPOSE(S) OF THE SYSTEM:

Records in this system are used by NASA to facilitate processes and procedures associated with the recruitment, evaluation, and selection of United States astronaut candidates, as defined in 14 CFR part 1214, subpart 1214.11 (NASA Astronaut Candidate Recruitment and Selection Program).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information on persons who have applied to the agency for consideration as candidates for and recipients of training associated with NASA Astronaut and Human Space Flight Programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system include identifying information for the individuals in employment applications and resumes and records of specialized training, honors and awards. The system also contains relevant human resource correspondence, records an individual's qualifications for participation in a specialized program, evaluations of candidates, and final NASA determinations of candidates' qualification for the program.

RECORD SOURCE CATEGORIES:

Civil servant application information is received by the NASA Astronaut Candidate Selection System from applicants themselves via an electronic interface with OPM USA Staffing that receives all applicant records from the *USAJobs.gov* website, operated by the United States Office of Personnel Management (OPM), and into which applicants enter their own application data. Candidate Qualification input is received directly from individuals used as references who have direct knowledge of applicant capabilities. In certain circumstances, updates to this information may be submitted by the individual on whom the record is maintained and/or the NASA Personnel Office(s).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Any disclosures of information will be compatible with the purpose for which the Agency collected the information. Under the following routine use that is unique to this system of records, information in this system may be disclosed to the news media and the public, with the approval of the Senior Agency Official for Privacy in

consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of NASA or is necessary to demonstrate the accountability of NASA's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy, or that disclosure would violate any federal statute or regulation.

In addition, information may be disclosed under the following NASA Standard Routine Uses:

1. *Law Enforcement*—When a record on its face, or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order, if NASA determines by careful review that the records or information are both relevant and necessary to any enforcement, regulatory, investigative or prosecutive responsibility of the receiving entity.

2. *Certain Disclosures to Other Agencies*—A record from this SOR may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to an NASA decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. *Certain Disclosures to Other Federal Agencies*—A record from this SOR may be disclosed to a Federal agency, in response to its request, for a matter concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. *Department of Justice*—A record from this SOR may be disclosed to the Department of Justice when (a) NASA, or any component thereof; or (b) any employee of NASA in his or her official capacity; or (c) any employee of NASA in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, where NASA determines that litigation is likely to affect NASA or any of its components, is a party to litigation or has an interest in such litigation, and by careful review, the use of such records by the Department of Justice is deemed by NASA to be relevant and necessary to the litigation.

5. *Courts*—A record from this SOR may be disclosed in an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when NASA determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant and necessary to the proceeding.

6. *Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to appropriate agencies, entities, and persons when (1) NASA suspects or has confirmed that there has been a breach of the system of records; (2) NASA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, NASA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NASA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. *Contractors*—A record from this SOR may be disclosed to contractors, grantees, experts, consultants, students, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish a NASA function related to this SOR. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NASA employees.

8. *Members of Congress*—A record from this SOR may be disclosed to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

9. *Disclosures to Other Federal Agencies in Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to another Federal agency or Federal entity, when NASA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

10. *National Archives and Records Administration*—A record from this SOR may be disclosed as a routine use to the officers and employees of the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

11. *Audit*—A record from this SOR may be disclosed to another agency, or organization for purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are maintained on electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved from the system by any one or a combination of name, Discipline Area, or unique identification number.

POLICIES AND PROCEDURES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and transferred to the National Archives in accordance with NASA Records Retention Schedules, Schedule 8, Item 35.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained within a secure, electronic database and protected in accordance with the requirements and procedures of FISMA, the NASA regulations at 14 CFR 1212.605, NASA Procedural Requirements (NPR) 2810.1A, ITS–HBK–AASTEP1.v1.0.0, and, utilizing database servers with self-encrypting ''data-at-rest'' technologies, located in secured, monitored, restricted access rooms. Electronic messages sent within

and outside of the Agency that convey sensitive data are encrypted and transmitted by staff via pre-approved electronic encryption systems as required by NASA policy. An approved security plan for this system has been established in accordance with OMB Circular A–130, Management of Federal Information Resources. Only key authorized employees with appropriately configured system roles can access the system through approved authentication methods, and only from workstations within the NASA Intranet or via a secure VPN connection that requires two-factor authentication.

RECORD ACCESS PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

CONTESTING RECORD PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

NOTIFICATION PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

80 FR 79937
78 FR 40515

[FR Doc. 2023–26354 Filed 11–29–23; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 23–122]

Privacy Act of 1974; System of Records

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, the National Aeronautics and Space Administration is issuing public notice of its proposal to modify a previously noticed system of records Headquarters History Archives, NASA 10HQHA. This notice incorporates NASA Standard Routine Uses previously published separately from, and cited by reference in, this and other NASA systems of records notices. This notice also changes one location of records and subsystem manager; and other edits, as set forth below under the caption **SUPPLEMENTARY INFORMATION**.

DATES: Submit comments within 30 calendar days from the date of this publication. The changes will take effect at the end of that period, if no adverse comments are received.

ADDRESSES: Bill Edwards-Bodmer, Privacy Act Officer, Office of the Chief Information Officer, National Aeronautics and Space Administration Headquarters, Washington, DC 20546–0001, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

FOR FURTHER INFORMATION CONTACT: NASA Privacy Act Officer, Bill Edwards-Bodmer, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

SUPPLEMENTARY INFORMATION: This system notice updates records access, notification, and contesting procedures consistent with NASA Privacy Act regulations. It also incorporates in whole, as appropriate, information formerly published separately in the **Federal Register** as Appendix A, Location Numbers and Mailing Addresses of NASA Installations at which Records are Located, and Appendix B, Standard Routine Uses—NASA. The name of the system has been changed from History Archives Biographical Collection, NASA 10HABC to Headquarters History Archives, NASA 10HQHA. This notice also removes one system location and updates the titles to system managers. Finally, this notice includes minor revisions to NASA's existing system of records notice to bring its format into compliance with OMB guidance.

William Edwards-Bodmer,

NASA Privacy Act Officer.

SYSTEM NAME AND NUMBER:

Headquarters History Archives, NASA 10HQHA.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Mary W. Jackson NASA Headquarters, National Aeronautics and Space Administration (NASA), Washington, DC 20546–0001.

SYSTEM MANAGER(S):

Chief Archivist, Mary W. Jackson NASA Headquarters, National Aeronautics and Space Administration (NASA), Washington, DC 20546–0001.

Chief Historian, Mary W. Jackson NASA Headquarters, National Aeronautics and Space Administration (NASA), Washington, DC 20546–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

51 U.S.C. 20112; 44 U.S.C. 3101.

PURPOSE(S) OF THE SYSTEM:

Records in this system are used by History Office staff to answer reference queries from the media and are made available to visiting historians and other researchers to support their research and writing projects.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information on individuals who are of historical significance in aeronautics, astronautics, space science, and other concerns of NASA.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains (1) biographical data; (2) speeches and articles by an individual; (3) correspondence, interviews, and various other tapes and transcripts of program activities.

RECORD SOURCE CATEGORIES:

Press releases, newspapers, journals, copies of internal Agency records, and the individuals themselves.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Any disclosures of information will be compatible with the purpose for which the Agency collected the information. Under the following routine uses that are unique to this

system of records, information in this system may be disclosed:

1. to scholars (historians and other disciplines) or any other interested individuals for research in writing dissertations, articles, and books, for government, commercial, and nonprofit publication or developing material for other media use; and

2. by History Office staff to members of the media or NASA staff in response to reference requests, and to visiting historians and other researchers to support their research and writing projects.

In addition, information may be disclosed under the following NASA Standard Routine Uses:

1. *Law Enforcement*—When a record on its face, or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order, if NASA determines by careful review that the records or information are both relevant and necessary to any enforcement, regulatory, investigative or prosecutive responsibility of the receiving entity.

2. *Certain Disclosures to Other Agencies*—A record from this SOR may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to a NASA decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. *Certain Disclosures to Other Federal Agencies*—A record from this SOR may be disclosed to a Federal agency, in response to its request, for a matter concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. *Department of Justice*—A record from this SOR may be disclosed to the Department of Justice when (a) NASA, or any component thereof; or (b) any employee of NASA in his or her official capacity; or (c) any employee of NASA in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, where NASA determines that litigation is likely to affect NASA or any of its components, is a party to litigation or has an interest in such litigation, and by careful review, the use of such records by the Department of Justice is deemed by NASA to be relevant and necessary to the litigation.

5. *Courts*—A record from this SOR may be disclosed in an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when NASA determines that the records are relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

6. *Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to appropriate agencies, entities, and persons when (1) NASA suspects or has confirmed that there has been a breach of the system of records; (2) NASA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, NASA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NASA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. *Contractors*—A record from this SOR may be disclosed to contractors, grantees, experts, consultants, students, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish a NASA function related to this SOR. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NASA employees.

8. *Members of Congress*—A record from this SOR may be disclosed to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

9. *Disclosures to Other Federal Agencies in Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to another Federal agency or Federal entity, when NASA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

10. *National Archives and Records Administration*— A record from this SOR may be disclosed as a routine use to the officers and employees of the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

11. *Audit*—A record from this SOR may be disclosed to another agency, or organization for purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are maintained as hard-copy documents and on electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The records are retrieved from the system by the individual's name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained indefinitely in Agency reference collections in history offices, but may be destroyed when no longer needed in accordance with NASA Records Retention Schedules, Schedule 1 Item 10.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Because these records are archive material and, therefore, a matter of public information, there are no special safeguard procedures required.

RECORD ACCESS PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data

concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

CONTESTING RECORD PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

NOTIFICATION PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

80 FR 79937.
78 FR 77503.
72 FR 55817.
64 FR 69556.
63 FR 4290.

[FR Doc. 2023–26355 Filed 11–29–23; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 23–121]

Privacy Act of 1974; System of Records

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the National Aeronautics and Space Administration is providing public notice of its proposal to modify a previously noticed system of records NASA Guest Operations System/NASA 10GOS. This notice incorporates locations and NASA Standard Routine Uses previously published separately from, and cited by reference in, this and other NASA systems of records notices. This notice also updates: records access, notification, and contesting procedures; technical safeguards; revises a routine use and adds routine new one, as set forth below under the caption **SUPPLEMENTARY INFORMATION**.

DATES: Submit comments within 30 calendar days from the date of this publication. The changes will take effect at the end of that period if no adverse comments are received.

ADDRESSES: Bill Edwards-Bodmer, Privacy Act Officer, Office of the Chief Information Officer, National Aeronautics and Space Administration Headquarters, Washington, DC 20546–0001, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

FOR FURTHER INFORMATION CONTACT: NASA Privacy Act Officer, Bill Edwards-Bodmer, (757) 864–7998, *NASA-PAOfficer@nasa.gov.*

SUPPLEMENTARY INFORMATION: This system notice includes updates records access, notification, and contesting procedures, as well as technical safeguards, consistent with NASA Privacy Act regulations and current NASA information technology security protocols. It incorporates in whole, as appropriate, information formerly published separately in the **Federal Register** as Appendix A, Location Numbers and Mailing Addresses of NASA Installations at which Records are Located, and Appendix B, Standard Routine Uses—NASA and removes reference to the appendices. Finally, this notice includes minor revisions to NASA's existing system of records notice to bring its format into compliance with OMB guidance

William Edwards-Bodmer,
NASA Privacy Act Officer.

SYSTEM NAME AND NUMBER:

NASA Guest Operations System, NASA 10GOS.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Lyndon B. Johnson Space Center (NASA), Houston, TX 77058–3696.

SYSTEM MANAGER(S):

Guest Operations Manager, Office of Communications, Mary W. Jackson NASA Headquarters, Washington, DC 20546–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

51 U.S.C. 20113(a); 44 U.S.C. 3101.

PURPOSE(S) OF THE SYSTEM:

Records in this system are used by the Agency for the purpose of communicating with guests to NASA events.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information on individuals who have been invited to attend NASA events. These individuals can be (1) members of the NASA community such as principal and prominent management and staff officials, program and project managers, scientists, engineers, speakers, or other selected employees involved in newsworthy activities; (2) other participants in Agency programs; or (3) members of the general public who are invited to attend NASA events.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system may include personal information about the individuals invited or attending events, such as their names, email addresses, phone numbers, and nationality.

RECORD SOURCE CATEGORIES:

The information contained in the NASA Guest Operations System (GOS) is obtained directly from the individuals, who provide the information on a voluntary basis.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Any disclosures of information in this system of records will be relevant, necessary, and compatible with the purpose for which the Agency collected the information. Under the following NASA Standard Routine Uses, records from this system may be disclosed.

1. *Law Enforcement*—When a record on its face, or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order, if NASA determines by careful review that the records or information are both relevant and necessary to any

enforcement, regulatory, investigative or prosecutive responsibility of the receiving entity.

2. *Certain Disclosures to Other Agencies*—A record from this SOR may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to a NASA decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. *Certain Disclosures to Other Federal Agencies*—A record from this SOR may be disclosed to a Federal agency, in response to its request, for a matter concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. *Department of Justice*—A record from this SOR may be disclosed to the Department of Justice when (a) NASA, or any component thereof; or (b) any employee of NASA in his or her official capacity; or (c) any employee of NASA in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, where NASA determines that litigation is likely to affect NASA or any of its components, is a party to litigation or has an interest in such litigation, and by careful review, the use of such records by the Department of Justice is deemed by NASA to be relevant and necessary to the litigation.

5. *Courts*—A record from this SOR may be disclosed in an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when NASA determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant and necessary to the proceeding.

6. *Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to appropriate agencies, entities, and persons when (1) NASA suspects or has confirmed that there has been a breach of the system of records; (2) NASA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, NASA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NASA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. *Contractors*—A record from this SOR may be disclosed to contractors, grantees, experts, consultants, students, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish a NASA function related to this SOR. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NASA employees.

8. *Members of Congress*—A record from this SOR may be disclosed to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

9. *Disclosures to Other Federal Agencies in Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to another Federal agency or Federal entity, when NASA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

10. *National Archives and Records Administration*—A record from this SOR may be disclosed as a routine use to the officers and employees of the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

11. *Audit*—A record from this SOR may be disclosed to another agency, or organization for purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained electronically in a central secure database.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are searched and retrieved by name, business, or address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in a computer database and managed, retained and dispositioned in accordance with the guidelines defined in the NASA Records Retention Schedules (NRRS), Schedule 1, Item 37A.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records are maintained on secure NASA servers and protected in accordance with all Federal standards and those established in NASA regulations at 14 CFR 1212.605. An approved security plan for this system has been established in accordance with OMB Circular A–130, *Management of Federal Information Resources.* Individuals will have access to the system only in accordance with approved authentication methods. Electronic messages sent within and outside of the Agency that convey sensitive data are encrypted and transmitted by staff via pre-approved electronic encryption systems in accordance with NASA guidelines for managing sensitive information. Only key authorized employees with appropriately configured system roles can access the system and only from workstations within the NASA Intranet.

RECORD ACCESS PROCEDURE:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

CONTESTING RECORD PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests

must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

NOTIFICATION PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

80 FR 79937.
80 FR 60410.
76 FR 64112.

[FR Doc. 2023–26353 Filed 11–29–23; 8:45 am]

BILLING CODE 7510–13–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–70 and CP2024–71; MC2024–71 and CP2024–73; MC2024–72 and CP2024–74; MC2024–73 and CP2024–75]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 4, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–70 and CP2024–71; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 113 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 22, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* December 4, 2023.

2. *Docket No(s).:* MC2024–71 and CP2024–73; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 114 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 22, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* December 4, 2023.

3. *Docket No(s).:* MC2024–72 and CP2024–74; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 115 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 22, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* December 4, 2023.

4. *Docket No(s).:* MC2024–73 and CP2024–75; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 116 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 22, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* December 4, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2023–26344 Filed 11–29–23; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Change in Rates and Classes of General Applicability for Competitive Products

AGENCY: Postal Service™.

ACTION: Notice of a change in rates and classifications of general applicability for competitive products.

SUMMARY: This notice sets forth changes in rates and classifications of general applicability for competitive products.

DATES: *Applicability date:* No earlier than July 1, 2024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: On November 13, 2023, pursuant to their authority under 39 U.S.C. 3632, the Governors of the Postal Service established prices and classification changes for competitive products to establish Zone 10 prices for Priority Mail Express, Priority Mail, and USPS Ground Advantage. The Governors' Decision and the record of proceedings in connection with such decision are reprinted below in accordance with section 3632(b)(2). Mail Classification Schedule language containing the new prices and classification changes can be found at *www.prc.gov.*

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

Decision of the Governors of the United States Postal Service on Changes in Rates and Classifications of General Applicability for Competitive Products (Governors' Decision No. 23–6)

November 14, 2023

Statement of Explanation and Justification

Pursuant to authority under section 3632 of title 39, as amended by the Postal Accountability and Enhancement Act of 2006 (''PAEA''), we establish prices and classifications of general applicability for certain competitive products in order to establish Zone 10 rates for offshore locations. Specifically, Zone 10 rates will be added to the price charts for the Postal Service's ''full network'' competitive products: Priority Mail Express, Priority Mail, and USPS Ground Advantage. The rates will apply to mail destinating in Alaska, Hawaii, and US Territories, and not originating in the same state or territory. Prices are designed to be five percent higher than the January 2024 proposed prices for Zone 8. Additionally, USPS Ground Advantage prices for Zone 9 will be increased to align with the new Zone 10 prices. Classification changes will be made in the relevant price charts to include new columns for Zone 10 prices. A detailed description of the changes can be found in the Postal Service's associated draft Mail Classification Schedule change document. That document contains the draft Mail Classification Schedule sections with classification changes in legislative format, and new prices displayed in the price charts.

As shown in the nonpublic annex being filed under seal herewith, the changes we establish should enable each affected competitive product to cover its attributable costs (39 U.S.C. 3633(a)(2)) and should result in competitive products as a whole complying with 39 U.S.C. 3633(a)(3), which, as implemented by 39 CFR 3035.107(c), requires competitive products collectively to contribute a minimum of 9.9 percent to the Postal Service's institutional costs. Accordingly, no issue of subsidization of competitive products by market dominant products should arise (39 U.S.C. 3633(a)(1)). We therefore find that the new prices and classification changes are in accordance with 39 U.S.C. 3632–3633 and 39 CFR 3035.102 and 104.

Order

The changes in prices and classes set forth herein shall be effective no earlier than July 1, 2024, on a date and time determined at the discretion of management. We direct the Secretary to have this decision published in the **Federal Register** in accordance with 39 U.S.C. 3632(b)(2) and direct management to file with the Postal Regulatory Commission appropriate notice of these changes.

By The Governors:

/s/

Roman Martinez IV,

Chairman, Board of Governors.

United States Postal Service Office of The Board of Governors

Certification of Governors' Vote on Governors' Decision No. 23–6

Consistent with 39 U.S.C. 3632(a), I hereby certify that, on November 13, 2023, the Governors voted on adopting Governors' Decision No. 23–6, and that a majority of the Governors then holding office voted in favor of that Decision.

Date: November 13, 2023.

/s/ _____

Michael J. Elston,

Secretary of the Board of Governors.

[FR Doc. 2023–26359 Filed 11–29–23; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) the practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

1. Title and purpose of information collection: Application and Claim for Unemployment Benefits and Employment Service; OMB 3220–0022.

Section 2 of the Railroad Unemployment Insurance Act (RUIA) (45 U.S.C. 231), provides unemployment benefits for qualified railroad employees. These benefits are generally payable for each day of unemployment in excess of four during a registration period (normally a period of 14 days).

Section 12 of the RUIA provides that the RRB establish, maintain and operate free employment facilities directed toward the reemployment of railroad employees. The procedures for applying for the unemployment benefits and employment service and for registering and claiming the benefits are prescribed in 20 CFR 325.

The RRB utilizes the following forms to collect the information necessary to pay unemployment benefits: Form UI–1 (or its internet equivalent, Form UI–1 (Internet)), *Application for Unemployment Benefits and Employment Service,* is completed by a claimant for unemployment benefits once in a benefit year, at the time of first registration. Completion of Form UI–1 or UI–1 (Internet) also registers an unemployment claimant for the RRB's employment service.

The RRB also utilizes Form UI–3, (or its internet equivalent Form UI–3 (Internet)) *Claim for Unemployment Benefits* for use in claiming unemployment benefits for days of unemployment in a particular registration period, normally a period of 14 days.

Completion of Forms UI–1, UI–1 (Internet), UI–3 and UI–3 (Internet) is required to obtain or retain benefits. The number of responses required of each claimant varies, depending on their period of unemployment.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (88 FR 66067 on September 26, 2023) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Application and Claim for Unemployment Benefits and Employment Service.

OMB Control Number: 3220–0022.

Forms submitted: UI–1, UI–1 (Internet), UI–3, UI–3 (Internet).

Type of request: Revision of a currently approved collection.

Affected public: Individuals or Households.

Abstract: Under section 2 of the Railroad Unemployment Insurance Act, unemployment benefits are provided for qualified railroad employees. The collection obtains the information needed to determine the eligibility to and amount of such benefits for railroad employees.

Changes proposed: The RRB proposes no changes to the forms in the collection.

The burden estimate for the ICR is as follows:

UI–1	2,118	10	323
UI–1 (Internet)	7,549	10	1,258
UI–3	23,724	6	2,372
UI–3 (Internet)	82,027	6	8,203
Total	115,418		12,186

2. Title and purpose of information collection: Placement Service; OMB 3220–0057.

Section 12(i) of the Railroad Unemployment Insurance Act (RUIA) (45 U.S.C. 362), authorizes the RRB to establish, maintain, and operate free employment offices to provide claimants for unemployment benefits with job placement opportunities. Section 704(d) of the Regional Railroad Reorganization Act of 1973, as amended, and as extended by the Consolidated Omnibus Budget Reconciliation Act of 1985, required the RRB to maintain and distribute a list of railroad job vacancies, by class and craft, based on information furnished by rail carriers to the RRB. Although the requirement under the law expired effective August 13, 1987, the RRB has continued to obtain this information in keeping with its employment service responsibilities under section 12(k) of the RUIA. Application procedures for the job placement program are prescribed in 20 CFR 325. The procedures pertaining to the RRB's obtaining and distributing job vacancy reports furnished by rail carriers are described in 20 CFR 346.1.

The RRB currently utilizes four forms to obtain information needed to carry out its job placement responsibilities. Form ES–2, *Central Register Notification,* is used by the RRB to obtain information needed to update a computerized central register of separated and furloughed railroad employees available for employment in the railroad industry. Forms ES–21, *Referral to State Employment Service,* and ES–21c, *Report of State Employment Service Office,* are used by the RRB to provide placement assistance for unemployed railroad employees through arrangements with State Employment Service offices. Form UI–35, Field Office Record of Claimant Interview, is used primarily by the RRB to conduct in-person interviews of claimants for unemployment benefits.

Completion of these forms is required to obtain or maintain a benefit. In addition, the RRB also collects Railroad Job Vacancies information received voluntarily from railroad employers.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (88 FR 66068 on September 26, 2023) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Placement Service.

OMB Control Number: 3220–0057.

Form(s) submitted: ES–2, ES–21, ES–21c, UI–35 and Job Vacancies Report.

Type of request: Extension without change of a currently approved collection.

Affected public: Private Sector, Businesses or other for-profits; Individuals or Households; State, Local, and Tribal Governments.

Abstract: Under the RUIA, the Railroad Retirement Board provides job placement assistance for unemployed railroad workers. The collection obtains information from job applicants, railroad employers, and State Employment Service offices for use in placement, for providing referrals for job openings, reports of referral results and for verifying and monitoring claimant eligibility.

Changes proposed: The RRB proposes no changes to the forms in this information collection.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
ES–21	80	1.00	1
ES–21c	25	2.00	1
UI–35 in person	6,300	7.00	735
UI–35 by mail	700	11.00	128
Job Vacancies	470	10.00	78
Total	7,575		943

3. Title and purpose of information collection: Report of Medicaid State Office on Beneficiary's Buy-In Status; OMB 3220–0185.

Under section 7(d) of the Railroad Retirement Act (45 U.S.C. 231), the RRB administers the Medicare program for persons covered by the railroad retirement system. Under section 1843 of the Social Security Act, states may enter into ''buy-in agreements'' with the Secretary of Health and Human Services for the purpose of enrolling certain groups of low-income individuals under

the Medicare medical insurance (Part B) program and paying the premiums for their insurance coverage. Generally, these individuals are categorically needy under Medicaid and meet the eligibility requirements for Medicare Part B. States can also include in their buy-in agreements, individuals who are eligible for medical assistance only. The RRB uses Form RL–380–F, Report to State Medicaid Office, to obtain information needed to determine if certain railroad beneficiaries are entitled to receive Supplementary Medical Insurance program coverage under a state buy-in agreement in states in which they reside. Completion of Form RL–380–F is voluntary. One response is received from each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (88 FR 66068 on September 26, 2023) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Report of Medicaid State Office on Beneficiary's Buy-In Status.

OMB Control Number: 3220–0185.

Forms submitted: RL–380–F.

Type of request: Revision of a currently approved collection.

Affected public: State, local, and Tribal governments.

Abstract: Under the Railroad Retirement Act, the Railroad Retirement Board administers the Medicare program for persons covered by the railroad retirement system. The collection obtains the information needed to determine if certain railroad beneficiaries are entitled to receive Supplemental Medical Insurance program coverage under a state buy-in agreement in states in which they reside.

Changes proposed: The RRB proposes the following changes to Form RL–380–F:

- Change 'Medicare Number' box on righthand side of form to 'Medicare Beneficiary Identifier'.
- Remove box 6 on righthand side of form 'Social Security Number' as it is a duplicate of box 4 'Beneficiary's Own Social Security Number'.
- In Question 4, change 'Medicare number under which state paid premium (if different from RRB Medicare claim number' to 'Medicare Beneficiary Identifier Number (MBI) in which state paid premium'.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
RL–380–F	600	10	100

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Kennisha Money at (312) 469–2591 or *Kennisha.Money@rrb.gov*. Comments regarding the information collection should be addressed to Brian Foster, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–1275 or *Brian.Foster@rrb.gov*.

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.

Brian Foster,

Clearance Officer.

[FR Doc. 2023–26332 Filed 11–29–23; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99017; File No. SR–MEMX–2023–25]

Self-Regulatory Organizations; MEMX LLC; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Its Fee Schedule To Establish an Options Regulatory Fee

November 24, 2023.

I. Introduction

On September 27, 2023, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (file number SR–MEMX–2023–25) to adopt an Options Regulatory Fee (''ORF'').[3] The proposed rule change was immediately effective upon filing with the Commission pursuant to section 19(b)(3)(A) of the Act.[4] The proposed rule change was published for comment in the **Federal Register** on October 4, 2023.[5]

Pursuant to section 19(b)(3)(C) of the Act,[6] the Commission is hereby: (1) temporarily suspending file number SR–MEMX–2023–25; and (2) instituting proceedings to determine whether to approve or disapprove file number SR–MEMX–2023–25.

II. Description of the Proposed Rule Change

The Exchange proposes to establish an ORF in the amount of $0.0015 per contract side.[7] The per-contract ORF will be collected by the Options Clearing Corporation (''OCC'') on behalf of the Exchange for each options transaction, cleared or ultimately cleared by an Exchange member in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF is collected from either: (1) a Member that was the ultimate clearing firm for the transaction; or (2) a non-Member that was the ultimate clearing firm where a Member was the executing clearing firm for the transaction.[8]

According to the Exchange, the amount of the proposed ORF fee is ''based on historical industry volume, projected volumes on the Exchange, and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 98585 (September 28, 2023), 88 FR 68692 (October 4, 2023) (''Notice'').

[4] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as ''establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.'' 15 U.S.C. 78s(b)(3)(A)(ii).

[5] *See* Notice, *supra* note 3.

[6] 15 U.S.C. 78s(b)(3)(C).

[7] *See* Notice, *supra* note 3, at 68692.

[8] *Id.*

projected Exchange regulatory costs.'' [9] The Exchange states that ''revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs.'' [10] The Exchange notes that it will monitor the amount of ORF revenue it collects ''to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs.'' [11]

The Exchange proposes that the ORF will automatically sunset on September 30, 2024, approximately one year after the operative date.[12] The Exchange believes this will allow it time to ''gather the necessary data, including its actual regulatory costs and revenues, as well as the cost of regulating executions that clear in a customer capacity and executions that occur on away markets, while also allowing it to adequately cover a portion of the projected costs associated with the regulation of its Members.'' [13] According to the Exchange, allowing the collection of ORF from the outset of its operations on September 27, 2023 until September 30, 2023, when the fee will automatically sunset, will allow the Exchange to fund its regulatory program and collect evidence to provide to the Commission and inform its approach to ORF after the sunset period.[14]

III. Suspension of the Proposed Rule Change

Pursuant to section 19(b)(3)(C) of the Act,[15] at any time within 60 days of the date of filing of an immediately effective proposed rule change pursuant to section 19(b)(1) of the Act,[16] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization (''SRO'') 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. As discussed below, the Commission believes a temporary suspension of the proposed rule change is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act to allow for additional analysis of the proposed rule change's consistency with the Act and the rules thereunder.

When exchanges file their proposed rule changes with the Commission, including fee filings like the Exchange's present proposal, they are required to provide a statement supporting the proposal's basis under the Act and the rules and regulations thereunder applicable to the exchange.[17] The instructions to Form 19b–4, on which exchanges file their proposed rule changes, specify that such statement ''should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements'' [18]

Section 6 of the Act, including Sections 6(b)(4), (5), and (8), require the rules of an exchange to: (1) provide for the equitable allocation of reasonable fees among members, issuers, and other persons using the exchange's facilities; [19] (2) perfect the mechanism of a free and open market and a national market system, protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers; [20] and (3) not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[21]

In justifying its proposal, the Exchange stated that establishing an ORF in the amount of $0.0015 is reasonable because it ''will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs'' and ''is lower than the amount of ORF assessed on other exchanges.'' [22] According to the Exchange, its ORF is designed to ''generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than 75% of the Exchange's regulatory costs. . . .'' [23]

The Exchange also asserted that the ORF is equitably allocated and not unfairly discriminatory because ''it is charged to all Members on all their transactions that clear as customer at the OCC'' and is ''directly based on the amount of customer options business they conduct.'' [24] In addition, the Exchange stated that ''[r]egulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive.'' [25] Further, the Exchange stated that it has ''broad regulatory responsibilities with respect to a Members' activities, irrespective of where their transactions take place'' and notes that it ''will not be able to effectively surveil [its Members'] conduct without looking at and evaluating activity across all options markets.'' [26] Consequently, the Exchange imposes the ORF on all customer-range transactions cleared by a Member, even if the transactions do not take place on the Exchange and regardless of whether the transaction was executed by a member.[27]

Furthermore, the Exchange notes that implementing the proposed ORF with a sunset date of approximately one year after the operative date is reasonable because ''it will give the Exchange adequate time to collect and analyze pertinent data while ensuring the Exchange, as a new entrant into equity options trading, is able to adequately fund its regulatory program to the same extent as its competitors.'' [28]

In temporarily suspending the Exchange's proposed rule change, the Commission intends to further consider whether the proposal to establish an ORF in the amount of $0.0015 is consistent with the statutory requirements applicable to a national securities exchange under the Act. In particular, the Commission will consider whether the proposed rule change satisfies the standards under the Act and the rules thereunder requiring, among other things, that an exchange's rules provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and do not

[9] *Id.* at 68693.

[10] *Id.*

[11] *Id.*

[12] *Id.* at 68692 and 68695.

[13] *Id.* at 68695.

[14] *Id.*

[15] 15 U.S.C. 78s(b)(3)(C).

[16] 15 U.S.C. 78s(b)(1).

[17] *See* 17 CFR 240.19b–4 (Item 3 entitled ''Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change'').

[18] *Id.*

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(8).

[22] *See* Notice, *supra* note 3, at 68695–96. Several other exchanges have a lower ORF rate than that proposed by the Exchange. *See, e.g.,* Nasdaq ISE, available at *https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207* ($0.0013); Nasdaq GEMX, available at Rules | Nasdaq GEMX ($0.0012); CboeEDGX, available at Cboe EDGX Options Exchange Fee Schedule ($0.0001); and MIAX Emerald, available at *https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Emerald_Fee_Schedule_10122023_3.pdf* ($0.0006).

[23] *See* Notice, *supra* note 3, at 68696.

[24] *Id.*

[25] *Id.*

[26] *Id.* at 68693 and 68696.

[27] *Id.* The Exchange also states that its proposed collection method which is similar to that utilized by other options exchanges ''was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.'' *Id.* at 68696.

[28] *Id.* at 68697.

impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[29]

Therefore, the Commission finds that it is necessary or appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule change.[30]

IV. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change

In addition to temporarily suspending the proposal, the Commission also hereby institutes proceedings pursuant to sections 19(b)(3)(C)[31] and 19(b)(2)(B) of the Act[32] to determine whether the Exchange's proposed rule change should be approved or disapproved. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to section 19(b)(2)(B) of the Act,[33] the Commission is providing notice of the grounds for possible disapproval under consideration:

- Whether the Exchange has demonstrated how its proposed fee is consistent with section 6(b)(4) of the Act, which requires that the rules of a national securities exchange ''provide for the *equitable allocation* of *reasonable* dues, fees, and other charges among its members and issuers and other persons using its facilities''[34] (emphasis added);
- Whether the Exchange has demonstrated how its proposed fee is consistent with section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange not be ''designed to permit *unfair discrimination* between customers, issuers, brokers, or dealers''[35] (emphasis added); and
- Whether the Exchange has demonstrated how its proposed fee is consistent with section 6(b)(8) of the Act, which requires that the rules of a national securities exchange ''not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].''[36]

As noted above, the Exchange proposes to establish an ORF in the amount of $0.0015 per contract side ''based on historical industry volume, projected volumes on the Exchange, and projected Exchange regulatory costs.''[37] The Exchange also states that ''revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs.[38] However, those and other statements in support of its proposed establishment of an ORF are general in nature and lack sufficient detail and specificity.

For example, the Exchange does not elaborate on the ''material portion'' of options regulatory expenses that it seeks to recover from the ORF and why the threshold it selected (*i.e.,* that ORF will ''not exceed more than 75% of total annual regulatory costs'') correlates to the degree of regulatory responsibility and expenses borne by the Exchange as it relates to the regulation of customer options transactions.[39] Further, the Exchange has not provided any quantifiable information to support its assertion that regulating customer trading activity is ''much more labor-intensive'' and therefore, more costly. The Exchange does not claim in its filing that its regulation of customer activity will consume 75% of total regulatory costs nor does it assert that customer activity will require a level of effort that will occupy 75% of the regulatory department's attention. Further, the Exchange does not sufficiently analyze how funding 75% of its total regulatory costs (including direct and indirect expenses) from ORF constitutes an equitable allocation of reasonable fees among members, and it does not provide sufficient detail to allow the Commission and commenters to consider those issues.

Further, the Exchange has not provided specific or detailed information regarding the anticipated regulatory cost associated with regulating, monitoring, and surveilling on-exchange activity compared to activity that takes place on other exchanges (which exchanges assess their own ORF on those trades). In particular, the Exchange proposes to collect ORF on executions that do not occur on the Exchange. The proposed ORF rate is the same for on-exchange and off-exchange activity, so the proposal will result in the Exchange at least initially funding a very significant portion of its total regulatory costs from a fee charged on contracts that execute away from the Exchange. The Exchange does not provide a sufficiently detailed analysis or present specific facts to show the level of regulatory effort and regulatory costs it would expend on contracts that execute on other exchanges. Without more information in the filing on the Exchange's projected regulatory revenues, regulatory costs, and regulatory activities to supervise and regulate members, specifically, *e.g.,* customer versus non-customer activity and on-exchange versus off-exchange activity, the proposal lacks specific information that can speak to whether the proposed ORF is reasonable, equitably allocated, and not unfairly discriminatory, particularly given that the ORF is assessed only on transactions that clear in the ''customer'' range and regardless of the exchange on which the transaction occurs.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . . is on the [SRO] that proposed the rule change.''[40] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[41] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[42]

As explained above, the Exchange's statements in support of the proposed rule change are general in nature and

[29] *See* 15 U.S.C. 78f(b)(4), (5), and (8), respectively.

[30] For purposes of temporarily suspending the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change, section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[32] 15 U.S.C. 78s(b)(2)(B).

[33] 15 U.S.C. 78s(b)(2)(B). Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the exchange consents to the longer period. *See id.*

[34] 15 U.S.C. 78f(b)(4).

[35] 15 U.S.C. 78f(b)(5).

[36] 15 U.S.C. 78f(b)(8).

[37] *See* Notice, *supra* note 3, at 68692.

[38] *Id.* at 68693.

[39] *See* Notice, *supra* note 3, at 68693.

[40] 17 CFR 201.700(b)(3).

[41] *See id.*

[42] *See id.*

lack detail and specificity. The Commission cannot unquestionably rely on an exchange's statements and representations.[43] Instead, the Commission needs sufficient information to support independent findings that a proposal is consistent with the requirements of the Act.[44] Here, such an analysis includes, among other things, whether the proposed ORF is an equitable allocation of reasonable dues, fees, and other changes among the Exchange's members, as well as whether the proposed ORF is equitable and not unfairly discriminatory.

The Commission needs additional information from the Exchange to demonstrate how the proposal meets those and other applicable requirements of the Act, to assess whether the Exchange has established a sufficient nexus between the proposed ORF and the Exchange's regulation of customer trading activity both on and off exchange. While the Commission broadly solicits comment from all interested parties on the proposal, the Commission believes that the Exchange alone has access to much of the specific detail necessary to fully address these questions and concerns because these matters involve qualitative and quantitative information about the Exchange's operations. Specifically, among other things, the Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal contained in the Notice.[45] In particular, the Commission seeks comment on the following aspects of the proposal and asks commenters to submit data where appropriate to support their views:

1. *Information on the Exchange's Projected Regulatory Costs and Revenues.* The Exchange states that its proposed ORF rate is reasonable based on historical industry volume, projected volumes on the Exchange, and projected Exchange regulatory costs. The Exchange notes that its regulatory costs would include direct regulatory expenses and certain indirect expenses for work ''allocated in support of the regulatory function.'' [46] According to the Exchange, indirect regulatory expenses (including, among other things, human resources, legal, information technology, facilities and accounting, as well as certain shared expenses necessary to operate the Exchange and carry out its regulatory function) are anticipated to be approximately 24% of the Exchange's total regulatory costs for 2023 and 2024 and direct regulatory expenses are anticipated to be approximately 76% of the Exchange's total regulatory costs for 2023 and 2024.[47] Do commenters believe the Exchange has provided adequate detail regarding these metrics? If not, what additional information should be provided to demonstrate how the proposal is consistent with the Act?

2. *Information on the Exchange's Imposition of ORF on Customer Orders.* The Exchange states that it will ensure that revenue generated from ORF not exceed more than 75% of total annual regulatory costs.[48] Do commenters believe that the Exchange has sufficiently analyzed and justified its proposal to fund 75% of its total regulatory expenses from a fee imposed only on options transactions clearing in the customer-range, where those expenses include the regulation of transactions that clear in the non-customer-range (*e.g.,* broker-dealer and market maker trades)? In addition, explaining that the proposed ORF would be charged to ''all Members on all their transactions that clear as customer at the OCC,'' the Exchange states that such methodology ''ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct.'' [49] The Exchange further asserts that ''[r]egulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive.'' [50] According to the Exchange, ''the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.'' [51] Do commenters believe that the Exchange has provided sufficiently detailed quantitative and qualitative evidence in support of this aspect of its proposal? Specifically, examples of information that would be helpful to demonstrate how the assessment of ORF only on orders that clear in the customer-range correlates to the level of effort and costs the Exchange expends to regulate customer options transactions include: (a) the percentage of volume expected to clear in the customer-range both on and off the Exchange compared to the percentage of volume expected to clear in a range other than customer both on and off the Exchange; (b) the percentage of the Exchange's regulatory budget that would be attributable to the regulation of orders that are expected to clear in the customer-range compared to the percentage of the Exchange's regulatory budget that would be attributable to orders that are expected to clear in a range other than customer; (c) the anticipated percentage of the Exchange's regulatory level of effort that would be attributable to the regulation of orders that are expected to clear in the customer-range compared to the anticipated percentage of the Exchange's regulatory level effort that would be attributable to orders that are expected to clear in a range other than customer; and (d) the proportion of the Exchange's revenues, as reported in the most recent annual financials it submitted on Form1, that would be represented by expected ORF revenues if those revenues had been included in the most recent annual financials.

3. *Information on the Exchange's Assessment of ORF on Away-Market Activity.* The Exchange states that it has ''broad regulatory responsibilities with respect a Member's activities, irrespective of where their transactions take place. . . .'' [52] The Exchange therefore believes that it is appropriate to impose the ORF even where the transaction does not take place on the Exchange.[53] Do commenters believe that the Exchange has provided sufficiently detailed quantitative and qualitative evidence in support of how the assessment of ORF on away-market transactions correlates to the effort it will expend on regulating away-market transactions compared to the level of effort the Exchange will invest in regulating transactions on Exchange? Specifically, examples of information that would be helpful to assess the application of the ORF to executions that do not occur on the Exchange include: (a) the projected percentage of the Exchange's overall regulatory budget that is expected to be attributable to regulating away-market transactions compared to the projected percentage of the Exchange's overall regulatory budget that is expected to be attributable to regulating on-Exchange transactions; (b) the projected percentage of the Exchange's regulatory level of effort that is expected to be attributable to the regulation of away-market transactions compared to the projected percentage of

[43] *See Susquehanna Int'l Grp., LLP* v. *SEC,* 866 F.3d 442, 447 (August 8, 2017).

[44] *See id.*

[45] *See* Notice, *supra* note 3.

[46] *See* Notice, *supra* note 3, at 68693.

[47] *Id.*

[48] *See id.*

[49] *Id.* at 68696.

[50] *Id.*

[51] *Id.*

[52] *See id.* at 68694.

[53] *See id.*

the Exchange's regulatory level of effort that is expected to be attributable to the regulation of orders that execute on the Exchange; (c) the anticipated percentage of ORF revenue that is expected to be derived from away-market transactions compared to the anticipated percentage of ORF revenue that is expected to be derived from executions on the Exchange; and (d) more detail on the regulatory activities the exchange expects to perform for trades that do not occur on the Exchange.

4. *Information on the Exchange's Regulatory Program Concerning Clearing Brokers.* The Exchange states that ORF is collected on ''customer range'' options transactions cleared or ultimately cleared by an Exchange member regardless of the exchange on which the transaction occurs.[54] The Exchange also will collect ORF from a non-Member clearing broker where a member was the executing firm and a non-Member was the ultimate clearing firm. Do commenters believe that the Exchange has provided sufficiently detailed quantitative and qualitative evidence in support of this aspect of its proposal? Specifically, examples of information that would be helpful to provide context for the collection of ORF from member and non-member clearing brokers and determine whether a sufficient nexus exists between the ORF and the Exchange's regulation of clearing activity, include: (a) the percentage of the Exchange's regulatory expenses and level of regulatory activity that is expected to pertain to clearance and settlement activity and the percentage this is expected to account for with respect to the Exchange's overall regulatory costs and regulatory activity, and if that differs depending on whether the ultimate clearing firm is an Exchange member or not and whether the contract executes on the Exchange or not; (b) the number of ''ultimate clearing firms'' that are Exchange members compared to the number of ''ultimate clearing firms'' that are non-Members from which ORF is expected to be collected on behalf of the Exchange; and (c) the percentage of ORF revenues that is expected to be collected from Member clearing firms compared to the percentage of ORF revenue that is expected to be collected from non-Member clearing firms.

The Commission is instituting proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposed fees are consistent with the Act, and specifically, with the requirements that exchange fees be reasonable, equitably allocated, and not unfairly discriminatory.[55]

V. Commission's Solicitation of Comments

The Commission requests written views, data, and arguments with respect to the concerns identified above as well as any other relevant concerns. Such comments should be submitted by December 21, 2023. Rebuttal comments should be submitted by January 4, 2024. Although there do not appear to be any issues relevant to approval or disapproval which would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[56]

The Commission asks that commenters address the sufficiency and merit of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MEMX–2023–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MEMX–2023–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 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. 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–MEMX–2023–25 and should be submitted on or before December 21, 2023. Rebuttal comments should be submitted by January 4, 2024.

VI. Conclusion

It is therefore ordered, pursuant to section 19(b)(3)(C) of the Act,[57] that file number SR–MEMX–2023–25, be and hereby is, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule change should be approved or disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[58]

Christina Z. Milnor,

Assistant Secretary.

[FR Doc. 2023–26263 Filed 11–29–23; 8:45 am]

BILLING CODE 8011–01–P

[54] *See id.* at 68692.

[55] *See* 15 U.S.C. 78f(b)(4), (5), and (8).

[56] 15 U.S.C. 78s(b)(2). Section 19(b)(2) of the Act grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by an SRO. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[57] 15 U.S.C. 78s(b)(3)(C).

[58] 17 CFR 200.30–3(a)(57) and (58).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20114 and #20115; California Disaster Number CA–20002]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–4750–DR), dated 11/21/2023.

Incident: Tropical Storm Hilary.

Incident Period: 08/19/2023 through 08/21/2023.

DATES: Issued on 11/21/2023.

Physical Loan Application Deadline Date: 01/22/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 08/20/2024.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/21/2023, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Imperial, Inyo, Kern, Riverside, Siskiyou.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 20114B and for economic injury is 201150.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2023–26293 Filed 11–29–23; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Delegation of Authority No. 547]

Delegation of Authority Under the Creating Helpful Incentives To Produce Semiconductors (CHIPS) Act of 2022

By virtue of the authority vested in the Secretary of State by the laws of the United States, including section 1 of the State Department Basic Authorities Act (22 U.S.C. 2651a) and section 102(c) of the CHIPS Act of 2022 (Div. A, Pub. L. 117–167) (CHIPS Act), I hereby delegate the following functions to the extent authorized by law:

• To the Director and the Deputy Director of the Office of U.S. Foreign Assistance, the function conferred upon the Secretary of State by section 102(c)(1) of the CHIPS Act to approve the transfer of amounts in the Creating Helpful Incentives to Produce Semiconductors (CHIPS) for America International Technology Security and Innovation Fund (ITSI Fund) to foreign assistance accounts within the Department of State and the United States Agency for International Development and to accounts within the Export-Import Bank and the United States International Development Finance Corporation, as appropriate, to be used for such purposes and under the terms and conditions of the account to which transferred.

• To the Under Secretary for Management, the function conferred upon the Secretary of State by section 102(c)(1) of the CHIPS Act to approve the transfer of amounts in the CHIPS ITSI Fund to diplomatic engagement accounts within the Department of State to be used for such purposes and under the terms and conditions of the account to which transferred.

The Secretary, the Deputy Secretary, and the Deputy Secretary for Management and Resources may exercise any function or authority delegated herein. Any reference in this delegation of authority to a statute shall be deemed to be a reference to such statute as amended from time to time and shall be deemed to apply to any provision of law that is the same or substantially the same as such statute. This delegation of authority does not repeal or otherwise affect any other delegation of authority currently in effect.

This delegation of authority will be published in the **Federal Register**.

Dated: July 3, 2023.

Antony J. Blinken,

Secretary of State.

Editorial Note: This document was received for publication by the Office of the Federal Register on November 27, 2023.

[FR Doc. 2023–26362 Filed 11–29–23; 8:45 am]

BILLING CODE 4710–10–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Reallocation of Unused Fiscal Year 2024 WTO Tariff-Rate Quota Volume for Raw Cane Sugar

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country reallocations of the fiscal year (FY) 2024 in-quota quantity of the World Trade Organization (WTO) tariff-rate quota (TRQ) for imported raw cane sugar.

DATES: This notice is applicable on November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Erin Nicholson, Office of Agricultural Affairs, at 202–395–9419 or *erin.h.nicholson@ustr.eop.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTSUS), the United States maintains WTO TRQs for imports of raw cane and refined sugar. Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the U.S. Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On July 5, 2023, U.S. Department of Agriculture established the FY2024 TRQ for imported raw cane sugar at the minimum quantity to which the United States is committed pursuant to the WTO Uruguay Round Agreements (1,117,195 metric tons raw value (MTRV) conversion factor: 1 metric ton = 1.10231125 short tons). On July 19, 2023, USTR provided notice of country-by-country allocations of the FY2024 in-quota quantity of the WTO TRQ for imported raw cane sugar. *See* 88 FR 46363. Based on consultation with quota holders, the U.S. Trade Representative has determined to reallocate 223,740 MTRV of the original TRQ quantity from those countries that

have stated they do not plan to fill their FY2024 allocated raw cane sugar quantities. The U.S. Trade Representative is allocating the 223,740 MTRV to the following countries in the amounts specified below:

Country	FY2024 raw sugar unused reallocation (MTRV)
Argentina	15,592
Australia	30,098
Belize	3,989
Bolivia	2,901
Brazil	52,581
Colombia	8,703
Costa Rica	5,439
Ecuador	3,989
El Salvador	9,428
Eswatini (Swaziland)	5,802
Guatemala	17,406
Guyana	4,352
Honduras	3,626
Jamaica	3,989
Malawi	3,626
Mauritius	4,352
Mozambique	4,714
Panama	10,516
Peru	14,868
South Africa	8,340
Thailand	5,077
Zimbabwe	4,352

The allocations of the raw cane sugar WTO TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin. Certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

Douglas McKalip,

Chief Agricultural Negotiator, Office of the United States Trade Representative.

[FR Doc. 2023–26298 Filed 11–29–23; 8:45 am]

BILLING CODE 3390–F4–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2023–0050]

Agency Information Collection Activities: Notice of Request for Reinstatement of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for reinstatement of a previously approved information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new (periodic) information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on September 6, 2023. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0050 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.*

Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Spencer Stevens, 202–366–6221, Office of Planning, Environment and Realty, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, between 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Planning and Research Program Administration.

OMB Control #: 2125–0039.

Background: The Planning and Research Program Administration is covered under 23 CFR part 420. 23 CFR part 420 regulation includes administrative requirements and procedures for PL funds (23 U.S.C. 104(b)(6)) provided for Metropolitan Planning Organizations (MPOs) to carry out metropolitan planning, and SPR funds (provided under the provisions of 23 U.S.C. 505) for State Departments of Transportation (State DOTs) to implement statewide transportation planning and research, development and technology (RD&T) work activities. Also, at a State DOT's option, other Title 23 funds as identified in the definition of FHWA planning and research funds in 23 U.S.C. 505 and 23 CFR 420.103 may be used to perform planning activities. Different from this request, the information collection requirement for work performed by MPOs is a joint Federal Highway Administration/Federal Transit Administration requirement and is covered under OMB Control Number 2132–0529.

In accordance with government-wide grant management procedures, a grant application must be submitted for these funds. In addition, recipients must submit periodic progress and financial reports. The content and frequency of submission of progress and financial reports specified in 23 CFR part 420 is as specified in 2 CFR 200 grant management regulations. With the implementation of 2 CFR 200, the focus will be more on using data to determine the grant's achievement outcomes and less on accountability compliance. FHWA and the State DOTs are called upon to identify clear performance goals, indicators, and milestones for the grants. This information collection supports the DOT's Strategic Objective of ''Organizational Excellence'' by providing an ongoing mechanism to review applications and approve Federal grants to States for their transportation planning and research, development, and technology work programs.

Respondents: Each State, the District of Columbia and the Commonwealth of Puerto Rico are required to provide information. The annual number of burden hours (professional and clerical staff) per respondent for preparation of work programs and progress and financial reports is estimated to be 720 (18 weeks × 40 hours per week). The total annual burden for all respondents is estimated to be 37,440 burden hours (720 burden hours per respondent times 52 respondents).

Frequency: This annual burden consists of staff time of each respondent for preparation of the work programs, and progress and financial reports. For those respondents that elect to use biennial work programs, the burden for preparation of work programs would be significantly less for the second year.

Estimated Average Burden per Response:

Professional staff time for preparation of work programs: 400 hours/respondent.

Professional staff time for preparation of progress and financial reports: 120 hours/respondent.

Clerical staff time: 200 hours/respondent.

Estimated Total Annual Burden Hours: 720 hours/respondent × 52 respondents = 37,400 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is

necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: November 27, 2023.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2023–26360 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of calendar year 2024 random drug and alcohol testing rates.

SUMMARY: This notice announces the calendar year 2024 drug and alcohol random testing rates for specific recipients of FTA financial assistance. The minimum random drug testing rate will remain at 50 percent, and the random alcohol testing rate will remain at 10 percent.

DATES: *Applicability Date:* January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Iyon Rosario, Drug and Alcohol Program Manager in the Office of Transit Safety and Oversight, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–366–2010 or email: *Iyon.Rosario@dot.gov*).

SUPPLEMENTARY INFORMATION: On January 1, 1995, FTA required large transit employers to begin drug and alcohol testing of employees performing safety-sensitive functions, and to submit annual reports by March 15 of each year beginning in 1996, pursuant to drug and alcohol regulations adopted by FTA at 49 CFR parts 653 and 654 in February 1994. The annual report includes the number of employees who had a verified positive test for the use of prohibited drugs, and the number of employees who tested positive for the misuse of alcohol during the reported year. Small employers commenced the required testing on January 1, 1996, and began reporting the same information as the large employers beginning March 15, 1997.

FTA updated the testing rules by merging them into a new 49 CFR part 655, effective August 1, 2001 (66 FR 42002). The regulation maintained a random testing rate for prohibited drugs at 50 percent and the misuse of alcohol at 10 percent. The Administrator may lower the random testing rate to 25 percent if the violation rates drop below 1.0 percent for drug testing and 0.5 percent for alcohol testing for two consecutive years. Accordingly, in 2007, FTA reduced the random drug testing rate from 50 percent to 25 percent (72 FR 1057). In 2018, however, FTA returned the random drug testing rate to 50 percent for calendar year 2019 based on verified industry data for calendar year 2017, which showed that the rate had exceeded 1 percent (83 FR 63812).

Pursuant to 49 CFR 655.45, the Administrator's decision to determine the minimum annual percentage rate for random drug and alcohol testing is based, in part, on the reported positive drug and alcohol violation rates for the entire public transportation industry. The information used for this determination is drawn from the Drug and Alcohol Management Information System (MIS) reports required by 49 CFR 655.72. To ensure the reliability of the data, the Administrator must consider the quality and completeness of the reported data, may obtain additional information or reports from employers, and may make appropriate modifications in calculating the industry's verified positive results and violation rates.

For calendar year 2024, the Administrator has determined that the minimum random drug testing rate for covered employees will remain at 50 percent based on a verified positive rate for prohibited drug use of 1.09 percent for calendar year 2022 and 0.99 percent for calendar year 2021. Further, the Administrator has determined that the minimum random alcohol testing rate for calendar year 2024 will remain at 10 percent, because the violation rate again was lower than 0.5 percent for calendar years 2022 and 2021. The random alcohol violation rates were 0.18 percent for 2022 and 0.13 for 2021.

Detailed reports on FTA's drug and alcohol testing data collected from transit employers may be obtained from FTA, Office of Transit Safety and Oversight, 1200 New Jersey Avenue SE, Washington, DC, 20590, (202) 366–2010, or at: *https://transit-safety.fta.dot.gov/DrugAndAlcohol/Publications/Default.aspx.*

Nuria I. Fernandez,

Administrator.

[FR Doc. 2023–26347 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 2024 Competitive Funding Opportunity: All Stations Accessibility Program

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for approximately $343 million in competitive grants under the fiscal year (FY) 2024 All Stations Accessibility Program (ASAP).

DATES: Complete proposals must be submitted electronically through the *GRANTS.GOV* ''APPLY'' function by 11:59 p.m. Eastern time on January 30, 2024. Prospective applicants should initiate the process by registering on the *GRANTS.GOV* website promptly to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA's website at *https://www.transit.dot.gov/howtoapply* and in the ''FIND'' module of *GRANTS.GOV.* The funding opportunity ID is FTA–2024–001–TPM–ASAP.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, please contact Kevin Osborn, All Stations Accessibility Program Manager, via email at *Kevin.Osborn@dot.gov* or call 202–366–7519.

SUPPLEMENTARY INFORMATION:

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A. Program Description

Division J of the Bipartisan Infrastructure Law (enacted as the Infrastructure Investment and Jobs Act, Pub. L. 117–58) authorizes FTA to award grants for public transportation rail station accessibility projects, for

''legacy'' stations, through a competitive process, as described in this notice. Legacy stations for purposes of this NOFO are defined as public transportation stations already constructed or where construction began prior to January 25, 1992, or for commuter rail stations already constructed or where construction began prior to October 7, 1991, that were not identified as key stations and remain not accessible to or usable by persons with disabilities, including wheelchair users. ASAP provides funding to States (including territories and Washington, DC) and local governmental authorities to help finance capital projects to upgrade the accessibility of legacy rail fixed guideway public transportation systems (*e.g.,* subway, commuter rail, light rail) for persons with disabilities, including those who use wheelchairs, by increasing the number of existing stations or facilities, such as outdoor light-rail boarding and alighting areas, that are fully accessible. For purposes of this NOFO, ''fully accessible'' means all of the passenger-use publicly accessible areas in the station(s) or facilities for passenger use meet or exceed the standards for new construction under title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12131 *et seq.*) as incorporated into appendix A of 49 CFR part 37. Grants under this program are for (1) capital projects to repair, improve, modify, retrofit, or relocate infrastructure of stations or facilities for passenger use, including load-bearing members that are an essential part of the structural frame; or (2) for planning projects to develop or modify a plan for pursuing public transportation accessibility projects, assessments of accessibility, or assessments of planned modifications to stations or facilities for passenger use.

This funding opportunity can be found under Federal Assistance Listing 20.533. FTA seeks to fund projects that create proportional impacts to all populations in a project area, remove transportation related disparities to all populations in a project area, and increase equitable access to project benefits, consistent with Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009). In addition, the Department intends to use the program to support the creation of good-paying jobs with the free and fair choice to join a union and the incorporation of strong labor standards and training and placement programs, especially registered apprenticeships, in project planning stages, consistent with Executive Order 14025, Worker Organizing and Empowerment (86 FR 22829), and Executive Order 14052, Implementation of the Infrastructure Investment and Jobs Act (86 FR 64335). The Department also intends to use the program to support wealth creation, consistent with the Department's Equity Action Plan, through the inclusion of local inclusive economic development and entrepreneurship, such as the utilization of Disadvantaged Business Enterprises.

B. Federal Award Information

The Bipartisan Infrastructure Law appropriated $350,000,000 for FY 2024 for ASAP. After the administrative oversight and Office of Inspector General takedown of $7,000,000, FTA is announcing the availability of $343,000,000 for ASAP grants through this notice. FTA may also award any additional funds made available for ASAP prior to project selections. FTA may cap the amount a single recipient or State may receive as part of the selection process.

FTA will grant pre-award authority to incur costs for selected projects beginning on the date FY 2024 project selections are announced on FTA's website. Funds are available for obligation for three fiscal years after the fiscal year in which the competitive awards are announced. Funds are available only for eligible costs incurred after the date project selections are announced. FTA intends to fund as many meritorious projects as possible.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants for ASAP include designated recipients that operate or allocate funds to inaccessible pre-ADA—or ''legacy''—rail fixed guideway public transportation systems, and States (including territories and Washington, DC) and local governmental entities that operate or financially support legacy rail fixed guideway public transportation systems and corresponding legacy stations/facilities. The law limits ASAP to legacy rail fixed guideway public transportation systems with stations or facilities for passenger use that are not already accessible to and usable by persons with disabilities, including wheelchair users. To be considered eligible, applicants must be able to demonstrate the requisite legal, financial, and technical capabilities to receive and administer Federal funds under this program. Assistance on this requirement is available from FTA's Regional Offices.

2. Cost Sharing or Matching

The maximum Federal share as identified in the law for an eligible project shall not exceed 80 percent of the net project cost.

Eligible sources of match include the following: state or local government revenues, cash from non-government sources other than revenues from providing public transportation services; revenues derived from the sale of advertising and concessions; amounts received under a service agreement with a State or local social service agency or private social service organization; revenues generated from value capture financing mechanisms; funds from an undistributed cash surplus; replacement or depreciation cash fund or reserve; new capital; or in-kind contributions. Transportation development credits or in-kind match may be used for local match if identified and documented in the application.

3. Eligible Projects

Eligible projects under ASAP include (1) capital projects to repair, improve, modify, retrofit, or relocate infrastructure of stations or facilities for passenger use, including load-bearing members that are an essential part of the structural frame; or (2) for planning projects to develop or modify a plan for pursuing public transportation accessibility projects, assessments of accessibility, or assessments of planned modifications to stations or facilities for passenger use projects; or programs of projects in an eligible area. Please note, capital projects are limited to only those that, upon completion, will meet or exceed the standards for new construction under title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12131 *et seq.*), as incorporated into appendix A of 49 CFR part 37. Eligible costs are limited to project costs associated with the accessibility improvements.

Neither a capital grant nor a planning grant awarded under this program may be used to upgrade a station or facility for passenger use that is already accessible to and usable by individuals with disabilities, including individuals who use wheelchairs, consistent with the construction standards under title II of the Americans with Disabilities Act of 1990 (ADA) (42 U.S.C. 12131 *et seq.*) in place at the time the station or passenger facility was originally constructed or upgraded. Only legacy stations or passenger facilities that existed prior to the ADA and were not

made accessible in the intervening time are therefore eligible.

Any project of station upgrades or passenger facility that does not result in full accessibility consistent with title II of the ADA as incorporated by appendix A of 49 CFR part 37 and usability by persons with disabilities, including wheelchair users, is not eligible under this program. Any project to upgrade a station previously identified as one already required to be accessible to and usable by persons with disabilities, including those that use wheelchairs, per the requirements of 49 CFR part 37, including key stations and intercity rail stations, is not eligible under this program. Projects for maintenance or repair activities for elements of existing accessible stations or passenger facilities that are otherwise subject to the ongoing maintenance requirements under 49 CFR 37.161(a) are not eligible under this program. Maintenance and repair activities for stations altered under this program are subject to the same ongoing maintenance provision, and are similarly ineligible.

D. Application and Submission Information

1. Address To Request Application Package

Application materials may be accessed on grants.gov. Applications must be submitted electronically through *GRANTS.GOV.* General information for accessing and submitting applications through *GRANTS.GOV* can be found at *https://www.fta.dot.gov/howtoapply* along with specific instructions for the forms and attachments required for submission. A complete proposal submission for each program consists of two forms: the SF–424 Application for Federal Assistance (available at *GRANTS.GOV*) and the supplemental form for the FY 2024 All Stations Accessibility Program (downloaded from *GRANTS.GOV* or the FTA website at *https://www.transit.dot.gov/grants/all-stations-accessibility-program*). Please note that if an applicant is applying for both a planning and construction project, they must submit two different applications via *GRANTS.GOV.* Failure to submit the information as requested can delay review or disqualify the application.

2. Content and Form of Application Submission

a. Proposal Submission

A complete proposal submission for each program consists of two forms: (1) the SF–424 Application for Federal Assistance; and (2) the supplemental form for the FY 2024 All Stations Accessibility Program. The supplemental form and any supporting documents must be attached to the ''Attachments'' section of the SF–424. The application must include responses to all sections of the SF–424 Application for Federal Assistance and the supplemental form, unless indicated as optional. The information on the supplemental form will be used to determine applicant and project eligibility for the program, and to evaluate the proposal against the selection criteria described in section E of this notice.

FTA will accept only one supplemental form per SF–424 submission. FTA encourages States and other applicants to consider submitting a single supplemental form that includes multiple activities to be evaluated as a consolidated proposal. If a State or other applicant chooses to submit separate proposals for individual consideration by FTA, each proposal must be submitted using a separate SF–424 and supplemental form. Applicants applying for both a planning and a construction project must submit two separate applications, one for each type of project.

Applicants may attach additional supporting information to the SF–424 submission, including but not limited to letters of support, project budgets, accessibility information, or excerpts from relevant planning documents. Any supporting documentation must be described and referenced by file name in the appropriate response section of the supplemental form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, local match amount, description of areas served, etc. may be requested in varying degrees of detail on both the SF–424 and supplemental form. Applicants must fill in all fields unless stated otherwise on the forms. If information is copied into the supplemental form from another source, applicants should verify that pasted text is fully captured on the supplemental form and has not been truncated by the character limits built into the form. Applicants should use both the ''Check Package for Errors'' and the ''Validate Form'' validation buttons on both forms to check all required fields on the forms, and ensure that the Federal and local amounts specified are consistent. Applicants should enter their information in the supplemental form (fillable PDF) that is made available on FTA's website or through the *GRANTS.GOV* application package, and should attach this to the application in its original format. Applicants should not use scanned versions of the form, ''print'' the form to PDF, convert or create a version using another text editor, etc.

The Department may share application information within the Department or with other Federal agencies if the Department determines that sharing is relevant to the respective program's objectives.

b. Application Content

The SF–424 Application for Federal Assistance and the supplemental form will prompt applicants for the required information, including:

i. Applicant name.

ii. Unique Entity Identifier.

iii. Key contact information (including contact name, address, email address, and phone).

iv. Congressional district(s) where project will take place.

v. Project information (including title, an executive summary, and type).

vi. A detailed description of the need for the project.

vii. A detailed description on how the project will support the Program's objectives.

viii. Evidence that the project is consistent with local and regional planning documents.

ix. Evidence that the applicant can provide the local cost share.

x. A description of the technical, legal, and financial capacity of the applicant.

xi. A detailed project budget—Project budgets should show how different funding sources will share in each activity and present those data in dollars and percentages. The budget should identify other Federal funds the applicant is applying for or has been awarded, if any, that the applicant intends to use. Funding sources should be grouped into three categories: non-Federal, ASAP and other Federal with specific amounts from each funding source.

xii. An explanation of the scalability of the project—Applicants are encouraged to identify scaled funding options in case insufficient funding is available to fund a project at the full requested amount. If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. Proposed scalable projects must still result in a station or passenger facility with full accessibility to and usability by persons with disabilities, including wheelchair users. The applicant must provide a clear explanation of how the project budget would be affected by a

reduced award. FTA may award a lesser amount regardless of whether a scalable option is provided.

xiii. Details on the non-Federal matching funds.

xiv. Details on any other Federal funds awarded or applied for.

xv. A detailed project timeline.

xvi. A system map and listing of accessible vs inaccessible stations, and which station(s) they are proposing to upgrade.

xvii. Address all the applicable criteria and priority considerations identified in section E.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant has an exemption approved by FTA pursuant to 2 CFR 25.110(c) or is otherwise excepted from registration requirements. FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant.

All applicants must provide a unique entity identifier provided by SAM. Registration in SAM may take as little as 3–5 business days, but since there could be unexpected steps or delays (for example, if there is a need to obtain an Employer Identification Number), FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit *https://www.sam.gov.*

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern time on January 30, 2024. *GRANTS.GOV* attaches a time stamp to each application at the time of submission. Proposals submitted after the deadline will only be considered under extraordinary circumstances when the lateness was for reasons not under the applicant's control. Mail and fax submissions will not be accepted.

Within 48 hours after submitting an electronic application, the applicant should receive an email message from *GRANTS.GOV* with confirmation of successful transmission to *GRANTS.GOV.* If a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

FTA urges applicants to submit applications at least 72 hours prior to the due date to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website. Deadlines will not be extended due to scheduled website maintenance.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registrations up to date before submissions can be made successfully. For example, registration in SAM is renewed annually, and persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

5. Funding Restrictions

Funds under this NOFO cannot be used to reimburse applicants for otherwise eligible expenses incurred prior to FTA award of a grant agreement until FTA has issued pre-award authority for selected projects. FTA expects to issue pre-award authority to incur costs for selected projects beginning on the date that project selections are announced. FTA does not provide pre-award authority for competitive funds until projects are selected, and even then, there are Federal requirements that must be met before costs are incurred. FTA will issue specific guidance to awardees regarding pre-award authority at the time of selection. For more information about FTA's policy on pre-award authority, please see the most recent Apportionment Notice on FTA's website. Refer to section C.3., Eligible Projects, for information on activities that are allowable in this grant program. Allowable direct and indirect expenses must be consistent with the Government-wide Uniform Administrative Requirements and Cost Principles (2 CFR part 200) and FTA Circular 5010.1E. Funds may not be used to support or oppose union organizing.

6. Other Submission Requirements

All applications must be submitted via the *GRANTS.GOV* website. FTA does not accept applications on paper, by fax machine, email, or other means. For information on application submission requirements, please see section D.1. of this notice, Address to Request Application.

E. Application Review Information

1. Criteria

Projects will be evaluated primarily on the responses provided in the supplemental form. Additional information may be provided to support the responses; however, any additional documentation must be directly referenced on the supplemental form, including the file name where the additional information can be found. FTA will evaluate proposals based on the criteria described in this notice.

a. Demonstration of Need

For station or passenger facility accessibility improvement projects:

FTA will evaluate the need for the project, including supporting information that describes the lack of accessibility at, the condition, of and age of the stations or passenger facilities for passenger use to be made fully accessible. Applicants are encouraged to include a detailed project description and scope that explains how the proposed project will make all of the passenger-use publicly accessible areas in the station(s) or facilities for passenger use fully accessible in accordance with title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12131 *et seq.*), as incorporated into appendix A of 49 CFR part 37. Applicants should demonstrate that this is a legacy rail station that was not already required to be made fully accessible in accordance with the ADA.

FTA will evaluate whether the project (1) addresses an overall lack of accessible stations in a particular geographic area; (2) is at a major interchange point with other transportation modes; (3) serves major activity or cultural centers, such as employment or government centers, sports or entertainment venues, centers of economic activity or commerce, cultural or community centers,

institutions of higher education, hospitals or other major health care facilities, or other facilities that are major trip generators; (4) is a transfer station(s) on a rail line, between rail lines, or is an end of the line station; (5) is a station or passenger facility where passenger boardings exceed average station or facility passenger boardings on the rail system and/or (6) is able to demonstrate reductions in ADA paratransit reliance through paratransit origin-to-destination pairs analysis.

For planning projects:

FTA will evaluate how well the applicant demonstrates that the proposed planning project will develop or modify a plan for pursuing public transportation accessibility projects, assessments of accessibility, or assessments of planned modifications to stations or facilities for passenger use. Applicants are encouraged to reference how the project supports local and regional prioritization of increased accessibility at their existing legacy rail fixed guideway public transportation stations or passenger facilities.

b. Demonstration of Benefits

For station or passenger facility accessibility improvement projects:

FTA will evaluate how well the applicant details how the project will increase the accessibility of legacy rail fixed guideway public transportation systems for persons with disabilities, including those who use wheelchairs, by increasing the number of existing stations or passenger facilities for passenger use that meet or exceed the standards for new construction under title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12131 *et seq.*) as incorporated into appendix A of 49 CFR part 37. See: *https://www.access-board.gov/files/ada/ADAdotstandards.pdf.* FTA will rate projects higher if they propose to exceed the construction standards, by providing multiple paths of travel for people with physical disabilities (including those who use wheelchairs) or technologies to improve accessibility for people with sensory or cognitive disabilities, as examples. FTA will evaluate if the applicant described how the proposed station, stations, or facilities for passenger use were analyzed and selected to improve accessibility and usability for passengers with disabilities within the system.

For planning projects:

FTA will evaluate how well the applicant details how the resulting planning project will advance accessibility for persons with disabilities, including wheelchair users, and result in a future capital project that will make a legacy station or facility fully accessible. FTA will evaluate how well the applicant addresses the timeline and steps remaining after the project would be completed, before a construction project could commence to repair, improve, modify, retrofit, or relocate infrastructure of stations or facilities for passenger use.

c. Planning and Local or Regional Prioritization

FTA will evaluate how the applicant demonstrates how the proposed project is consistent with local and regional long-range planning documents and local government priorities. FTA will evaluate applications based on the extent to which the project is consistent with the transit priorities or illustrative projects identified in the metropolitan long-range plan or the investment prioritization portion of the transit asset management plan of the recipient pursuant to part 625 of title 49 of the Code of Federal Regulations. Applicants may submit copies of the relevant pages of such plans to support their application. FTA will also consider letters of support from local and regional planning organizations, local government officials, public agencies, non-profit or private sector organizations, and other relevant stakeholders.

FTA will evaluate if the applicant provided any information documenting outreach to, engagement with, and support for the project among the surrounding local disability community, such as centers for independent living, as well as other communities likely to be affected by the project, and explained how feedback received during the outreach was or was not meaningfully incorporated into project plans. Applications will be rated higher that demonstrate how the passenger stations or facilities proposed for investment were selected from a stakeholder engagement process with local disability community members and organizations, including individuals with physical disabilities (including those who use wheelchairs), sensory disabilities, and intellectual or developmental disabilities. Letters of support may be submitted with the application that demonstrate that each station proposed for investment is supported by stakeholders in the surrounding disability community.

FTA will evaluate if the applicant documented compliance with all civil rights and other applicable legal requirements, as well as any information relevant to advancing the goal of environmental justice for all, such as access for persons with limited English proficiency, persons with disabilities, and persons experiencing environmental injustices.

FTA will evaluate if the applicant identified current and future climate and natural hazard risks to the proposed project, or provided information in support of or the lack thereof. This includes consideration of risks over the service life of the project and identification of approaches to reduce potential disruptions to passengers from natural hazards. To support this narrative, the applicant may reference and include applicable excerpts from climate and/or environmental justice planning documents such as local or regional climate action plans.

d. Local Financial Commitment

FTA will evaluate if the applicant identified the source of the non-Federal cost share and describe whether such funds are currently available for the project or will need to be secured if the project is selected for funding. FTA will consider the availability of the non-Federal cost share as evidence of local financial commitment to the project. FTA will evaluate if the applicant submitted evidence of the availability of funds for the project, for example, by including a board resolution, letter of support from the State, a budget document highlighting the line item or section committing funds to the proposed project, or other documentation of the source of non-Federal funds. The applicant should also identify other Federal funds the applicant is applying for or has been awarded, if any, that the applicant intends to use.

e. Project Implementation Strategy

FTA will rate projects higher if grant funds can be obligated within 12 months of selection and the project can be implemented within a reasonable time frame. In assessing when funds can be obligated, FTA will consider whether the project qualifies for a Categorical Exclusion (CE), or whether the required environmental work has been initiated or completed for a project that requires an Environmental Assessment (EA) or Environmental Impact Statement (EIS) under the National Environmental Policy Act of 1969 (NEPA). As such, applicants should submit information describing the project's anticipated path and timeline through the environmental review process for all proposals, including whether the project qualifies for a CE. The proposal must state when grant funds can be obligated and indicate the timeframe under which the Metropolitan Transportation Improvement Program (TIP) and

Statewide Transportation Improvement Program (STIP) can be amended, if necessary, to include the proposed project.

In assessing whether the proposed implementation plans are reasonable and complete, FTA will review the proposed project implementation plan, including all necessary project milestones and the overall project timeline. For projects that will require formal coordination, approvals, or permits from other agencies or project partners, the applicant must demonstrate coordination with these organizations and their support for the project, such as through letters of support.

f. Technical, Legal, and Financial Capacity

FTA will evaluate if the applicant demonstrates that they have the technical, legal, and financial capacity to undertake the project.

FTA will review relevant oversight assessments and records to determine whether there are any outstanding legal, technical, or financial issues with the applicant that would affect the outcome of the proposed project. Applicants with outstanding legal, technical, or financial compliance issues from an FTA compliance review or FTA grant-related Single Audit finding must explain how corrective actions taken will mitigate negative impacts on the proposed project.

2. Review and Selection Process

A technical evaluation committee will evaluate proposals based on the published evaluation criteria. FTA may request additional information from applicants, if necessary. Based on the review of the technical evaluation committee, the FTA Administrator will determine the final selection of projects for program funding. In determining the allocation of program funds, FTA may consider geographic diversity, diversity in the size of the transit systems receiving funding, and the applicant's receipt of other competitive awards. FTA may also consider capping the amount a single applicant may receive.

After applying the above criteria, and in support of Executive Order 14052, Implementation of the Infrastructure Investment and Jobs Act, FTA will give priority based on several considerations.

FTA will provide priority consideration for applicants that describe how their projects support workforce development, job quality, and wealth creation as follows: Applicants for facility projects should identify whether they will commit to registered apprenticeship positions and use apprentices on the funded project, sometimes called an apprenticeship utilization requirement (*e.g.,* requiring that a certain percent of all labor hours will be performed by registered apprentices); and detail partnerships with high-quality workforce development programs with supportive services [1] to help train, place, and retain underrepresented communities in jobs and registered apprenticeships on the project; and, for facility projects over $35 million in total project cost, whether the project will use a Project Labor/Community Workforce Agreement and, for facility projects over $35 million, whether the recipient commits to participate in the U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) Mega Construction Project Program if selected by OFCCP (see F.2.e. *Federal Contract Compliance*).

FTA will also give priority consideration to projects that support the Justice40 initiative, *https://www.transportation.gov/equity-Justice40.* In support of Executive Order 14008, DOT has been developing a geographic definition of Historically Disadvantaged Communities as part of its implementation of the Justice40 Initiative. Consistent with the Interim Guidance for the Justice40 Initiative, Historically Disadvantaged Communities include (a) certain qualifying census tracts identified as disadvantaged due to categories of environmental, climate, and socioeconomic burdens, as identified by the Climate and Economic Justice Screening Tool, and (b) any Federally Recognized Tribes or Tribal entities, whether or not they have land.[2] Applicants should use Climate & Economic Justice Screening Tool (CEJST), a new tool by the White House Council on Environmental Quality (CEQ), that aims to help Federal agencies identify disadvantaged communities as part of the Justice40 initiative to accomplish the goal that 40% of overall benefits from certain federal investments reach disadvantaged communities. See *https://screeningtool.geoplatform.gov/.* Applicants should use CEJST as the primary tool to identify disadvantaged communities (Justice40 communities). Applicants are strongly encouraged to supplement their use of the CEJST by employing the USDOT Equitable Transportation Community (ETC) Explorer to understand how their community or project area is experiencing disadvantage related to lack of transportation investments or opportunities. Through understanding how a community or project area is experiencing transportation-related disadvantage, applicants are able to address how the benefits of a project will reverse or mitigate the burdens of disadvantage and demonstrate how the project will address challenges and accrued benefits. *https://www.transportation.gov/priorities/equity/justice40/etc-explorer.* Additionally, in support of the Justice40 Initiative, the applicant also should provide evidence of any strategies that the applicant has used in the planning process to seek out and consider the needs of those historically disadvantaged and underserved by existing transportation systems. For technical assistance using either mapping tool, please contact *GMO@dot.gov.* [3]

3. Integrity and Performance Review

Prior to making an award with a total amount of Federal share greater than the simplified acquisition threshold (currently $250,000), FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information Systems (FAPIIS) accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.206.

F. Federal Award Administration Information

1. Federal Award Notices

FTA will announce the final project selections on the FTA website. Selectees should contact their FTA Regional Offices for additional information regarding allocations for projects. At the time the project selections are announced, FTA expects to extend pre-award authority for the selected projects

[1] Supportive services are critical to help women and people facing systemic barriers to employment be able to participate and thrive in training and employment. Supportive services include childcare, tools, work clothing, application fees and other costs of apprenticeship or required pre-employment training, transportation and travel to training and work sites, and services aimed at helping to retain underrepresented groups such as mentoring, support groups, and peer networking.

[2] *https://www.whitehouse.gov/wp-content/uploads/2023/01/M-23-09_Signed_CEQ_CPO.pdf.*

[3] See also *https://static-data-screeningtool.geoplatform.gov/data-versions/1.0/data/score/downloadable/CEQ-CEJST-Instructions.pdf.*

(see section D.5 of this notice for more information). There is no pre-award authority for these projects before announcement.

2. Administrative and National Policy Requirements

a. Grant Requirements

If selected, awardees will apply for a grant through FTA's Transit Award Management System (TrAMS). Recipients of funding in urban areas are subject to the grant requirements of the Urbanized Area Formula Grants program (49 U.S.C. 5307), including those of FTA Circular ''Urbanized Area Formula Program: Program Guidance and Application Instructions'' (FTA.C.9030.1E). Recipients of funding in rural areas are subject to the grant requirements of the Formula Grants for Rural Areas Program (49 U.S.C. 5311), including those of FTA Circular ''Formula Grants for Rural Areas: Program Guidance and Application Instructions'' (FTA.C.9040.1G). All recipients must accept the FTA Master Agreement and follow FTA Circular ''Award Management Requirements'' (FTA.C.5010.1E) and the labor protections required by Federal public transportation law (49 U.S.C. 5333(b)). Technical assistance regarding these requirements is available from the relevant FTA regional office.

By submitting a grant application, the applicant assures that it will comply with all applicable Federal statutes, regulations, Executive Orders, directives, FTA circulars and other Federal administrative requirements in carrying out any project supported by the FTA grant, including the Davis-Bacon Act (40 U.S.C. 3141–3144, and 3146–3148) as supplemented by Department of Labor regulations (29 CFR part 5, ''Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction''). Further, the applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

As authorized by section 25019 of the BIL, applicants are encouraged to implement a local or other geographical or economic hiring preference relating to the use of labor for construction of a project funded by the grant, including pre-hire agreements, subject to any applicable State and local laws, policies, and procedures.

b. Made in America

A project funded under this NOFO must comply with FTA's Buy America (49 U.S.C. 5323(j)) and the Build America, Buy America Act's domestic preference requirements for infrastructure projects (sections70901–70927 of the Infrastructure Investment and Jobs Act, Pub. L. 117–58), which together require that all iron, steel, manufactured goods, and construction materials used in the project be produced in the United States and set minimum domestic content and final assembly requirements for rolling stock.

Any proposal that will require a waiver of any domestic preference standard must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted.

c. Civil Rights Requirements

Applications should demonstrate that the recipient has a plan for compliance with civil rights obligations and nondiscrimination laws, including title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act, and accompanying regulations. This should include a current title VI program plan and a completed Community Participation Plan (alternatively called a Public Participation Plan and often part of the overall title VI program plan), if applicable. Applicants who have not sufficiently demonstrated the conditions of compliance with civil rights requirements will be required to do so before receiving funds.

Recipients of Federal transportation funding will be required to comply fully with the DOT's regulations and guidance for the ADA and all relevant civil rights requirements. The Department's and FTA's Office of Civil Rights will work with awarded grant recipients to ensure full compliance with Federal civil rights requirements.

d. Disadvantaged Business Enterprise

Recipients of planning or capital assistance that will award prime contracts, the cumulative total of which exceeds $250,000 in FTA funds in a Federal fiscal year, must comply with the Disadvantaged Business Enterprise (DBE) program regulations (49 CFR part 26).

e. Federal Contract Compliance

As a condition of grant award all applicants must comply with E.O. 11246, Equal Employment Opportunity (30 FR 12319, and as amended). Under section 503 of the Rehabilitation Act and its implementing regulations, affirmative action obligations for certain contractors include an aspirational employment goal of 7 percent workers with disabilities.

The U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) is charged with enforcing Executive Order 11246, section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veterans' Readjustment Assistance Act of 1974. OFCCP has a Mega Construction Project Program through which it engages with project sponsors as early as the design phase to help promote compliance with non-discrimination and affirmative action obligations. OFCCP may identify construction projects that receive an award under this notice that have a project cost above $35 million to participate in OFCCP's Mega Construction Project Program. If selected and the applicant agrees to participate, OFCCP will ask selected project sponsors to make clear to prime contractors in the pre-bid phase that award terms may require their participation in the Mega Construction Project Program. Additional information on how OFCCP makes their selections for participation in the Mega Construction Project Program is outlined under ''Scheduling'' on the Department of Labor website: *https://www.dol.gov/agencies/ofccp/faqs/construction-compliance.*

As authorized by section 25019 of the BIL, applicants are encouraged to implement a local or other geographical or economic hiring preference relating to the use of labor for construction of a project funded by the grant, including pre-hire agreements, subject to any applicable State and local laws, policies, and procedures.

f. Critical Infrastructure Security and Resilience

It is the policy of the United States to strengthen the security and resilience of its critical infrastructure against both physical and cyber threats. TSA issued Security Directive 1582–21–01B, ''Enhancing Public Transportation and Passenger Railroad Cybersecurity'' on October 24, 2023. The Security Directive, which extends previous Security Directives, applies to all public

passenger rail owners and operators identified in 49 CFR 1582.101, requires four critical actions:

1. Designate a cybersecurity coordinator who is required to be available to TSA and the DHS's CISA at all times (all hours/all days) to coordinate implementation of cybersecurity practices, and manage of security incidents, and serve as a principal point of contact with TSA and CISA for cybersecurity-related matters;

2. Report cybersecurity incidents to CISA;

3. Develop a Cybersecurity Incident Response Plan to reduce the risk of operational disruption should their Information and/or operational technology systems be affected by a cybersecurity incident; and

4. Conduct a cybersecurity vulnerability assessment using the form provided by TSA and submit the form to TSA. The vulnerability assessment will include an assessment of current practices and activities to address cyber risks to information and operational technology systems, identify gaps in current cybersecurity measures, and identify remediation measures and a plan for the owner/operator to implement the remediation measures to address any vulnerabilities and gaps.

TSA issued IC–2021–01, ''Enhancing Surface Transportation Cybersecurity'', dated December 31, 2021, which applies to each passenger railroad, public transportation agency, or rail transit system owner/operator identified in 49 CFR 1582.1. This circular provides the same four recommendations for enhancing cybersecurity practices listed above. While this document is guidance and does not impose any mandatory requirements, TSA strongly recommends the adoption of the measures set forth in the circular.

On February 10, 2023, FTA published a Cybersecurity Assessment Tool for Transit (CATT). This tool was developed with the goal to onboard public transit organizations develop and strengthen their cybersecurity program to identify risks and prioritize activities to mitigate these risks.

g. Planning

FTA encourages applicants to notify the appropriate State departments of transportation and Metropolitan Planning Organizations (MPOs) in areas likely to be served by the project funds made available under this program. Selected projects must be incorporated into the long-range plans and transportation improvement programs of States and metropolitan areas before they are eligible for FTA funding.

h. Performance and Program Evaluation

As a condition of grant award, grant recipients may be required to participate in an evaluation undertaken by DOT or another agency or partner. The evaluation may take different forms such as an implementation assessment across grant recipients, an impact and/or outcomes analysis of all or selected sites within or across grant recipients, or a benefit/cost analysis or assessment of return on investment. As a part of the evaluation, as a condition of award, grant recipients must agree to: (1) make records available to the evaluation contractor or DOT staff; (2) provide access to program records, and any other relevant documents to calculate costs and benefits; (3) in the case of an impact analysis, facilitate the access to relevant information as requested; and (4) follow evaluation procedures as specified by the evaluation contractor or DOT staff.

Recipients and subrecipients are also encouraged to incorporate program evaluation including associated data collection activities from the outset of their program design and implementation to meaningfully document and measure their progress towards meeting an agency priority goal(s). title I of the Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act), Public Law 115–435 (2019) urges Federal awarding agencies and Federal assistance recipients and subrecipients to use program evaluation as a critical tool to learn, to improve equitable delivery, and to elevate program service and delivery across the program lifecycle. Evaluation means ''an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency.'' 5 U.S.C. 311. Credible program evaluation activities are implemented with relevance and utility, rigor, independence and objectivity, transparency, and ethics (OMB Circular A–11, part 6 section 290).

3. Reporting

Post-award reporting requirements include the electronic submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system. Recipients of funds made available through this NOFO are also required to regularly submit data to the National Transit Database. Recipients should include any goals, targets, and indicators referenced in their applications in the Executive Summary of the TrAMS application.

FTA is committed to making evidence-based decisions guided by the best available science and data. In accordance with the Foundations for Evidence-based Policymaking Act of 2018 (Evidence Act), FTA may use information submitted in discretionary funding applications; information in FTA's Transit Award Management System (TrAMS), including grant applications, Milestone Progress Reports (MPRs), Federal Financial Reports (FFRs); transit service, ridership and operational data submitted in FTA's National Transit Database; documentation and results of FTA oversight reviews, including triennial and state management reviews; and other publicly available sources of data to build evidence to support policy, budget, operational, regulatory, and management processes and decisions affecting FTA's grant programs.

As part of completing the annual certifications and assurances required of FTA grant recipients, a successful applicant must report on the suspension or debarment status of itself and its principals. If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of an award made pursuant to this notice, the recipient must comply with the Recipient Integrity and Performance Matters reporting requirements described in appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact Kevin Osborn, ASAP Program Manager, via email at *Kevin.Osborn@dot.gov,* or by phone at 202–366–7519. A TDD is available for individuals who are deaf or hard of hearing at 800–877–8339. In addition, FTA will post answers to questions and requests for clarifications on FTA's ASAP homepage at: *https://www.transit.dot.gov/grants/all-stations-accessibility-program.* To ensure applicants receive accurate information about eligibility or the program, applicants are encouraged to contact FTA with questions directly, rather than through intermediaries or third parties. Contact information for FTA's regional offices can be found on FTA's website at *https://www.transit.dot.gov/about/regional-offices/regional-offices.*

For technical issues with *GRANTS.GOV,* please contact *GRANTS.GOV* by phone at 1–800–518–4726 or by email at *support@grants.gov.*

H. Other Information

User-friendly information and resources regarding DOT's discretionary grant programs relevant to rural applicants can be found on the Rural Opportunities to Use Transportation for Economic Success (ROUTES) website at *https://www.transportation.gov/rural.*

This program is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.''

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If an applicant submits information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant must provide that information in a separate document, which the applicant may reference from the application narrative or other portions of the application. For the separate document containing confidential information, the applicant must do the following: (1) state on the cover of that document that it ''Contains Confidential Business Information (CBI);'' (2) mark each page that contains confidential information with ''CBI;'' (3) highlight or otherwise denote the confidential content on each page; and (4) at the end of the document, explain how disclosure of the confidential information would cause substantial competitive harm. FTA will protect confidential information complying with these requirements to the extent required under applicable law. If FTA receives a Freedom of Information Act (FOIA) request for the information that the applicant has marked in accordance with this section, FTA will follow the procedures described in DOT's FOIA regulations at 49 CFR 7.29. Only information that is in the separate document, marked in accordance with this section, and ultimately determined to be confidential will be exempt from disclosure under FOIA.

Nuria I. Fernandez,

Administrator.

[FR Doc. 2023–26346 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0210]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SPRAY (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0210 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0210 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0210, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SPRAY is:

—*Intended Commercial Use of Vessel:* ''6 Pack Charter wind sailing in San Diego Bay.''

—*Geographic Region Including Base of Operations:* ''California. (Base of Operations: Costa Mesa, CA)''

—*Vessel Length and Type:* 34′ Sail.

The complete application is available for review identified in the DOT docket as MARAD 2023–0210 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0210 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that

you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26321 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0205]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: GYPSEA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0205 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0205 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0205, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel GYPSEA is:

—*Intended Commercial Use of Vessel:* ''Recreational Charters.''

—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Fort Lauderdale, FL).''

—*Vessel Length and Type:* 68.7′ Motor Yacht.

The complete application is available for review identified in the DOT docket as MARAD 2023–0205 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0205 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26313 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0214]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: YA CHA CHA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0214 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0214 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0214, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, D.C. 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel YA CHA CHA is:Q P=≥02≥≤

—*Intended Commercial Use of Vessel:* ''Fishing charters of 4—6 passengers Salmon Fishing on Lake Michigan.''

—*Geographic Region Including Base of Operations:* ''Wisconsin, Michigan. (Base of Operations: Kenosha, WI)''

—*Vessel Length and Type:* 40′ Motor Yacht.

The complete application is available for review identified in the DOT docket as MARAD 2023–0214 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES.** Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0214 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such

confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26322 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0209]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: CARLO (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0209 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0209 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0209, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel CARLO is:

—*Intended Commercial Use of Vessel:* ''sightseeing, scuba diving, charters on Puget Sound WA.''
—*Geographic Region Including Base of Operations:* ''Washington state. (Base of Operations: Seattle, WA)''
—*Vessel Length and Type:* 42.8′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2023–0209 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0209 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be

followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26310 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0215]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: FREEDOM @60 (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0215 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0215 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0215, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel FREEDOM @60 is:

—*Intended Commercial Use of Vessel:* ''Commercial Passenger Charter.''
—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Virginia, Delaware. (Base of Operations: Fenwick Island, DE)''
—*Vessel Length and Type:* 42.3′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2023–0215 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0215 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the

individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26323 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0213]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: Serendipity (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0213 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0213 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0213, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel Serendipity is:

—*Intended Commercial Use of Vessel:* ''Hosting a private charter in which we will take our guests around the Florida Keys in January and December.''

—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Miami, FL)''

—*Vessel Length and Type:* 62′ Catamaran.

The complete application is available for review identified in the DOT docket as MARAD 2023–0213 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0213 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26319 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0207]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MISS YACHT Z (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0207 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0207 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0207, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MISS YACHT Z is:

—*Intended Commercial Use of Vessel:* ''recreational charters.''

—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Palm Beach Gardens, FL)''

—*Vessel Length and Type:* 61.4′ Motor Yacht.

The complete application is available for review identified in the DOT docket as MARAD 2023-xxxx at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0207 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26315 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0212]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: PAPARELLA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0212 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0212 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0212, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel PAPARELLA is:

—*Intended Commercial Use of Vessel:* ''Carrying passengers for pleasure cruising in the southeast area of Florida such as West Palm Beach, Jupiter, and Stuart.''

—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Palm Beach Shores, FL)''

—*Vessel Length and Type:* 56′ motor.

The complete application is available for review identified in the DOT docket as MARAD 2023–0212 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0212 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26317 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0211]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: 45 NORTH (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–02111 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–211 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0211, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel 45 NORTH is:

—*Intended Commercial Use of Vessel:* ''Experience cruising for understanding and appreciation of United States inland waterways. Guests, usually 4 or less, would experience approximately 10-day segments of ''America's Great Loop''. Additional segments would include destinations within Lakes Michigan and Huron.''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Maryland, New Jersey, New York, Alabama, Mississippi, Tennessee, Kentucky, Missouri, Illinois, Ohio, Michigan. (Base of Operations: Leland, MI)''

–*Vessel Length and Type:* 58′ Pilothouse Motor yacht

The complete application is available for review identified in the DOT docket as MARAD 2023–0211 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0211 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26309 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0216]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: PURA VIDA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0216 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0216 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0216, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel PURA VIDA is:

—*Intended Commercial Use of Vessel:* ''Crewed Passenger Charter.''
—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Boca Raton, FL)''
—*Vessel Length and Type:* 66′ Cabin Motor.

The complete application is available for review identified in the DOT docket as MARAD 2023–0216 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES.** Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0216 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26318 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0206]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: FORTRESS II (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0206 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0206 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0206, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel FORTRESS II is:

—*Intended Commercial Use of Vessel:* ''for daytime Charters on Lake Washington and San Juan Islands.''

—*Geographic Region Including Base of Operations:* ''Washington state. (Base of Operations: Bellevue, WA)''

—*Vessel Length and Type:* 65.7′ Motor Yacht.

The complete application is available for review identified in the DOT docket as MARAD 2023–0206 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0206 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26312 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0208]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: EVER SUMMER (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry

no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0208 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0208 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0208, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel EVER SUMMER is:

—*Intended Commercial Use of Vessel:* ''passenger charters.''

—*Geographic Region Including Base of Operations:* ''Florida. (Base of Operations: Key West, FL)''

—*Vessel Length And Type:* 44′ Power Catamaran.

The complete application is available for review identified in the DOT docket as MARAD 2023–0208 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0208 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26311 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0204]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ISLAND TIME (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0204 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov*. Search MARAD–2023–0204 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0204, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov*.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ISLAND TIME is:

—*Intended Commercial Use of Vessel:* ''The intended commercial use of the vessel is to rent it to private individuals, as peer-to-peer boat rental. In addition, intend to use the boat for charter up to 10 passengers. The intended commercial use of the vessel is only to carry passengers.''

—*Geographic Region Including Base of Operations:* ''California, Oregon, Washington state. (Base of Operations: Emeryville, CA)''

—*Vessel Length and Type:* 33.8′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2023–0204 at *https://www.regulations.gov*. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0204 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov*. Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy*.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26314 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0203]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: *MULAN* (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 2, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number

MARAD–2023–0203 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0203 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0203, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel *MULAN* is:

Intended Commercial Use of Vessel: ''Sailing tours with a maximum capacity of 12 guests around the Hawaiian Islands.''

Geographic Region Including Base of Operations: ''Hawaii. (Base of Operations: Honolulu, HI)''

Vessel Length and Type: 70.3′ Sailing Catamaran.

The complete application is available for review identified in the DOT docket as MARAD 2023–0203 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0203 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–26316 Filed 11–29–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Enforcement, Compliance & Analysis, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*ofac.treasury.gov*).

Notice of OFAC Action(s)

On November 17, 2023, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals

1. AL-BAHADLI, Imad Naji (Arabic: عماد ناجي البهادلي) (a.k.a. MOHAMMED, Imad Naji Mohammed), Iraq; DOB 25 May 1975; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport A10722899 (Iraq) expires 14 Dec 2023 (individual) [SDGT] (Linked To: KATA'IB HIZBALLAH).

   Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism," 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (E.O. 13224, as amended), for having acted or purported to act for or on behalf of, directly or indirectly, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. AL-HUSAYNI, Ja'far (Arabic: جعفر الحسيني) (a.k.a. AL-HUSSAINI, Jafar), Iraq; DOB 01 Jan 1968; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: KATA'IB HIZBALLAH).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. ALSKENI, Khalid Kadhim Jasim (Arabic: خالد كاظم جاسم السكيني) (a.k.a. AL-SUKAYNI, Abu-Humayyid), Iraq; DOB 01 Sep 1972; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport A17876107 (Iraq) expires 01 Feb 2029 (individual) [SDGT] (Linked To: KATA'IB HIZBALLAH).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

4. DARRAJI, Habib Hasan Mughamis (Arabic: حبيب حسن مغامس الدراجي) (a.k.a. DARRAJI, Habeeb Hasan Mghames; a.k.a. "AL-DARRAJI, Abu-Rida"), Iran; DOB 18 Sep 1976; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport A14309260 (Iraq) expires 12 Sep 2026; alt. Passport A15392136 (Iraq) expires 12 May 2027 (individual) [SDGT] (Linked To: KATA'IB HIZBALLAH).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

5. JAHANDUST, Mojtaba (a.k.a. MARGHUB, Mojtaba Jahandust (Arabic: مجتبى جهاندوست مرغوب)), Iran; DOB 15 Apr 1985; POB Tehran, Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 0072441364 (Iran) (individual) [SDGT] [IRGC] (Linked To: KATA'IB HIZBALLAH).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

6. AL-MAJIDI, Basim Mohammad Hasab (Arabic: باسم محمد حسب المجيدي) (a.k.a. AL-MAJIDI, Basim Hasan), Iraq; DOB 02 May 1969; POB Baghdad, Iraq; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport G1240293 (Iraq) (individual) [SDGT] (Linked To: KATA'IB HIZBALLAH).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KATA'IB HIZBALLAH, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: November 17, 2023.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2023–26291 Filed 11–29–23; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8941

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Credit for Small Employer Health Insurance Premiums.

DATES: Written comments should be received on or before January 29, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Number 1545–2198–Credit for Small Employer Health Insurance Premiums'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to

Martha R. Brinson, at (202)317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Credit for Small Employer Health Insurance Premiums.

OMB Number: 1545–2198.

Form Number: 8941.

Abstract: Section 1421 of the Patient Protection and Affordable Care Act, Public Law 111–148, allows qualified small employers to elect, beginning in 2010, a tax credit for 50% of their employee health care coverage expenses. Form 8941, Credit for Small Employer Health Insurance Premiums, has been developed to help employers compute the tax credit.

Current Actions: There are no changes being made to this form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Business or other for-profit groups, Not-for-profit institutions, Farms, Federal Government, State, Local, or Tribal Governments.

Estimated Number of Respondents: 181,000.

Estimated Time per Respondent: 11 hours 15 minutes.

Estimated Total Annual Burden Hours: 2,036,250.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103. Request for comments: Comments submitted in response to this notice will be summarized and/or included in the

request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 23, 2023.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2023–26371 Filed 11–29–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Social Impact Partnerships To Pay for Results Act Projects

Notice of Funding Availability (NOFA): Social Impact Partnerships to Pay for Results Act (SIPPRA) Projects.

Announcement Type: Initial announcement.

Funding Opportunity Number: UST–SIPPRA–2024–002.

Catalog of Federal Domestic Assistance (CDFA) Number: 21.017.

Application Deadline: Applications under this NOFA must be submitted no earlier than February 12, 2024 and no later than 11:59 p.m. Eastern Time April 15, 2024 electronically via *www.Grants.gov.*

Funding Ceiling: $47 million ($40.9 million for social impact projects, $6.1 million for evaluations).

Period of Performance: Expected 48–60 months but project dependent.

Anticipated Time to Awards: October 15, 2024. There will not be a rolling review.

For More Information: Potential applicants are advised to review the **Federal Register** Notices for previous awards and other materials at *https://home.treasury.gov/services/social-impact-partnerships/sippra-pay-for-results.* Questions may be directed to Matthew Cook, SIPPRA Director, at *SIPPRA@treasury.gov.*

Summary: The Department of the Treasury (Treasury) is issuing this Notice of Funding Availability (NOFA) to invite applications from State and local governments for awards under the Social Impact Partnerships to Pay for Results Act (the ''Act''). An award recipient will receive payment if a specified outcome of the social impact partnership project is achieved as determined by the project's independent evaluator. The payment to the Awardee must be less than or equal to the value of the outcome to the federal government over a period not exceeding ten years from the date implementation commences. Awards made under this NOFA will be administered by Treasury or by another federal agency with expertise in the social benefits addressed in the proposed project. Treasury expects to award up to approximately $40.9 million in such competitive project grants under this NOFA. Treasury will prioritize projects that directly benefit children in order to meet the statutory threshold that 50 percent of awarded funds be used on awards that directly benefit children. In addition, State and local governments receiving project grants will be eligible to receive a grant for up to 15 percent of the project grant amount to pay for all or a portion of the cost of a statutorily required independent evaluation, which will be paid regardless of whether outcomes have been met. Treasury expects up to approximately $6.1 million to be available to pay for the costs of independent evaluations under this NOFA.

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A. Program Description

1. Program Purpose and Authorizing Legislation

In 2018, Congress appropriated $100 million to Treasury to implement the Social Impact Partnership to Pay for Results Act (the ''Act''), which established a new grant demonstration program to encourage funding social programs that achieve results (the ''SIPPRA program'').[1] Under this NOFA, Treasury announces the availability of approximately $40.9 million for payments for successful outcomes of social impact partnership projects through grants to State and local governments, and, for required project evaluations, the availability of up to approximately $6.1 million. All awards provided through this NOFA are subject to funding availability.

As stated in the Act, the purposes of the SIPPRA program are:

(1) To improve the lives of families and individuals in need;

(2) To redirect funds away from programs that, based on objective data, are ineffective, and into programs that achieve demonstrable, measurable results;

(3) To ensure federal funds are used effectively on social services to produce positive outcomes for both service recipients and taxpayers;

(4) To establish the use of social impact partnerships to address some of the Nation's most pressing problems;

(5) To facilitate the creation of public-private partnerships that bundle philanthropic or other private resources with existing public spending to scale up effective social interventions already being implemented;

(6) To bring pay for performance to the social sector, allowing the United States to improve the impact and effectiveness of vital social services programs while redirecting inefficient or duplicative spending; and

(7) To incorporate outcomes measurement and randomized controlled trials or other rigorous methodologies for assessing program impact.[2]

2. Funding Type

The Act provides funds for two types of awards: (1) social impact partnership project grants, including grants to pay for independent evaluations for such projects, and (2) feasibility study grants. This NOFA only relates to funds for social impact partnership project grants and funds for the cost of a grantee's independent evaluation. An awardee under this NOFA will receive a disbursement only if the awardee achieves one or more outcomes specified in the award agreement and if such outcomes are validated by an independent evaluation. The federal payment to the awardee for each specified outcome must be less than or equal to the value of the outcome to the

[1] For more information, please see the program web page at *https://home.treasury.gov/services/social-impact-partnerships/sippra-pay-for-results.*

[2] *See* 42 U.S.C. 1397n.

federal government over a period not exceeding ten years from the date implementation commences. Payment for the independent evaluation will be made regardless of whether outcomes have been met.

3. Limitations

a. Treasury Discretion To Make Awards

Treasury may make awards to all, some, or none of the applicants under this NOFA and may make awards for amounts less than the amounts requested by applicants. Treasury is placing an upper limit on the amount of each project award—not including the associated independent evaluation—of $10 million.

b. Savings to the Federal, State, or Local Government

According to the Act, projects may only be awarded if they produce savings to the federal, State, or local government, as defined in Section A.5 Outcome Valuation Methodology.

c. Positive Benefit Cost Analysis (BCA)

For this NOFA, Treasury will only consider applications that have a positive Benefit-Cost Analysis (BCA), as explained in Section A.5 Outcome Valuation Methodology.

d. Directly Benefit Children

The Act requires that ''[n]ot less than 50 percent of all Federal payments made to carry out agreements under this section shall be used for initiatives that directly benefit children.'' [3] Treasury will prioritize the funds available under this NOFA for projects designed to directly benefit children in order to meet the 50 percent threshold laid out in statute. To meet this threshold, taking into account the composition of the awards issued under the previous NOFA, 65 percent of the total possible award amount under this competition will be reserved for projects that directly benefit children. Other projects will be considered as long as Treasury reaches 50 percent of the overall available funding with its awards. Treasury will consider a project to ''directly benefit children'' if (1) the target population is children (aged 0–19 at the beginning of the intervention); or (2) the target population is parents of children. If the project benefits parents, in order to be considered a project that directly benefits children, the application must present strong evidence demonstrating a close logical, causal, and consequential relationship between the project's effect on parents and the resulting positive effect on the parents' children, and being a parent must be a part of the intervention's eligibility criteria. Portions of projects can directly benefit children without having the entire project directly benefit children. Treasury welcomes questions regarding whether a specific project concept would qualify as a project that directly benefits children.

4. Pay for Results Framework

This section provides an overview of the main features of the SIPPRA program's social impact partnerships: the pay for results model, outcomes, outcome payments, partnership formation, and the independent evaluations. Social impact partnerships are part of a pay for results model where groups of stakeholders including state and local governments, service providers, philanthropy, intermediaries, or others seek to produce outcomes that result in social benefit and federal, State, or local savings. Treasury, the Commission (Section E.2.c Phase 3: Consistency Review and Commission Recommendation), and the Interagency Council (Section E.2.d Phase 4: Interagency Council Certification and Treasury Determination) expect that approaches to these partnerships will differ across applications.

Applications under this NOFA must provide all required application elements set out in the Act at 42 U.S.C. 1397n–1(c)(1)–(24).

a. The Pay for Results Model

The pay for results model mandated by the Act differs from many other federal grant programs, in which the federal government funds the cost of programs and services prior to implementation of the programs. Under the pay for results model (also referred to as the ''pay for success'' model), the federal government agrees to make payments only if specific, pre-determined, measurable outcomes are achieved. If the intervention does not achieve the pre-determined outcomes, then the federal government will not make an outcome payment. The Act provides that the federal government's payment for an outcome must be less than or equal to the value of the outcome to the federal government over a period not exceeding ten years from the date implementation commences. Value to the federal government in this NOFA is defined as the net benefits from a BCA. For additional information, see Section A.5.a Federal Value for the SIPPRA Program.

b. Outcomes

The Act requires that the social impact partnership ''produce one or more measurable, clearly defined outcomes that result in social benefit and federal, State, or local savings.'' [4] An outcome is a positive impact on a target population that an Applicant expects to achieve as a result of an intervention over the duration of a project. The partnership's ability to identify, achieve, and agree upon suitable outcomes is a key determinant of whether pay for results is the appropriate funding instrument for addressing the identified social issue. The statute identifies the following outcomes:

(1) Increasing work and earnings by individuals in the United States who are unemployed for more than 6 consecutive months.

(2) Increasing employment and earnings of individuals who have attained 16 years of age but not 25 years of age.

(3) Increasing employment among individuals receiving Federal disability benefits.

(4) Reducing the dependence of low-income families on Federal means-tested benefits.

(5) Improving rates of high school graduation.

(6) Reducing teen and unplanned pregnancies.

(7) Improving birth outcomes and early childhood health and development among low-income families and individuals.

(8) Reducing rates of asthma, diabetes, or other preventable diseases among low-income families and individuals to reduce the utilization of emergency and other high-cost care.

(9) Increasing the proportion of children living in two-parent families.

(10) Reducing incidences and adverse consequences of child abuse and neglect.

(11) Reducing the number of youth in foster care by increasing adoptions, permanent guardianship arrangements, reunifications, or placements with a fit and willing relative, or by avoiding placing children in foster care by ensuring they can be cared for safely in their own homes.

(12) Reducing the number of children and youth in foster care residing in group homes, child care institutions, agency-operated foster homes, or other non-family foster homes, unless it is determined that it is in the interest of the child's long-term health, safety, or psychological well-being to not be placed in a family foster home.

(13) Reducing the number of children returning to foster care.

(14) Reducing recidivism among juvenile offenders, individuals released

[3] *See* 42 U.S.C. 1397n–2(f).

[4] *See* 42 U.S.C. 1397n–1(b).

from prison, or other high-risk populations.

(15) Reducing the rate of homelessness among our most vulnerable populations.

(16) Improving the health and well-being of those with mental, emotional, and behavioral health needs.

(17) Improving the educational outcomes of special-needs or low-income children.

(18) Improving the employment and well-being of returning United States military members.[5]

(19) Increasing the financial stability of low-income families.

(20) Increasing the independence and employability of individuals who are physically or mentally disabled.

(21) Other measurable outcomes defined by the State or local government that result in positive social outcomes and Federal savings.[6]

An outcome is measured by one or more indicators that are specific, unambiguous, and observable. The outcomes must be measured for the duration of the intervention period.[7] These outcomes must result in social benefit and savings to the federal, State, or local government. Outcome measurements are used to calculate the value to the federal government as discussed in Section A.5 Outcome Valuation Methodology.

c. Outcome Payments

The federal government will only make a payment if the evaluation successfully shows, using the outcome valuation methodology described in Section A.5 Outcome Valuation Methodology, that an Awardee achieved the pre-determined outcome levels as a result of the intervention. To qualify for an outcome payment, an Awardee's project must meet one or more positive outcome targets.[8] An outcome payment must be less than or equal to the value of the outcome to the federal government over a period not exceeding ten years from the date implementation commences, and for projects under this NOFA, Treasury is capping outcome payments at $10 million. Under this NOFA, an applicant may propose one or multiple project outcomes and receive separate payments at separate points in time for each outcome achieved depending on how the partnership designs the intervention.

d. Partnership Formation

The State or local government as the eligible applicant may work with other entities, referred to as ''partners,'' to successfully achieve the outcomes. In addition to the Applicant, the partnership may include investors, service providers, and intermediaries. The Applicant also may fulfill one or more of these roles. Below are examples of possible partners:

- *Investor(s)* are entities that, if the Applicant is not doing so, provide the funding for the social service interventions. Investors may be not-for-profit or for-profit entities or public sector funds. They accept the risk that they will not be repaid in the event that the target outcome(s) are not achieved as a result of the intervention.
- *Intermediary(ies)* may be selected by the Applicant to coordinate the pay for results arrangement. The role of the intermediary may include (1) being responsible for achieving the negotiated outcome(s) for the target population by contracting with service providers; (2) raising funds from investors (if applicable) to cover the operating costs of implementing the services or programs; (3) changing or modifying service delivery methods and providers, with concurrence of the other partners, including the independent evaluator and, if applicable, investors; and (4) if outcome target(s) are met, receiving outcome payments from the Awardee and making payments to the investors, if applicable. The partnership is not required to include an intermediary organization, and a service provider, described below, may also serve as an intermediary.
- *Service provider(s)* deliver the intervention designed to achieve the outcomes sought in a pay for results partnership agreement. An applicant, or, where applicable, an intermediary arranges with a service provider to provide services and/or administer the interventions. Note that a service provider may be a State or local government agency.

e. Independent Evaluations

The Applicant must contract with an independent evaluator to determine if the project achieved the pre-determined outcome levels as outlined in the project agreement. To ensure the objectivity of evaluations and to preserve the independence of evaluators, the statute requires that the federal government enter an agreement separate from the project grant to recipients exclusively to fund an evaluator's work on the project. State and local governments receiving project grants will be eligible to receive up to 15 percent of the project grant to pay for all or a portion of the cost of a statutorily required independent evaluator.[9] Treasury will make the payment for the independent evaluator regardless of whether outcomes have been met. This separate grant may not be used to pay for other project expenses or for fees associated with project stakeholder participation in the project. The independent evaluator must not have a financial or other stake in the project that would undermine its objectivity, and the Applicant must avoid the selection of an independent evaluator whose objectivity might be impaired. See Section D.2.a.g.4 Independent evaluator qualifications for the independent evaluator's required qualifications.

The independent evaluator must determine whether the intervention achieved the expected outcome(s) following the evaluation design plan. If successful, the federal government will then make a payment or payments to the Awardee based on the agreed upon payment schedule. See Section A.6. Independent Evaluation for more information on the requirements for the independent evaluation.

5. Outcome Valuation Methodology

Applications for social impact partnership projects must describe one or more outcome goals for the project, and then determine the value of each outcome to the federal government using outcome valuation. Outcome valuation is the process, at the application stage, for rigorously laying out the evidence and data used to determine the value to the federal government, and thus the appropriate payment from the federal government, for the improved outcomes resulting from project interventions. For projects under this NOFA, *value to the federal government* is defined as the net benefits derived from a benefit-cost analysis (BCA) over a period not exceeding ten years from the date implementation commences.

As explained in detail below, the Applicant must first show that, as a result of the anticipated outcome of the project intervention, there will be savings to the federal, State, or local government. *Savings* is defined as reductions in governmental outlays that are directly the result of the project intervention net of the project's cost. Increased revenues as a result of the intervention are not considered savings. There must be savings for a project to

[5] This may include improving the employment and well-being of United States military members as they transition to civilian status either as non-activated members of the National Guard or Reserves or as they become Veterans of the Armed Forces.

[6] *See* 42 U.S.C. 1397n–1(b).

[7] The duration of a SIPPRA project may not exceed 10 years. 42 U.S.C. 1397n–2(c)(1)(C).

[8] *See* 42 U.S.C. 1397n–2(c).

[9] *See* 42 U.S.C. 1397n–4(a) and (f).

be funded through the SIPPRA program.[10]

Applicants must then perform a BCA that will be used to determine the value to the federal government. The Applicant may use savings to the federal, State, or local governments, calculated in the previous step, as one of the benefits used in the calculation.

Using the BCA process, the Applicant will then determine the net benefits of a project outcome, which is the monetized value of the benefits minus the costs. If this number is greater than zero (*i.e.,* benefits exceed costs), then there is a positive value to the federal government. If the net benefit is not greater than zero, there is not a positive value to the federal government, and therefore the project is not eligible for payment. The federal payment to an Awardee must be less than or equal to the value of the outcome to the federal government over a period not exceeding ten years from the date implementation commences. Treasury is placing an upper limit of $10 million on the amount of each project award (not including amounts for the associated independent evaluation).

a. Federal Value for the SIPPRA Program

Applicants must use benefit-cost analysis (BCA) to determine the value to the federal government, which is the maximum amount that the Applicant can receive as an outcome payment. BCA is a systematic process for identifying, quantifying, and comparing expected benefits and costs of a potential project, policy, or action to society. In executing the BCA, Applicants must account for both social benefits (including savings to a State or local government or to the federal government) that provide positive value to the federal government, and costs, which result in negative value, to determine the net value to the federal government.

The rest of this section provides a recommended guide for calculating benefits and costs through BCA to determine the value to the federal government for the purposes of the SIPPRA program.[11] Applicants may consult OMB Circulars A–4 and A–94 for additional guidance.

Step 1. Demonstrate Savings to the Federal, State, or Local Government

Over the course of the period of performance of a project, interventions *must* provide savings to the State or local government or to the federal government, in the form of reduced outlays as described below. This step is a threshold requirement and must be presented as a separate calculation in the application, prior to those savings being incorporated into the BCA as a social benefit of the project outcome.

The federal, State, and local savings calculation analysis requires estimating the savings—reductions in outlays [12]—that accrue to the federal, State, and local governments that are the result of the intervention, over the period of performance of the project. The savings calculation must incorporate increases in costs due to intended or unintended impacts of the intervention. In some cases (particularly where there are complex program interactions), it may be necessary to estimate baseline outlays and compare outlays under the intervention to arrive at an appropriate estimate of savings. The application must provide sufficient information (*e.g.,* all data sources, related literature, assumptions, and justifications) to show how the Applicant estimated savings that occur as a direct result of the proposed intervention. Applicants must document and submit their estimates of changes to outlays as a direct result of each proposed intervention such that these analyses can be replicated. Only Applicants with federal, State, or local savings will be considered for the SIPPRA program.[13] Savings to each level of government should be presented separately to show how outlays are changing at each level of government as a result of the intervention.

The Applicant must carefully consider how the project intervention may cause the substitution of benefits delivered through one social program for another. Specifically, the Applicant must consider how the intervention will affect eligibility for other federal programs and how this will affect the change in outlays. For example, an intervention that increases employment could decrease participation in government assistance programs while increasing eligibility for reimbursable employment-based tax credits. Both the decrease in assistance outlays and the increase in refundable tax credit expenditures are changes in government outlays resulting from the project intervention and must be taken into account in the savings calculation.

In estimating the project intervention's effect on the outlays of a government program, the Applicant must carefully consider the funding structure of the program and whether or not the program is oversubscribed, *i.e.,* the program has more eligible individuals than funding available for services, such that when one individual is removed from the program another eligible individual replaces that individual.

For applicants who plan to use savings from Medicaid or CHIP, see Section J. Appendix II: Integration of Managed Care Information/Data for the integration of managed care information/data. This information is required to certify such savings.

Step 2. Assess Costs and Benefits From the Intervention's Effect to the ''Target'' Population for Each Time Period

The next step of the outcome valuation process is to use BCA to assess the costs and benefits of the intervention on its target population. BCA is a systematic process for identifying, quantifying, and comparing expected benefits and costs to society of a potential project, policy, or action.

Estimated benefits are based on the projected social impacts of the project, valued in monetary terms. There are a wide range of benefits that can be included in a BCA, and which ones to include will be heavily dependent on the type of intervention that is designed. For example, if the program seeks to increase economic opportunity through a job training program, it might be expected to result in increased wages, increased revenues to the federal, State, and local government, and decreased outlays on programs like SNAP or Medicaid.

The savings calculated in Step 1 must be included in the BCA. Such benefits must be adjusted by the Marginal Cost of Public Funds, a cost adjustment which accounts for the distortion effect of taxes on the cost-benefit tradeoff of actions (this effect is referred to as Dead Weight Loss). Because of Dead Weight Loss, the cost of every dollar of public funds (the Marginal Cost of Public Funds) is greater than $1. For the purposes of consistency within the SIPPRA program, all benefits from government savings must be multiplied by the Marginal Cost of Public Funds of $1.25.[14] Similarly, any increases in revenues to any level of government must be adjusted by the Marginal Cost of Public Funds. See Appendix I for an

[10] *See* 42 U.S.C. 1397n–1(b); 42 U.S.C. 1397n–5(a)(8).

[11] This guide is not intended to be a general guide for BCA and is for the purposes of the SIPPRA program only.

[12] Applicants proposing to generate value to the federal government only through reductions in federal administrative expenses will not be considered eligible.

[13] *See* 42 U.S.C. 1397n–1(b); 42 U.S.C. 1397n–5(a)(8).

[14] For further explanation of these principles, see OMB Circular A–94, pg. 17.

example of how to apply the Marginal Cost of Public Funds.

Costs include the resources required to develop the project and the costs to facilitate the project over time. Costs associated with impacted federal, State, and local programs must be included in the estimated cost of the program, and these should also be multiplied by the Marginal Cost of Public Funds.

Applicants are encouraged to use existing research, incorporating analytical tools grounded in microeconomic theory, to quantify the costs and benefits of their expected outcomes. For a greater discussion of analytical tools for BCA see Section K. Appendix III: Benefit-Cost Analysis Tools. When possible, stated preference (for example, surveys of how much an individual values a particular good or service) should be avoided in arriving at any of the core assumptions of the BCA.

Step 3. Assess External Costs and Benefits

Applicants' BCA must also consider the effects of interventions that extend beyond the target population. In particular, some interventions may generate positive or negative unpriced external effects, known as externalities. For example, when a person consumes a gallon of gasoline, they pay a price, and receive a benefit. However, that gallon of gasoline also produces air pollutants, both in its production and final consumption. Therefore, when the consumer uses the gallon of gasoline, air pollution is a negative externality of that purchase. Similar externalities, whether positive or negative, must be considered in the Applicant's BCA.

Additionally, when considering external costs and benefits, applicants must guard against double-counting, since some benefits or costs are embedded in other broader measures. To balance this goal with concerns about under-counting meaningful effects by excluding potentially overlapping benefits or costs, it may be helpful to include a range—with the lower-bound estimate prioritizing the avoidance of double-counting and the upper-bound estimate prioritizing avoidance of omitted categories of impacts. See OMB Circular A–4 for additional guidance.

Step 4. Sum Costs and Benefits by Time Period

As illustrated in the example provided in Appendix I: Example of Outcome Valuation Process, for each time period in the analysis, sum the costs and benefits calculated in Steps 1–3. Calculate the net benefits for each time period by subtracting the costs from the benefits.

Step 5. Appropriately Account for Inflation and Sum Across Time Periods

In order to ensure a meaningful comparison between benefits and costs, it is important that all monetized values used in a BCA be expressed in common terms. Data obtained for use in BCAs is sometimes expressed in nominal dollars from several different years. Nominal dollars reflect the effects of inflation over time and are sometimes also called current or year of expenditure (YOE) dollars. Such values must be converted to real dollars (also referred to as constant dollars), using a common base year, to net out the effects of inflation. Applicants must use the Consumer Price Index (All Urban) from the FY 2024 President's Budget Mid-Session Review for all inflation adjustments.[15] Projects that have benefits and costs beyond 2033 should assume an inflation rate of 2.3%.

In some benefit-cost calculations, after netting out the effects of inflation, a second distinct adjustment, called discounting, is made to account for the time value of money. However, the SIPPRA program operates over a relatively short period of time, lowering the impact of discounting on value calculations. Therefore, do not discount costs and benefits.

For the BCA used in SIPPRA, a 10-year time period is allowed in which to accrue benefits.[16] Once each time period is adjusted for inflation, sum across the time periods—up to 10 years.[17] Also, calculate the benefit-cost ratio by dividing the benefits by the costs. Only projects with a benefit-cost ratio greater than one will be considered for SIPPRA.

For an example of how to apply these steps, see Section I. Appendix I: Example of Outcome Valuation Process.

b. ''Tips'' for Conducting BCA for SIPPRA Program Projects

The following recommendations may be helpful to applicants in conducting BCA for SIPPRA projects.

Tip #1. Avoid any Effects of Your Program to the General Economy

Some changes have big enough impacts to change the prices of goods or services in a market. For example, a national change to the replacement rates for unemployment insurance will have large enough effects to adjust wages for everyone, not just individuals in a program (known as general equilibrium effects). However, programs and policy changes of the size that are eligible under SIPPRA are not large enough to affect prices. For example, a small job training program for unskilled workers is unlikely to move the market price for unskilled labor. Therefore, when assessing the benefits of the program, the BCA analyst must only consider the additional wages the worker receives and not consider any benefit to employers.

Tip #2. Do Not Give Different Weights to Different Groups or Populations of People

Some BCAs use distributional weights, an approach in which different weights are applied to costs and benefits for different groups. For the purposes of SIPPRA, Treasury is not considering distributional weights.

Tip #3. Do Not Use Discounting for Time Preference

When performing forward-looking BCA, future costs and benefits are sometimes discounted. However, given that the SIPPRA program operates over a relatively short period of time, costs and benefits will not be discounted for time preference. As explained above, however, adjusting for inflation is required.

6. Independent Evaluation

This section addresses post-award independent evaluations, including evaluation design, research methodologies, and expected coordination of activities.

a. Overview

By statute, SIPPRA program projects must have evaluations conducted by independent evaluators.[18] Awardees can expect to commit significant time and resources to the formal evaluations of their project. All applicants are eligible to receive evaluation funding to support post-award evaluation costs, regardless of whether outcomes are met.

The federal government will fund up to 15 percent of the amount of the estimated project award (not including the cost of the evaluation) for an independent evaluation of the project.[19] The federal government will base its maximum award of funds for the grantee's cost of an independent

[15] *https://www.whitehouse.gov/wp-content/uploads/2023/07/msr_fy2024.pdf,* p. 6.

[16] *See* 42 U.S.C. 1397n–2(c)(1)(B).

[17] As described above, for purposes of meeting the SIPPRA statutory requirement that a project provide savings to the State or local government, or to the federal government, savings must be achieved by the time of project completion. *See* 42 U.S.C 1397n–5(a)(9). However, for purposes of counting savings as benefits towards the BCA calculation, savings may be calculated up to a 10-year time period like other benefits.

[18] *See* 42 U.S.C. 1397n–1(c)(22); 42 U.S.C. 1397n–4(b).

[19] *See* 42 U.S.C. 1397n–4(a) and (f).

evaluator on the amount of the top tier outcome payment. The federal government will fund only completed post-award evaluation work. The federal government will not pay for pre-award costs or the portion of an evaluator's contract contemplating evaluation work that is not completed in the event a project terminates earlier than expected.

b. Evaluation Requirements

The Act requires projects to establish that the outcomes ''have been achieved as a result of the intervention.'' [20] The evaluation used to determine whether a State or local government will receive outcome payments under SIPPRA shall use experimental designs with random assignment or other reliable evidence-based research methodologies that, as certified by the Interagency Council, allow for the strongest possible causal inferences when random assignment is not feasible.[21] The project's independent evaluation must be designed to assess the strength of the causal evidence, *i.e.,* the degree to which the evaluation establishes the causal impact of the intervention on the outcomes of interest not due to other factors.[22]

Randomized controlled trials (RCTs) are generally considered to be the most rigorous type of experimental design. In RCTs, a sample is randomly split into two groups—treatment and control. One will receive the intervention and the other will continue as normal. These studies are designed to minimize the chance that the observed difference in outcomes is due to an alternative explanation.

Treasury will also accept other reliable, evidence-based research methodologies commonly known as quasi-experimental design studies. These are studies with an evaluation design in which outcomes for the treatment group, or a broader target population that includes both the treatment group and those outside the treatment group, are measured relative to a comparison group. Such a design attempts to approximate an experimental design and can support causal conclusions, without random assignment. Sophisticated analytic techniques are used to control for factors that might be associated with the outcome being analyzed. Applicants that cannot implement an RCT study will not be deemed less competitive or penalized for implementing a quasi-experimental design. Applicants using a quasi-experimental design must address other possible causes of the outcomes, such as selection, other policies, economic conditions, and other confounding factors. This should include a description of the contrast in services that the comparison and treatment group will receive during the project period.

A part of this evaluation will be a statistical significance requirement where the coefficient on the treatment variable is statistically significant (supporting rejection of the null hypothesis of no impact). For purposes of the SIPPRA program, the coefficient will be considered statistically significant if the null hypothesis falls outside of the 80 percent confidence interval. The choice of how to best calculate standard errors and confidence intervals is left to the independent evaluator, who must follow best practices based on the identification strategy. The power calculation (see guideline #12 on pg. 20) required in the evaluation design plan will be a critical input for Treasury to consider when evaluating the application.

Applicants may use classical statistical analysis or Bayesian statistical analysis. For applicants using Bayesian statistical analysis, the appropriate Bayesian tests must be used to show the equivalent of classical statistical significance at the 80 percent level. Additionally, applicants using Bayesian statistical analysis must conduct prior sensitivity analysis to ensure any causal result is not due only to a dominant prior. Applicants using this approach must use high-quality experimental or quasi-experimental evidence to justify the prior distribution.

c. Evaluation Design Plan

The Applicant must provide an evaluation design plan that includes a range of information related to design, implementation, statistics, and data. The full list of requirements is available in Section D.2.a.(g)5 Evaluation design plan.

The design plan may evolve during a project's early implementation period (approximately the first 6–12 months) to ensure proper measurement of project outcomes. However, outcome goals may not change without prior approval from Treasury or the administering federal agency. Grantees must submit the design plan to Treasury or the administering federal agency once it is finalized. Elements of the evaluation design plan may be posted on the Federal Interagency Council on Social Impact Partnerships (Interagency Council) website.[23]

d. Evidence Standard

The Act requires Treasury to take into consideration the likelihood, based on evidence provided in the application and other evidence, that the State or local government in collaboration with the intermediary and the service providers will achieve the specified outcomes.[24] The evidence base should consist of well-designed and well-implemented experimental studies or quasi-experimental studies that support the effectiveness of the practice, strategy, or program; and/or large, well-designed, and well-implemented randomized controlled, multi-site trials that support the effectiveness of the practice, strategy, or program. The magnitude of the impact assumed for the SIPPRA project must be derived from this evidence base.

For each project application, the Subject Matter Expert Panel (see Section E.2.b) will determine the strength of the evidence provided, as described further below. Projects with strong or moderate evidence are most likely the best candidates for the SIPPRA program, but all projects will be considered.

- *Strong evidence* means that the evidence base can support causal conclusions for the specific program proposed by the applicant with the highest level of confidence. The evidence must support causal conclusions (*i.e.,* studies with high internal validity) and include enough of the range of participants and settings to support scaling up to the state, regional, or national level (*i.e.,* studies with high external validity). The following are examples of strong evidence: (1) More than one well-designed and well-implemented experimental study or well-designed and well-implemented quasi-experimental study that supports the effectiveness of the practice, strategy, or program; or (2) one large, well-designed and well-implemented randomized controlled, multi-site trial that supports the effectiveness of the practice, strategy, or program.
- *Moderate evidence* means that there is a reasonably developed evidence base that can support causal conclusions. Evidence from previous studies on the program, the designs of which can support causal conclusions (*i.e.,* studies with high internal validity) but have limited generalizability (*i.e.,* moderate external validity). This also can include studies for which the reverse is true—studies that only support moderate

[20] *See* 42 U.S.C. 1397n–1(c)(7).

[21] *See* 42 U.S.C. 1397n–4(c).

[22] More information on evidence standards in the context of Federal program evaluations can be found at *https://home.treasury.gov/system/files/136/SLFRF-Compliance-and-Reporting-Guidance.pdf.*

[23] *See* 42 U.S.C. 1397n–10(3)(J).

[24] *See* 42 U.S.C. 1397n–2(b)(3).

causal conclusions but have broad general applicability. The following would constitute moderate evidence: (1) At least one well-designed and well-implemented experimental or quasi-experimental study supporting the effectiveness of the practice strategy, or program, with small sample sizes or other conditions of implementation or analysis that limit generalizability; (2) at least one well-designed and well-implemented experimental or quasi-experimental study that does not demonstrate equivalence between the intervention and comparison groups at program entry but that has no other major flaws related to internal validity; or (3) correlational research with strong statistical controls for selection bias and for discerning the influence of internal factors.

• *Preliminary evidence* means that the evidence base can support conclusions about the program's contribution to observed outcomes. The evidence base consists of at least one non-experimental study. A study that demonstrates improvement in program beneficiaries over time on one or more intended outcomes OR an implementation (process evaluation) study used to learn about and improve program operations would constitute preliminary evidence. Examples of research that meet the standards include: (1) outcome studies that track program beneficiaries through a service pipeline and measure beneficiaries' responses at the end of the program; and (2) pre- and post-test research that determines whether beneficiaries have improved on an intended outcome.

The project narrative must include a theory of change and a logic model that builds from this evidence base. A theory of change must inform the intervention design by reflecting the logical (and evidence-informed) reasoning that supports the expectation the actions taken will lead to the intended outcomes. The logic model builds off this theory of change. A logic model provides a bridge between project design and the evaluation by clarifying the inputs, activities, outputs, outcomes, and impacts that can help to crystalize how each of those things can be measured and tracked.

e. Evaluation Facilitation

The Applicant is expected to participate in and manage several activities to ensure the successful independent evaluation of demonstration projects. These activities include:

• Working with the independent evaluator to facilitate the execution of the overall evaluation strategy and to ensure the intervention is performed according to the evaluation design plan described above;

• Reporting progress and final evaluation results to Treasury and/or the relevant federal agency on schedule;

• Over the course of the performance period, working with the independent evaluator to ensure that project randomization procedures and other evaluation processes are adhered to;

• Working with the independent evaluator to modify evaluation plans, as appropriate.

• Ensuring that the independent evaluator can collect all relevant data and has access to needed datasets.

f. Agreement With Independent Evaluator

Because the evaluation findings provide the basis for pay for results payments to the grantee, the agreement each applicant enters into with an independent evaluator must require an agreed-upon evaluation design and methodology, observed outcome measure(s), and findings regarding outcome targets. The agreement must address the following:

• Plan to obtain relevant datasets from various sources, for example, local agencies, state agencies, or other federal agencies, including the responsibilities of the grantee and evaluator in accomplishing this task;

• Design and coding of a management information system, as needed, that is tailored for research or evaluation, to track participants and obtain individual level data;

• Collection or assessment of individual-level data. The independent evaluator must work directly with the Applicant and other organizations to enter into one or more agreements for the access and use of the data. These agreements must include assuring data quality and adherence to all federal and state data privacy statutes and policies and data security standards;

• Institutional Review Board (IRB) approval or a plan to get IRB approval to ensure the protection of human subjects, to the extent applicable; and

• Submission of progress reports to Treasury, the Interagency Council, and the head of the relevant agency in accordance with the reporting requirements described in Section F.3.b Evaluation Progress Reports and Section F.3.c Evaluation Final Reports.

If the Applicant is unable to execute an agreement prior to the application deadline, Treasury will accept a draft agreement containing these elements.

B. Federal Award Information

1. Type of Federal Award

Treasury expects to award up to $40.9 million to fund projects under this NOFA, with an additional amount up to $6.1 million available to fund the independent evaluations. The total amount awarded under this NOFA will be determined based on the number and strength of applications for projects received and other programmatic considerations. Treasury reserves the right to make no awards or to make awards for amounts less than the amounts requested by applicants. As stated above, Treasury is placing an upper limit on the amount of each project award—not including the associated independent evaluation—of $10 million.

As noted above, for projects funded under this NOFA, the federal government, under separate agreements with grantees, will also make available up to 15 percent of the project award amount (not including the cost of the evaluation) for the cost of an independent evaluation. These agreements to pay for evaluations will provide for payment regardless of outcomes, but the agreements will limit payments to evaluation work performed.

2. Project Period

SIPPRA funds must be liquidated by September 2033. Therefore, the period of performance for SIPPRA project awards must end by September 2032, to allow for up to six months for final measurement, analysis, evaluation, submission of the independent evaluator's final report, and submission of payment requests to the federal government.[25] Applicants should carefully construct their project timeline to allow sufficient time for all required activities. Treasury expects the period of performance to generally be about 48–60 months, but this will be heavily dependent on the nature of the project interventions. Applicants must specify the intervention period and explain the basis for specifying such period. Requests to extend the period of

[25] The Act provides that the period of performance under the award agreements may not exceed 10 years. *See* 42 U.S.C. 1397n–2(c)(1)(C). Treasury will strive to maximize use of the amounts Congress appropriated to make awards and outcome payments. The Act appropriates funds that are available for ten years to make awards. *See* 42 U.S.C. 1397n–9 and 1397n–13. Federal law generally provides that disbursements of funds awarded within the SIPPRA program 10-year window (*e.g.,* outcome payments) must occur within five years after that 10-year window closes. *See* 31 U.S.C. 1552(a).

performance after an agreement is awarded will not be considered.

C. Eligibility Information

1. Eligible Applicants

Only States or local governments are eligible applicants; applications from any other entities will not be reviewed. The Act defines the term ''State'' to mean each State of the United States, the District of Columbia, each commonwealth, territory, or possession of the United States, and each federally recognized Indian tribe. For purposes of this NOFA, the term ''State'' shall, consistent with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance) at 2 CFR part 200, include any of a State's agencies or instrumentalities, and the terms ''local government'' and ''federally recognized Indian tribe'' shall have the meanings given in the Uniform Guidance. Multiple agencies within a state or local government are eligible to apply, or interjurisdictional groups of state or local governments may apply together. In both cases, a lead applicant must be identified. Local governments for SIPPRA purposes may include, but are not limited to, cities, counties, school districts, or other special districts.

Eligibility determinations in prior funding rounds have no bearing on and do not guarantee eligibility in this round of SIPPRA funding. Applicants are also not able to request changes or amendments to agreements based on this NOFA's criteria if made under the previous NOFA.

2. Cost Sharing or Matching

Cost sharing or matching funds, as defined in the Uniform Guidance,[26] are not required, and the financial contributions from any investors for project implementation are not characterized as cost sharing or matching funds.

3. Other

The identified social problem(s) or other social benefits to be addressed by the intervention must relate to one of the outcomes identified in SIPPRA and listed in Section A.4.b. Outcomes.

D. Application and Submission Information

1. How To Obtain an Application Package

This NOFA, found at *www.Grants.gov* and *www.Treasury.gov/SIPPRA,* contains all of the information and links to forms needed to apply for grant funding. An application package may be obtained from *Grants.gov* by using this NOFA's CFDA number: 21.017 or by emailing the SIPPRA Director Matthew Cook at *SIPPRA@treasury.gov.* Information on how to apply for grants can be found at *https://www.Grants.gov/web/grants/applicants/apply-for-grants.html.*

2. Content and Form of Application Submission

a. Application for Project Award

Applications submitted in response to this NOFA must include the following:

(a) SF–424, Application for Federal Assistance;

(b) SF–424A, Budget Information for Non-Construction Programs (if applicable);

(c) SF–424C, Budget Information for Construction Programs (if applicable);

(d) SF–LLL, Disclosure of Lobbying Activities;

(e) *Grants.gov* Lobbying Form;

(f) Project Narrative

The project narrative (page limit is 20 pages) must include the following:

(1) A not more than two-page project overview that will state the name of the project, amount of funding requested, project intervention period, total project timeline, name of service provider, name of intermediary (if any), name of investor(s), name of independent evaluator, if the project directly benefits children, a brief summary of the project, and brief summary of the expected outcomes to be achieved as a result of the intervention.

(2) The outcome goals of the project, formulated as discussed in Section A.4.b Outcomes, and describing the existing base of evidence and citing available research literature. This section must include a theory of change and logic model for how the intervention will lead to these outcome goals building from the available research. See Section A.6.d Evidence Standard for a discussion of the theory of change and the logic model;

(3) The project timeline, including the project intervention period;

(4) A description of each intervention in the project and anticipated outcomes of the intervention including a summary of the value of the anticipated outcomes that is laid out in detail in section #7 of the project narrative attachments;

(5) A service delivery plan for delivering the intervention through a social impact partnership model, including the proposed payment terms (*e.g.,* the terms of any tiered payment scheme proposed by the applicant) and performance thresholds (*i.e.,* the outcome goal or, in the case of a tiered payment scheme, a range of outcomes);

(6) The target population that will be served by the project and the criteria used to determine the eligibility of an individual for the project, including how the target population will be identified, how individuals will be referred to the project, how they will be enrolled in it, and the extent to which affected stakeholders will be engaged in the development and implementation of the project and evaluation;

(7) A succinct summary of the unmet need in the area where the intervention will be delivered or among the target population who will receive the intervention and the expected social benefits to participants who receive the intervention and others who may be impacted;

(8) A description of whether and how the applicant and service providers plan to sustain the intervention, if it is timely and appropriate to do so, to ensure that successful interventions continue to operate after the period of the social impact partnership;

(9) Whether (and if so, how and what percentage of) the project will directly benefit children; and

(10) The Applicant may also consider including information on how the intervention would foster innovation in social policy, yield a diversity of target populations and grantees, advance racial equity and support for underserved communities as described in Executive Order 13985, or include any other non-monetary benefits that could not be included in the BCA. Depending on the number of applications, Treasury may take these into consideration when choosing awardees.

(g) Project Narrative Attachments;

The following items are required to be submitted as attachments to the project narrative:

1. *Project budget:* Provide a narrative for the budget, including amounts expected to be expended by partners. Please limit this to 5 pages or fewer.

2. *Partnership agreements:* Provide a partnership agreement between the Applicant and all project partners. The partnership agreement must either be signed or, if submitted in draft form, must be accompanied by signed letters of intent to enter into such an agreement should the application be successful. The partnership agreement between the applicant and the partners, which must be attached to the grant application, must address each of the following.

(1) Clearly defined roles and responsibilities of each partner;

(2) A plan for sharing data among the partners, including but not limited to a

[26] *See* 2 CFR 200.29.

Memorandum of Understanding or Memorandum of Agreement, which may be conditioned on the award of a grant, that appropriately safeguards the privacy of individuals in the targeted population in accordance with applicable laws;

(3) A representation that all project partners have reviewed an independent evaluation plan for the project and an agreement by all the partners to cooperate in the implementation of the evaluation plan as necessary; and

(4) A payment arrangement between the applicant and project partners (including the intermediary and/or investors, as applicable), demonstrating that all partners understand that payment by the federal government is conditioned upon the independent evaluator's verification that the project's pre-determined outcome(s) and value generated have been met. This payment arrangement must include a plan and timeline describing each payment point that the project partners have agreed on, and the corresponding outcome targets that will be evaluated in the impact evaluation. Although the federal government generally will make payments to the grantee if the independent evaluator determines that the project achieved the specified outcome as a result of the intervention and the payment is less than or equal to the value of the outcome to the federal government,[27] the federal government is not responsible for making payments to the Awardee's partners.

3. *Partner qualifications:* Please limit this to 3 pages or fewer.

(1) Service provider. Describe the expertise of each service provider that will administer the intervention, including a summary of the experience of the service provider in delivering the proposed intervention or a similar intervention, or demonstrating that the service provider has the expertise necessary to deliver the proposed intervention. This description must include a discussion of the capacity of the service provider to deliver the intervention to the number of participants the State or local government proposes to serve in the project.

(2) Intermediary. With respect to any intermediary specifically, the application must discuss the intermediary's mission and goals; its experience and capacity for providing or facilitating the provision of the type of intervention proposed; information on whether the intermediary is already working with service providers that provide this intervention or an explanation of the capacity of the intermediary to begin working with service providers to provide the intervention; its experience working in a collaborative environment across government and non-governmental entities to implement evidence-based programs; its previous experience collaborating with public or private entities to implement evidence-based programs; its ability to raise or provide funding to cover operating costs, as applicable; its capacity and infrastructure to track outcomes and measure results, including its capacity to track and analyze program performance and assess program impact; its experience with performance-based awards or performance-based contracting and achieving milestones and targets; and an explanation of how the intermediary would monitor program success, including a description of the interim benchmarks and outcome measures.

(3) Investor. In addition, to the extent the Applicant intends to use investors and has not already identified and received commitments from them, the application must discuss the experience of the State or local government, intermediary, if any, or service provider in raising private and philanthropic capital to fund social service investments.

4. *Independent evaluator qualifications:* Provide a summary explaining the independence of the evaluator from the other entities involved in the project and the evaluator's experience in conducting rigorous evaluations of program effectiveness including, where available, well-implemented RCTs and quasi-experimental analyses on the intervention or similar interventions. When discussing experience, please note both personnel and organization experience. Applicants must address the following qualifications of the evaluator. Please limit this to 3 pages or fewer.

(1) Experience working with the datasets the project expects to use;

(2) Prior work in conducting implementation and causal impact evaluation and how their past methodologies and evaluation design experience will be used in the proposed project. Please provide examples of evaluations that they have completed of similar scope and complexity;

(3) Qualifications of the key personnel designing and overseeing the evaluation and ensuring its quality, including their education or training and type and years of experience;

(4) Experience in managing similar evaluation protocols (*e.g.,* this type of sampling, data collection, analysis); and

(5) Experience dealing with unforeseen data or implementation issues in other program evaluations. Provide specific examples and experiences dealing with unforeseen data or implementation issues.

5. *Evaluation design plan:* Provide an evaluation design plan by following the following guidelines. Please limit this to 10 pages or fewer.

Demonstrate a high-quality design by:

(1) Explaining how the proposed evaluation is best suited for the project;

(2) Documenting the project evaluation's research question(s), the data to be collected and analyzed, how data quality and integrity will be maintained, *e.g.,* how attrition will be minimized, and specify overall and subgroup samples;

(3) Describing how the project will be implemented with fidelity, *e.g.,* how random assignment to treatment and control groups will be ensured;

(4) Providing and justifying the selected evaluation strategy, *i.e.,* RCT or quasi-experimental design;

(5) Explaining how the methodology will measure relevant unintended outcomes and/or negative impacts;

(6) Stating whether the design is likely to generate evidence that can support causal conclusions, as described in Section A.6.d Evidence Standard;

(7) Describing anticipated challenges, such as attrition, failed randomization, and oversubscription and plans to mitigate them; and

(8) Showing how the evaluation will be independent of the intervention and financing structure.

Incorporate appropriate evaluation design by

(9) Describing the metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of the intervention including key outcomes and outcome targets; an explanation of how the metrics will be measured; and an explanation of how the metrics are independent, objective indicators of impact that are not subject to manipulation by the service provider, the intermediary, or investors, if any;

(10) Describing the statistical assumptions required to infer causal effects in the research design (*e.g.,* absence of spillovers, identifying conditions for non-RCTs, etc.). Provide examples of how these assumptions could be violated;

(11) Proposing all important covariates that will be used in evaluation analysis, including how these measures will be operationalized, and the data used for them;

[27] *See* 42 U.S.C. 1397n–2(c)(1)(B) and (2).

(12) Describing anticipated statistical and analytical methods (such as regression equations to be used), power calculations, and minimal detectable impacts for each proposed outcome. Please include the actual power and minimal detectable impact estimates for each proposed outcome;

(13) Describing what hypothesis testing procedure will be used (*e.g.,* p-values), what hypotheses will be tested, and how the tests will be conducted (*e.g.,* robust standard error estimators, etc.)

(14) Including the anticipated customized randomization plan if applicable;

(15) Describing an approach for coordinating all partners and required evaluation activities, including assisting the independent evaluator in collecting and accessing the necessary data, and include a timeline;

(16) Describing an approach for conducting an evaluation of program implementation, potentially using an implementation framework (*e.g.,* the Consolidated Framework for Implementation Research)

6. *Independent evaluator contract or agreement:* Provide a copy of the contract or agreement to be entered into between the State or local government and the independent evaluator. The contract or agreement must address the following information.

(1) Plan to obtain relevant datasets from various sources, for example, local agencies, state agencies, or other federal agencies, including the responsibilities of the grantee and evaluator in accomplishing this task;

(2) Design and coding of a management information system, as needed, that is tailored for research or evaluation, to track participants and obtain individual level data;

(3) Collection or assessment of individual-level data. The independent evaluator must work directly with the applicant and other organizations to enter into one or more agreements for the access and use of the data. These agreements must include assuring data quality and adherence to all federal and state data privacy statutes and policies and to all applicable data security standards;

(4) Institutional Review Board (IRB) approval or a plan to get IRB approval to ensure the protection of human subjects, to the extent applicable; and

(5) Submission of progress reports to Treasury, the Interagency Council, and the head of the relevant agency in accordance with the reporting requirements described in Section F.3.b Evaluation Progress Reports and Section F.3.c Evaluation Final Report.

7. *Outcome valuation:* Provide an attachment detailing the outcome valuation of the anticipated outcomes, as described in Section A.5 Outcome Valuation Methodology. Start by detailing the projected savings to the federal, state, or local government and make clear which level of government anticipates receiving savings. Then, provide a completed BCA that details the monetized benefits and costs including incorporating the federal, State, or local savings as a benefit. Applicants must provide the estimated total value and savings, estimated value and savings per project participant, estimated value and savings per dollar spent on the intervention, as well as the methodology used by the Applicant in arriving at such estimates. Also, provide the estimated savings over the course of the period of performance. Applicants should cite evidence that the reviewers can assess when deriving the estimated benefits and costs. Treasury strongly recommends that the Applicant provide an unprotected Excel spreadsheet that allows a reviewer to view and manipulate all underlying data. Please limit this to 10 pages or fewer.

8. *Legal compliance:* If the Applicant proposes a project including a construction component, the Applicant must identify the State and federal environmental laws, regulations, and policies that will apply to the project, and the environmental documents required under State and federal laws. If an applicant proposes a project including a transportation component, the applicant must identify applicable federal, State, and local laws relating to that component, and any transportation-related permitting and licensing documents required under federal, State and local laws. The applicant must identify laws applying to the population being served and demonstrate that the project will be in compliance with those laws. The applicant must also comply with applicable federal, State, and local privacy laws. The applicant must also identify any approved waivers of any existing laws or regulations, including but not limited to environmental or transportation laws or regulations, required by the intervention design; if waivers are pending, the applicant must include documentation that it has sought the waiver, that it is under consideration, and when approval is expected to be received. Failure to obtain a necessary waiver may be grounds for termination of a grant.

9. An application may contain additional supporting documentation as attachments, such as an existing feasibility study.

b. Form for Project Award

The project application must be prepared using the following formatting and organizational guidelines:

1. Number all pages.

2. The Project Narrative must:

i. include a table of contents;

ii. be double-spaced, with text in a single column;

iii. be a standard 12-point font, such as Times New Roman;

iv. use 1-inch margins;

v. not exceed 20 pages in length, excluding the table of contents and appendices. The only substantive portions that may exceed the 20-page limit are documents supporting assertions or conclusions made in the Project Narrative. See each individual attachment for page limits.

vi. As appropriate, include graphics, charts, or lists to make the information easier to review.

vii. If possible, provide website links to supporting documentation rather than copies of these supporting materials. It is important to ensure that the website links are currently active, accessible, and working.

viii. If supporting documents are submitted, applicants must clearly identify within the Project Narrative the relevant portion of the Project Narrative that each supporting document supports.

ix. Use appropriately descriptive file names (*e.g.,* ''Project Narrative,'' ''Chart,'' ''Evaluation Design Plan'') for all attachments.

x. All file names must be prefaced with the applicant's name or initials, *e.g.,* ''Land of Ozzie Oz'' or ''LOO.''

3. Unique Entity Identifier and System for Award Management (SAM)

Registration for *Grants.gov* is a critical prerequisite to applying for a grant. It is a multi-step process that may take several weeks to complete before an application may be submitted. *Grants.gov* scheduled maintenance and outage times are announced on the *Grants.gov* website, *http://www.Grants.gov.* The deadline will not be extended due to scheduled maintenance or outages. Applicants may incur significant risk by waiting to the last day to submit by *Grants.gov.* General information for registering and submitting applications through *Grants.gov* can be found at *https://www.Grants.gov/web/grants/applicants.html* along with specific instructions for the forms and attachments required for submission. Applicants encountering a problem with *Grants.gov* may call the *Grants.gov* Contact Center at 1–800–518–4726 or 606–545–5035 to speak to a Customer Support Representative, or email *support@Grants.gov.* The Contact

Center is open 24 hours a day, seven days a week, other than on federal holidays, when it is closed. All required documents comprising the application must be included at the time the application is submitted as set forth in Section D.2 Content and Form of Application Submission.

Applications may be withdrawn by providing written notice to *SIPPRA@Treasury.gov* at any time before an award is made.

Applicants must register with SAM, a federal government-wide portal used for acquisition and federal assistance processes and maintain an active SAM registration until the application process is complete and, if a grant is awarded, throughout the life of the award. SAM registration must be renewed annually.

Treasury suggests finalizing a new registration or renewing an existing one at least one month before the NOFA application deadline to allow time to resolve any issues that may arise. Applicants must use their SAM-registered legal name and address on all grant applications to Treasury. Treasury will not make an award to an applicant if the applicant has not complied with all applicable SAM requirements.[28]

On April 4, 2022, the federal government stopped using the DUNS Number to uniquely identify entities. Now, entities doing business with the federal government use a Unique Entity ID (UEID) created in *SAM.gov.* The UEID is a unique, multiple-digit sequence recognized as the universal standard for identifying and keeping track of over 70 million entities worldwide. Applicants for federal assistance are no longer required to go to a third-party website to obtain their identifier. This transition allows the government to streamline the entity identification and validation process, making it easier and less burdensome for entities to do business with the federal government.

Applicants must obtain this UEID number immediately to ensure all registration steps are complete prior to submitting an application. Applications will be identified by the UEID of the State or local government lead applicant. Information on how to obtain a UEID may be found at *SAM.gov,* or by calling 866–705–5711.

If your entity is registered in *SAM.gov* today, your UEID has already been assigned and is viewable in *SAM.gov.* This includes inactive registrations. The UEID is located on your entity registration record. You must be signed into your *SAM.gov* account to view the entity record. The UEID must be entered in the block with the applicant's name and address on the cover page of the application, block 8c on the Form SF 424, Application for Federal Assistance. The name and address in the application must be exactly as given for the UEID number.

4. Submission Date, Time, and Address

Applications must be submitted between 9:00 a.m. Eastern Time on February 12, 2024 and 11:59 p.m. Eastern Time on April 15, 2024. Applications must be submitted electronically through *Grants.gov.* Mail, email, telegram, or facsimile (FAX) submissions will not be accepted.

5. Intergovernmental Review

This funding opportunity is subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as amended by Executive Order 12416. Some States require that applicants contact their State's Single Point of Contact (SPOC) to comply with the State's SPOC process established pursuant to Executive Order 12372. Names and addresses of the SPOCs are listed on the Office of Management and Budget's homepage at *https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf.* Applications from federally-recognized Indian tribes are not subject to intergovernmental review.

6. Funding Restrictions

Grants will only be awarded to those entities and for those projects that are eligible as described in Section C. Eligibility Information. As discussed above in Section A.3.d Directly Benefit Children, the Act provides that not less than 50 percent of all federal payments made to carry out social impact partnership project agreements shall be used for initiatives that directly benefit children. According to the Act, projects may only be awarded if they produce savings to the federal, State, or local government, as defined in Section A.5 Outcome Valuation Methodology. For this NOFA, Treasury will only consider applications that have a positive Benefit-Cost Analysis (BCA), as explained in Section A.5 Outcome Valuation Methodology. Treasury is placing an upper limit on the amount of each project award—not including the associated independent evaluation—of $10 million. The federal government will fund up to 15 percent of the amount of the estimated project award for an independent evaluation of the project.[29] Federal awards will not allow reimbursement of pre-Federal award costs.

7. Ethical Conduct of Funded Projects

Federal award recipients bear primary responsibility for prevention and detection of research misconduct. They must foster an atmosphere conducive to research integrity and maintain and effectively communicate and train their staff regarding policies and procedures. In the event an application to Treasury results in a SIPPRA program award, the State or local government must designate an Authorized Representative (AR) who is a paid employee of the State or local government. The AR assures, through acceptance of the award, that the recipient will comply with these requirements. An award recipient must, upon request, make available to Treasury the policies, procedures, and documentation that support the training provided to its staff and providers.

Treasury recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local Institutional Review Board (IRB) rules, and local, State, and federal laws, and regulations. The rights and privacy of individuals and beneficiaries who participate in the implementation of this intervention project must be protected at all times. This includes human subjects assurance statements that the project has been reviewed and approved by an IRB or determined exempt from review. Data intended for broader use must be free of identifiers that would permit linkages to other data on project research participants and variables that could lead to deductive disclosure of the identity of individual participants and beneficiaries.

8. Privacy and Confidentiality

The Act establishes the Commission on Social Impact Partnerships (Commission) whose principal obligation is to make recommendations to Treasury regarding the funding of SIPPRA demonstration project and feasibility studies.[30] The Commission is subject to the provisions of the Federal Advisory Committee Act (FACA), which generally requires that documents made available to the Commission be made available for public inspection and copying.[31] Treasury may provide to the Commission all complete applications received under this NOFA from eligible applicants and expects to make these applications available for public

[28] For more information about SAM, see the information provided by the General Services Administration at *https://sam.gov/content/about/this-site.*

[29] *See* 42 U.S.C. 1397n–4(f).

[30] *See* 42 U.S.C. 1397n–6.

[31] *See* 5 U.S.C. App. 2 10(b).

inspection and copying. However, FACA also provides that trade secrets and commercial or financial information that is privileged or confidential under the Freedom of Information Act (confidential business information) need not be made publicly available.[32] In order to comply with FACA's public disclosure requirements while protecting confidential business information in accordance with FACA, each applicant may submit a package of proposed redactions of confidential business information. The Applicant may omit pages for which it does not propose any redactions in this package. Proposed redactions must be highlighted in a way that leaves the material proposed to be redacted visible to Treasury staff. Treasury will review the redactions proposed by each applicant. The Applicant should notify Treasury staff at *SIPPRA@treasury.gov* if they intend to submit any redactions.

E. Application Review Information

1. Criteria

The panel assigned to an application will score that application in accordance with the criteria set forth in the scoring rubric below, which reflects the application content requirements under the Act,[33] and the considerations that Treasury, in consultation with the Interagency Council and the head of the relevant federal agency, is required by the Act to consider when granting awards.[34] The scores will serve as a reference in subsequent phases of review, discussed below. Treasury is not required to make awards in rank order. The panel scores will not be binding with respect to subsequent phases of review. Furthermore, Treasury may reject applications that show significant deficiencies with respect to any one component that is critical to the success of the project under the pay for results model, *e.g.,* an application that does not identify an evaluator that is independent from the other project participants, regardless of the applicant's total score.

SUBJECT MATTER REVIEW SCORING RUBRIC

i. Value and Savings		30 points.
I. Savings to federal, state, and local government	10 points.	
II. Value to the federal government	20 points.	
ii. Likelihood of Achieving Outcomes		40 points.
I. Evidence demonstrating intervention can be expected to achieve desired outcome	15 points.	
II. Project budget and service delivery plan	15 points.	
III. Project partners	10 points.	
iii. Quality of Evaluation		25 points.
I. Evaluation design and metrics	15 points.	
II. Evaluator independence and experience	10 points.	
iv. Capacity and Commitment to Sustain the Intervention		5 points.
Total		100 points.

i. Value and Savings

This section has two components: savings to the federal, State, and local governments and value to the federal government. The magnitude of the estimated savings or value will not be a factor in the overall score of the application.

I. Savings to Federal, State, and Local Governments

The Act requires Treasury to take into consideration the savings to the federal, State and local governments.[35] The term ''savings'' refers to reduced outlays, whether by the federal or State or local government, as applicable, as a result of the project.[36] There must be savings to the State or local government, or to the federal government, for a project to be funded through the SIPPRA program.[37] Increased revenues as a result of the intervention are not considered savings.

The panels will ensure that the Applicant meets the threshold requirement of the presence of federal, State, or local savings. Then, they will assess the quality of the methodology used by the Applicant to arrive at the estimates, how likely the Applicant is to achieve these savings, and comprehensiveness of the estimated savings.

Applicants must include in the application the estimated total savings, estimated savings per project participant, and estimated savings per dollar spent on the intervention. Applicants must also provide the estimated total savings over the period of performance.

II. Value to the Federal Government

The federal payment to the State or local government for each specified outcome achieved as a result of the intervention must be less than or equal to the value of the outcome to the federal government over a period not exceeding ten years from the date implementation commences.[38]

Value calculated for the purpose of this NOFA is discussed in Section A.5.a Federal Value for the SIPPRA Program and includes social benefits as well as savings through the BCA. The federal payment to the State or local government for each specified outcome achieved as a result of the intervention will be limited to the value of the outcome to the federal government, which is the net benefit derived from the BCA.

The panel will determine how likely the project is to achieve the value determined through the BCA, how accurate the justification is that the proposed intervention will produce the value proposed by the Applicant, and the comprehensiveness of the Applicant's estimate. The panel will also review the data and approach to ensure it can easily be replicated, and that the data were sufficient for the analysis. The panel will take into account the extent to which the benefits exceed costs.

Applicants must include in the application the estimated total value, estimated value per project participant, estimated value per dollar spent on the

[32] *See id.;* 5 U.S.C. 552(b)(4).

[33] *See* 42 U.S.C. 1397n–1(c), 1397n–1(d).

[34] *See* 42 U.S.C. 1397n–2(b).

[35] *See* 42 U.S.C. 1397n–2(b)(4), (5).

[36] *See* 42 U.S.C. 1397n–2(b)(5).

[37] *See* 42 U.S.C. 1397n–1(b); 42 U.S.C 1397n–5(a)(8).

[38] *See* 42 U.S.C. 1397n–2(c)(1)(B).

intervention, and the ratio of benefits to costs.

ii. Likelihood of Achieving Outcomes

SIPPRA requires Treasury to take into consideration the likelihood, based on evidence provided in the application and other evidence, that the State or local government in collaboration with the intermediary and the service providers will achieve the specified outcomes.[39] Projects showing a greater likelihood of achieving outcomes will receive more points from the panels, as detailed below.

I. Evidence

The panels will review the applicant's identified target population, outcome goals, proposed intervention(s), and description of the unmet need in the area where the intervention will be delivered or among the target population that will receive the intervention.[40] [41] In connection with this consideration, panels will assess Applicants' compliance with the statutory requirement to provide evidence demonstrating that the intervention can be expected to produce the proposed outcomes.[42] More points will be given for applications providing strong evidence in support of the likelihood of achieving the outcomes; in particular, points will be awarded for evidence based on previous interventions or interventions similar to the proposed intervention that were shown to produce the desired outcomes as a direct result of the intervention and not as a result of other factors. See Section A.6.d Evidence for greater detail on evidence standards.

II. Service Delivery Plan, Project Budget, and Partnership Agreement

The likelihood of success of a SIPPRA program project is in part determined by whether the project is designed, structured, and implemented in a way that will foster success. To this end, the panels will assess the thoroughness and comprehensiveness of the applicant's service delivery plan for delivering the intervention. Panels will review the criteria used to determine the eligibility of an individual for the project, including how the target population will be identified, how individuals will be referred to the project, and how they will be enrolled in it.[43] Applications will be assessed based on the soundness of the methodology for identifying the target population and the thoroughness of the applicant's plan for referring and enrolling individuals, including assurances that the process avoids targeting easier-to-serve individuals from the target population for enrollment. The panel will consider whether, to the extent applicable, the Applicant has demonstrated that members of the target population are not being unfairly discriminated against in the selection, referral, and enrollment process. (See Section F.2.b, Non-discrimination laws and regulations). Panelists will also review the extent to which the target population and related community will be engaged in the development and implementation of the project and evaluation.

The panels will also assess the Applicant's project budget, including projected costs, and the project timeline.[44] The panels will assess the strength of the partnership agreement to the extent not covered under other components of the panel's scoring criteria. Applications will be assessed with respect to the thoroughness of the budget, timeline, and partnership agreement and the extent to which the intervention is achievable under the budget, service delivery plan, timeline, and partnership agreement. To the extent the Applicant intends to use investors and has not already identified and received commitments from them, the panel will consider the experience of the State or local government, intermediary, or service provider in raising private and philanthropic capital to fund social service investments.[45]

III. Project Partners

Because the likelihood of success is also determined by the capabilities of the project partners, the panels will assess the assigned responsibilities and the qualifications of the partners. This will include an assessment of the applicant's description of the roles and responsibilities of each entity involved in the project, including, to the extent applicable, any State or local government entity, intermediary, service provider, investor, or other stakeholder.[46] The panel will also assess the relevance and depth of expertise of each service provider and capacity of each service provider to deliver the intervention, as described by the applicant.[47] Likewise, the panel will review the relevance and depth of experience of any project intermediary and the capacity of the intermediary to fill the roles assigned to it.[48]

iii. Quality of Evaluation

I. Evaluation Design and Metrics

The Act requires Treasury to consider the expected quality of the evaluation of the proposed intervention that the independent evaluator will conduct. The panels will assess the project's evaluation design including the rigor and strength of the design, its capacity to determine that the outcomes were as a result of the intervention, feasibility of implementing the evaluation, the quality and availability of the required data, and the Applicant's explanation of how the metrics used in the evaluation are independent, objective indicators of impact.

II. Evaluator Independence and Experience

Panels will review the independence of the evaluator from the other entities involved in the project and the evaluator's experience in conducting rigorous evaluations of program effectiveness. Types of experience that will be reviewed include experience with the chosen evaluation design method on the intervention or similar interventions, the datasets the project expects to use, conducting implementation and causal impact analyses, managing similar evaluation protocols, and dealing with unforeseen data or implementation issues in other program evaluations. The qualifications of the individuals designing and overseeing the evaluation and ensuring its quality, including their education or training and type and years of experience, will also be taken into account.

iv. Capacity and Commitment To Sustain the Intervention

Finally, the Act requires Treasury to take into consideration the capacity and commitment of the State or local government to sustain the intervention, if appropriate and timely, and if the intervention is successful, beyond the period of the social impact partnership.[49] Panels will consider applicants' submissions with respect to State or local government and service providers' plans to sustain the intervention.[50] Although the primary focus will be on the project period, panels will provide additional points to applications that demonstrate a commitment from the State or local government and service providers and

[39] *See* 42 U.S.C. 1397n–2(b)(3).

[40] *See* 42 U.S.C. 1397n–1(c)(1), (2), (4), (14).

[41] *See* 42 U.S.C. 1397n–1(c)(8).

[42] *See* 42 U.S.C. 1397n–1(c)(3), 1397n–2(c)(1)(D).

[43] *See* 42 U.S.C. 1397n–1(c)(18).

[44] *See* 42 U.S.C. 1397n–1(c)(6), (16), (17).

[45] *See* 42 U.S.C. 1397n–1(c)(11).

[46] *See* 42 U.S.C. 1397n–1(c)(12), (d)(8).

[47] *See* 42 U.S.C. 1397n–1(c)(10), (13), (23).

[48] *See* 42 U.S.C. 1397n–1(d).

[49] *See* 42 U.S.C. 1397n–2(b)(7).

[50] *See* 42 U.S.C. 1397n–1(c)(24).

the availability of sufficient funding to extend the project, if appropriate, beyond the project period.[51]

2. Review and Selection Process

The following is the review process for determining the award recipients. Each step is explained in greater detail below.

- Phase 1: Completeness and Eligibility Review
- Phase 2: Subject Matter Expert Panel Review
- Phase 3: Consistency Review and Commission Recommendations
- Phase 4: Interagency Council Certification and Treasury Determination
- Phase 5: Review of Federal Awardee Performance and Integrity Information System Information Data and Risk Evaluation

a. Phase 1: Completeness and Eligibility Review

In the first review phase, Treasury will review all applications to determine eligibility and completeness, which will consist of a technical review to determine whether the applicant is a State or local government; whether the proposed project can qualify as a pay for results project as set forth in Section A.4.a The Pay for Results Model; whether the proposed project qualifies as an eligible project as set forth in Section A.4.b Outcomes; and whether each of the application content requirements set forth in Section D.2 Content and Form of Application Submission, has been satisfied. Prospective applicants are encouraged to consult the SIPPRA FAQs on Treasury's SIPPRA website page to help them determine if their proposed project is suitable under the pay for results model.[52] An application received from an ineligible entity or for an ineligible project will be rejected. Applicants are required to establish that the proposed project is an eligible project. Incomplete applications may, at Treasury's discretion, receive further consideration. Treasury expects to afford applicants a reasonable opportunity to fix any such issues, as appropriate.

b. Phase 2: Subject Matter Expert Panel Review

Treasury will assign complete applications submitted by eligible applicants to a panel of subject matter experts who will be selected based on their knowledge of the social benefit(s) or problem(s), technical expertise in the type of intervention, experience working with the target population that is the subject of the application, or other considerations. Review panelists will be selected from relevant federal agencies. Reviewers will be screened for conflicts of interest.

The panel will review the applications based on the criteria laid out above.

c. Phase 3: Consistency Review and Commission Recommendations

Following the panel review, Treasury will review application scores for consistency among subject matter experts on each panel and across panels and rank the applications. The Act establishes the Commission on Social Impact Partnerships (''the Commission'') whose principal obligation is to make recommendations to Treasury regarding the funding of SIPPRA program projects and feasibility studies. The nine-member advisory commission established by the Act consists of a non-federal Chair appointed by the President and eight non-federal members chosen by congressional leaders.[53] The members of the Commission are required to (1) be experienced in finance, economics, pay for performance, or program evaluation; (2) have relevant professional or personal experience in a field related to one or more of the outcomes listed in this division; or (3) be qualified to review applications for social impact partnership projects to determine whether the proposed metrics and evaluation methodologies are appropriately rigorous and reliant upon independent data and evidence-based research. The Commission will review the applications and make recommendations to Treasury.

d. Phase 4: Interagency Council Certification and Treasury Determination

The Act establishes the Federal Interagency Council on Social Impact Partnerships (''the Interagency Council''). This eleven-member body is chaired by the Director of the Office of Management and Budget and its other members are representatives from the Departments of Labor, Health and Human Services, Agriculture, Justice, Housing and Urban Development, Education, Veterans Affairs, and Treasury; the Social Security Administration; and the Corporation for National and Community Service. The Interagency Council has 10 enumerated responsibilities including certifying Federal savings, providing subject-matter expertise, and advising the Secretary of the Treasury.[54]

The Interagency Council is required to certify that applications contain rigorous, independent data and reliable, evidence-based research methodologies to support the conclusion that the project will yield savings to the State or local government or the federal government if the project outcomes are achieved before Treasury makes its award decision,[55] and accordingly, will determine which applications warrant certification based on these criteria.

Treasury, in consultation with the Interagency Council and the head of any federal agency (or their designee) administering a similar intervention or serving a population similar to that served by the project, will review the applications, taking into account the statutory considerations referenced above as well as the recommendations made by the Commission and the Interagency Council certification (or absence thereof). Depending on the number of meritorious applications, Treasury may consider how the intervention would foster innovation in social policy, yield a diversity of target populations and grantees, advance racial equity and support for underserved communities as described in Executive Order 13985, or any other non-monetary benefits that could not be included in the BCA.

e. Phase 5: Review of Federal Awardee Performance and Integrity Information System Information Data and Risk Evaluation

As required by the Uniform Guidance, Treasury will review and consider any information about an applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $250,000) over the period of performance. Each applicant may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

[51] As noted above, an applicant may discuss the commitment to scalability and building capacity or plans to maintain project benefits and/or continue the intervention beyond the project period in the event the intervention successfully addresses the needs of the target population. An applicant may include plans to make adaptations within its environment to strengthen or expand its proposed intervention beyond the period of performance.

[52] Department of Treasury, SIPPRA- Pay for Results, *https://home.treasury.gov/services/social-impact-partnerships/sippra-pay-for-results.*

[53] *See* 42 U.S.C. 1397n-6.

[54] *See* 42 U.S.C. 1397n–5.

[55] *See* 42 U.S.C. 1397n–5(a)(8).

Treasury will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in the Uniform Guidance.[56]

Further, as required by Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, or affirm that there is no new information to provide.[57] This applies to NFEs for which the total value of active grants, cooperative agreements, and procurement contracts received from all federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of an award or project. This means that Treasury may reject an application based on the information contained in FAPIIS even if the applicant otherwise achieves a high score under the 100-point scoring rubric discussed in Section E.1 Criteria, above.

3. Application Clarification and Feedback

During the course of the review process and risk assessment evaluation, Treasury may ask some applicants to provide confirming or clarifying information. Treasury staff uses such information to inform funding recommendations. A request for confirmation or clarification does not guarantee a grant award. If an applicant does not respond by the deadline to a request for information, Treasury may remove its application from consideration. Upon request, Treasury expects to provide feedback to unsuccessful applicants after grant awards have been announced.

4. Anticipated Announcement and Federal Award Dates

The deadline for submitting projects under this NOFA is April 15, 2024. Treasury will begin its review following this deadline. Review will not be conducted on a rolling basis. Treasury anticipates notifying the Applicant of the award decision six months after the application deadline.

F. Federal Award Administration Information

1. Federal Award Notices

Before a grant is awarded, Treasury may enter into negotiations with the applicant regarding program components, staffing and funding levels, and/or administrative systems in place to support grant implementation. If the negotiations do not result in a mutually acceptable submission, Treasury reserves the right to terminate the negotiations and decline to fund the award.

Treasury expects to announce the results of this competition by Q1 FY 2025. Treasury will provide successful applicants with a Notice of Award (NoA) that will set forth the amount of the award and other pertinent information. The NoA is the legal document issued to notify an applicant that an award has been made. Treasury expects that the NoA will also include standard Terms and Conditions and any Special Award Conditions related to participation in the SIPPRA program. A copy will also be sent to the electronic mail address listed on the SF–424. The applicant's signature on the SF–424, including electronic signature via E-Authentication on *http://www.grants.gov,* constitutes a binding offer by the applicant.

Note that any communication between Treasury and applicants prior to the issuance of the NoA and prior to the execution of any award agreement is not authorization to begin performance on the project.

Unsuccessful applicants will be notified of their status by electronic mail to the applicant listed on the SF–424. Unsuccessful applicants may apply under subsequent NOFAs, if any.

2. Administrative and National Policy Requirements

Successful applicants selected for awards must agree to comply with additional applicable legal requirements upon acceptance of an award. All grants are subject to the Office of Management and Budget's (OMB's) regulatory requirements for grants codified in the Uniform Guidance. Grantees must agree, as part of their award agreement, to comply with all requirements under 2 CFR part 200, as applicable. Subpart E of 2 CFR part 200 is not applicable to the project award, but federal funding for the independent evaluator is subject to subpart E of 2 CFR part 200.

a. Administrative Program Requirements

Awards under this NOFA are subject to federal laws, regulations, and policies concerning grants. Below is a non-exhaustive list of requirements with which the applicant will need to comply:

i. Lobbying Restrictions at 31 CFR part 21.
ii. Government-wide Debarment and Suspension Requirements at 31 CFR part 19.
iii. Government-wide Requirements for Drug-Free Workplace at 31 CFR part 20.
iv. Award Term for Trafficking in Persons at 2 CFR part 175.
v. Environmental Requirements

Treasury approval of financial assistance is subject to compliance with applicable federal and State environmental requirements. As discussed under Section D.2.a(g)8 (pg. 22) Legal Compliance, the Applicant must identify the State and federal environmental laws, regulations, and policies that may apply to the project and the environmental documents that may be required under State and federal laws. Pursuant to the National Environmental Policy Act of 1969, as amended (NEPA), project applications will be evaluated in accordance with Treasury's NEPA procedures and categorical exclusions. Grantees whose projects do not fall within Treasury's categorical exclusions will be required to assist Treasury in conducting an Environmental Analysis and an Environmental Impact Statement for the project, as applicable.

b. Non-Discrimination Laws and Regulations

All grantees, partners, and sub-recipients, if applicable, must comply with applicable non-discrimination statutes and regulations. These include but are not limited to: (a) title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000–2000d7), which prohibits discrimination on the basis of race, color of national origin, and Treasury's implementing regulations, 31 CFR part 22; (b) title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681–1683, and 1685–1686), which prohibits discrimination on the basis of sex, and Treasury's implementing regulation 31 CFR part 28; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of disability; (d) the Individuals with Disabilities Education Act, as amended (20 U.S.C. 1400 *et seq.*); (e) the Age Discrimination Act of 1975, as amended (42 U.S.C. 6101–6107), which prohibits discrimination on the basis of age, and Treasury's implementing regulations, 31 CFR part 23; (f) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (g) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91–616),

[56] *See* 2 CFR 200.205.
[57] *See* 2 CFR part 200, appendix XII.

as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (h) Section 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290dd-3 and 290ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; and (i) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 *et seq.*), as amended, relating to nondiscrimination in the sale, rental or financing of housing.

c. Transparency Act Requirements

Applicants must ensure that they have the necessary processes and systems in place to comply with the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282, as amended by § 6202 of Pub. L. 110–252) (Transparency Act). All Applicants, except for those excepted from the Transparency Act, must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements of the Transparency Act, should they receive funding. Upon award, Applicants will receive detailed information on the reporting requirements of the Transparency Act, as described in 2 CFR part 170, appendix A. No sub-award of an award made under this NOFA may be made to a sub-recipient that is subject to the terms of the Transparency Act unless that potential sub-recipient acquires and provides a Unique Entity Identifier.

d. Access to Records/Oversight

By accepting a project award under this NOFA, the Awardee agrees to make available to Treasury, the Comptroller General, agency Inspectors General, the administering agency, or any of their authorized representatives, all data and documents that might be needed, including contracts and agreements, regardless of whether outcomes are achieved and payment is received, in the Awardee's possession or available to the grantee. Awardees must also agree to provide timely and reasonable access to program operating personnel, project partners, and participants. This evaluation may make use of program management information system data, local administrative data, financial data, and program progress reports. It is critical that Awardees keep this information up to date and accurate for performance measurement, evaluation, and auditing purposes. Awardees may be required to: (1) provide access to pertinent documents; (2) host site visits; (3) facilitate interviews with grantee staff, partners and the independent evaluator; (4) attend grantee meetings; and (5) provide additional data. By accepting a project award under this NOFA, the Awardee also agrees to participate in a national cross-site evaluation in the event that the federal government conducts one.

e. Intellectual Property Rights

Intellectual property rights relating to the activities of the Awardee and all partners in the project, including the evaluator, intermediary, and service provider(s) are subject to 2 CFR 200.315.

f. Record Retention

Applicants must follow federal guidelines on record retention, which require Awardees to maintain all records pertaining to grant activities for a period of not less than three years from the time of final grant close-out.

g. Requirements Applicable to Construction and Real Property Acquisition

Additional requirements may apply to projects involving construction or the acquisition of real property. Applicants should discuss such projects with Treasury staff prior to submitting an application.

h. Other Requirements

Awardees must comply with existing laws and regulations governing the subject area of the project and the relevant federal agency administering the project. If the intervention design requires exceptions to any such existing laws and regulations, the applicant must obtain a waiver from the governing federal, State, or local agency.

i. Special Program Requirements

i. Evaluation Agreement

For each social impact project grant approved by Treasury, the head of the relevant federal agency, as recommended by the Interagency Council and determined by Treasury, will enter into an agreement with the grant recipient to pay for all or part of the independent evaluation for the project up to 15 percent of the award amount. Under the Act, the head of the relevant federal agency may not enter into an agreement with a State or local government unless the head determines that the evaluator is independent of the other parties to the agreement and has demonstrated substantial experience in conducting rigorous evaluations of program effectiveness including, where available, well-implemented RCTs and quasi-experimental analyses on the intervention or similar interventions.

ii. **Federal Register** Publication of Notice of Award

The Act provides that not later than 30 days after entering into an agreement for an award, Treasury must publish a notice in the **Federal Register** that includes the following information about the award.

- The outcome goals of the project.
- The target population that will be served by the project.
- A description of each intervention in the project.
- The expected social benefits to participants who receive the intervention and others who may be impacted.
- The detailed roles, responsibilities, and purposes of each federal, State, or local government entity, intermediary, service provider, independent evaluator, investor, if any, or other stakeholder.
- The payment terms, the methodology used to calculate outcome payments, the payment schedule, and performance thresholds.
- The project budget.
- The project timeline.
- The project eligibility criteria.
- The evaluation design.
- The metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of each intervention and how these metrics will be measured.
- The estimate of the savings to the federal, State, and local government, on a program-by-program basis and in the aggregate, if the agreement is entered into and implemented and the outcomes are achieved as a result of each intervention.

Additionally, the Act requires that this information, along with progress reports and final reports relating to each project, be posted on a website established and maintained by the Interagency Council.

iii. Changes to the Statement of Work

Upon grant of an award, the proposal will become the grant's statement of work. Treasury discourages any post-award changes to the target population, outcome(s), intermediary, and independent evaluator. Under extenuating circumstances, Treasury and/or the relevant federal agency administering the grant at its sole discretion may approve revisions to the statement of work. Changes to the intervention strategy and source of up-front project funding may be made with prior written approval from Treasury or the administering federal agency. To start this process, the Awardee must timely notify Matthew Cook, SIPPRA Director, at *SIPPRA@Treasury.gov* of

these changes as they occur and provide appropriate documentation to update the statement of work.

3. Reporting

Awardees must agree to meet the reporting requirements as listed below or as otherwise specified in the award agreement. Administrative reports must be submitted electronically to Treasury or to the relevant federal agency, as specified in the award agreement.

a. Performance Report

An Annual Performance Report form must be submitted within 90 days of the end of each calendar year of the award period of performance. A final performance report is due 90 calendar days after the period of performance end date. Each report must summarize project activities, including the current stage of program implementation; progress towards achieving the outcome goals, including number of people served; significant milestones of the Awardee, intermediary, investors, if any, and evaluator; and related results of the project. It must thoroughly document the partnership activities and decision-making structure used to implement the pay for results model. These reports may be made publicly available. Upon award, Treasury or the administering federal agency will provide detailed formal guidance about the data and other information that is required to be collected and reported on either a regular basis or special request basis.

b. Evaluation Progress Reports

Not later than two years after a project has been approved and biannually thereafter, the independent evaluator must submit a written report to the head of the relevant federal agency and the Interagency Council summarizing the progress that has been made in achieving each outcome specified in the award agreement. Data in evaluation progress reports and final reports will be made available to all federal agencies represented on the Interagency Council, and data content requirements will be specified in the agreement between the grantee and the head of the relevant federal agency.

When an Awardee's intervention has achieved one or more outcomes, pre-defined outcome target(s) have been met, and the grantee wishes to receive an outcome payment in accordance with the outcome payment structure originally proposed, the independent evaluator must submit to the head of the relevant federal agency and the Interagency Council a written report that includes the results of the evaluation conducted to determine whether an outcome payment must be made.

The report must include information on the unique factors that contributed to achieving or failing to achieve the outcome in the context of the intervention. This must include, but is not limited to, any major change in policy or law that may have affected the project intervention and the challenges faced in attempting to achieve the outcome. The report may also include information on what was learned during the evaluation including how to improve future service delivery or implementation.

The report must also assess the degree to which the project was delivered as intended, including a discussion of how closely the project's theory and intended procedures aligned with actual project implementation. The report must include information related to the intervention model, including whether it has evolved and whether the intervention was delivered with fidelity to the plan. The report should detail how staffing, recruitment/identification and screening of participants, selection, and enrollment were different from what was expected at the outset.

The progress report must include an assessment by the independent evaluator of the value to the federal government as discussed and defined in Section A.5.a Federal Value for the SIPPRA Program. In calculating the value to the federal government of the completed outcome(s), the independent evaluator may only take into consideration the benefits from the BCA achieved as a result of the outcome(s).

The Interagency Council will submit these reports to Treasury and to each committee of jurisdiction in the House of Representatives and Senate within 30 days of receipt.

c. Final Evaluation Report

Within six months of project completion, the independent evaluator must submit a final report to the head of the relevant federal agency and the Interagency Council. The report must assess the effects of the intervention and include a discussion of the findings and implications, as well as a definitive statement about whether the predetermined outcomes have been met and whether the State or local government has fulfilled each obligation of the agreement. This must include information on the unique factors that contributed to the achievement or failure to achieve outcomes, including but not limited to any major change in policy or law that may have affected the project intervention, a description of the research methods, *e.g.,* randomization of treatment and control groups, if applicable, data, sample size and characteristics, measures, and other factors, as well as findings, including impacts—for exploratory and confirmatory, short and long-term, subgroup analyses, and other findings.

The report must also assess whether, and the degree to which, the project was delivered as intended. This must include a discussion of how closely the project's theory and intended procedures aligned with actual project implementation. This portion of the report must include information related to the intervention model, including whether it has evolved and whether the intervention was delivered with fidelity; staffing; recruitment/identification and screening of participants; selection and enrollment; and how the intervention was implemented. The report must also discuss information regarding the improved future delivery of this or similar interventions.

The independent evaluator's final report for a project must include an assessment of the value to the federal government as discussed and defined in in Section A.5.a Federal Value for the SIPPRA Program. In calculating the value to the federal government of the completed outcome(s), the independent evaluator may only take into consideration the benefits from the BCA.

The Interagency Council will submit this final report to Treasury and to each committee of jurisdiction in the House of Representatives and Senate within 30 days of receipt. This report will be made publicly available.

G. Federal Awarding Agency Contact

For further information about this NOFA, please contact Matthew Cook, SIPPRA Director, at *SIPPRA@Treasury.gov.* Applicants should email all technical questions to *SIPPRA@treasury.gov* and must specifically reference NOFA/CFDA 21.017, and include a contact name and phone number. This NOFA is also available on Treasury's SIPPRA website at *https://www.treasury.gov/SIPPRA* and at *http://www.Grants.gov.*

H. Other Information

Treasury has determined that this NOFA imposes new information collection requirements subject to the Paperwork Reduction Act of 1995. The information collection for the Project Narrative, Administrative Reporting, and Records Retention provisions contained in this NOFA has been approved under OMB control number 1505–0260. Other information

requirements gathered via the SF–424 family of forms have already been approved under the following OMB control numbers: Information for Federal Assistance covered under 4040–0004, Budget Information for Non-Construction Programs covered under 4040–0006, Budget Information for Construction Programs covered under 4040–0008, Disclosure of Lobbying Activities covered under 4040–0013, Assurance for Non-Construction Programs covered under 4040–0007, Assurance for Construction Programs covered under 4040–0009 and Key Contacts, Project Abstract and Project/Performance Site Location covered under 4040–0010.

I. Appendix I: Example of Outcome Valuation Process

This example is meant to be a guide to the process of outcome valuation, not a specific recommendation of how to account for the costs and benefits of particular types of interventions.

A city is setting up a program with the hopes of reducing property and violent crimes by building in time in the work schedules of police officers to build relationships with members of the community. This city is divided into 100 police precincts, half of which are randomly assigned to participate in the program. The program will run for 10 years. For each of the 50 participating precincts, the per year cost of the program is $50,000 in 2023 dollars. The expectation is that participation in the program will result in five fewer violent crimes and 40 fewer property crimes each year. For the sake of simplicity, it is assumed that the program's effects are constant over time, and end immediately after ten years. Applying these estimates to average crime rates over the previous 10 years yields the estimates presented in the table below.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Property Crime Reduction	40	40	40	40	40	40	40	40	40	40
Violent Crime Reduction	5	5	5	5	5	5	5	5	5	5

Step 1—Demonstrate Savings to the Federal, State, or Local Government

The program will incur additional outlays in the form of program costs but will lower outlays on criminal justice costs. The net result is a reduction in outlays. The program will cost $50,000 each year. Reduced criminal activity results in lower costs to the city from criminal justice activity from reduced arrests and police costs, court costs, and the costs of incarceration. Drawing from Autor et al. (2017), the cost of criminal justice activity of each property crime is assumed to be $2,781 and the cost of each violent crime is assumed to be $19,519.[58] It is assumed that there will be 40 fewer property crimes and 5 fewer violent crimes each year. Thus, the total savings are 10 * (2,781 * 40 + 19,519 * 5 − 50,000) = $1,588,350.00.

SAVINGS BREAKDOWN

Federal Savings	$(500,000.00)
State & Local Savings	2,088,350.00
Total Savings	1,588,350.00

Step 2—Assess Costs and Benefits From the Intervention's Effect on the Target Population for Each Time Period

The distribution of property and violent crimes in the hypothetical city in this example are assumed to be the same as Cambridge, Massachusetts from 1992–2005, making a direct application of estimates from Table A2 of Autor et al. (2017) possible.[59] There are two categories of benefits (prevented criminal costs) that accrue to the target population. The first is the benefit of reduced ''victimization costs,''—*i.e.,* the monetary value of the disutility of being a victim of a crime. Based on estimates from Cohen and Piquero (2009), the victimization cost of a violent crime is $66,923 (in 2023 dollars) and the cost of a property crime is $1,830 (in 2023 dollars).[60] *The second benefit is the reduced ''offender productivity costs,'' i.e.*, the opportunity costs resulting from incarceration. These are approximated using lost wages. For violent crimes, the reduced offender productivity costs are $9,644 per crime and for property crimes, the reduced offender productivity costs are $1,149 per crime.

There are both costs and benefits that accrue to taxpayers as a result of the intervention. First, the program will cost $50,000 each year. Second, reduced criminal activity results in lower costs to the city from criminal justice activity. As stated above, drawing from Autor et al. (2017), the cost of criminal justice activity of each property crime is assumed to be $2,781 and the cost of each violent crime is assumed to be $19,519. These figures are all multiplied by 1.25, the Marginal Cost of Public Funds used in SIPPRA.

Step 3—Assess External Costs and Benefits

Crime imposes external costs on the community beyond the costs imposed on those directly affected. In other words, even if you are not directly the victim of a crime, there is still disutility from living in an area where others are victimized. However, there is little revealed-preference-based evidence on the willingness to pay to reduce criminal activity to prevent the disutility of crimes being committed against others. Thus, for this example, it is assumed that the external costs and benefits (other than criminal justice costs assessed in Step 3) are zero.

Step 4—Sum Costs and Benefits by Time Period

The table below gives the yearly costs ($50,000 to run the program) and the benefits (victimization cost reduction, productivity cost reduction, and criminal justice cost reduction) of the program.

[58] Autor, David H., Christopher J. Palmer, and Parag A. Pathak. Gentrification and the amenity value of crime reductions: Evidence from rent deregulation. No. w23914. National Bureau of Economic Research, 2017. *https://www.nber.org/system/files/working_papers/w23914/w23914.pdf.*

[59] Autor, David H., Christopher J. Palmer, and Parag A. Pathak. Gentrification and the amenity value of crime reductions: Evidence from rent deregulation. No. w23914. National Bureau of Economic Research, 2017. *https://www.nber.org/system/files/working_papers/w23914/w23914.pdf.* These estimates are themselves based on Cohen, Mark A., and Alex R. Piquero. ''New evidence on the monetary value of saving a high risk youth.'' Journal of Quantitative Criminology 25 (2009): 25–49. *https://link.springer.com/article/10.1007/s10940-008-9057-3.*

[60] All 2008 cost estimates are adjusted using CPI–U for all urban consumers. These cost estimates are based on a weighted average of the various crimes which constitute the category. The distribution of property and violent crimes in the hypothetical city in this example are assumed to be the same as Cambridge, Massachusetts, making a direct application of estimates from Table A2 of Autor et al. (2017) possible.

		Marginal Cost/Benefit										
		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Formula
Benefits												
Property Crime Reduction	Victimization Cost	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$ 73,200.00	$1,830X40
	Productivity Cost	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$ 45,960.00	$1,149X40
	Criminal Justice	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$ 139,050.00	$2,781X1.25X40
Violent Crime Reduction	Victimization Cost	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$ 334,615.00	$66,923X5
	Productivity Cost	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$ 48,220.00	$9,644X5
	Criminal Justice	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$ 121,993.75	$19,519X1.25X5
Costs												
Direct Cost		$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$ 62,500.00	$50,000X1.25
Total Net Benefits		$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	

Step 5 Appropriately Account for Inflation and Sum Across Time Periods

Finally, all dollars are put in constant (year 10) dollars assuming inflation grows at the rate set out in the FY 2024 Mid-Session Review of the Budget of the U.S. Government. Year 1 is 2024, and this example runs through 2033.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Net Benefits	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 700,538.75	$ 7,005,387.50
Net Benefits in Year 10 Dollars	$ 859,632.58	$ 840,305.55	$ 821,413.05	$ 802,945.31	$ 784,892.78	$ 767,246.11	$ 749,996.20	$ 733,134.12	$ 716,651.14	$ 700,538.75	$ 7,776,755.59

J. Appendix II: Integration of Managed Care Information/Data

For Applicants Who Plan To Use Savings From Medicaid or CHIP: Integration of Managed Care Information/Data

Treasury anticipates that applicants may have projects affecting individuals who receive managed care services from Medicaid or CHIP. To ensure that the calculations of benefits from reduced health care spending in these contexts properly demonstrate that those benefits accrue to the federal government or other public payers rather than to managed care organizations, applicants proposing projects that include a managed health care component must include a section in their application entitled ''Managed Health Care Information.'' This section must include, at a minimum, answers to the following questions, as applicable:

- To what degree will participants in the intervention be covered by comprehensive, risk-based managed care during the period of the demonstration?
- For intervention participants covered by a managed care organization, how would savings accrue to the federal government rather than the entity taking on risk?
- What services, if any, will be carved out of managed care for this population?
- If multiple capitation rates are used, which rate cells (by eligibility group or other category) will be used for the SIPPRA program project participants?
- With what frequency will capitation rates for the population covered by comprehensive, risk-based managed care be redetermined during the period of the SIPPRA program project?
- How would this intervention lead to reduced capitation rates?
- While the level of impact cost and utilization data will have on a capitation rate will vary, if the anticipated intervention effect is small and/or the population impacted by the intervention makes up a relatively small proportion of the rate cell (or grouping of Medicaid beneficiaries with similar characteristics for the purposes of determining a capitation rate), it may be unlikely that the effect will be large enough to change the capitation rate, even if the cost and utilization reductions occur. Is the impact of the intervention effect (or impacted population size) meaningful relative to size of the managed care program?
- For the population covered by managed care, what proportion of individuals covered under the relevant rate cell(s) are participants in the intervention?
- Is the proportion sufficient to trigger changes in the capitation rate under current procedures? If not, please be specific about how you will work with your State Medicaid Agency to ensure cost and utilization changes among this population due to the intervention are captured and incorporated into adjustments to the capitation rate.
- Please clarify if you will have access to robust historical (*e.g.,* at least 2 years) data to ensure that the comparison group is matched as well as possible to the actual cost or claims data to accurately assess federal savings through the evaluation.
- Please note that lags in realization of governmental savings in managed care contexts, relative to those in Fee for Service contexts, will not preclude consideration so long as the savings are realized within the ten-year time period and the BCA procedures discussed above are followed.

K. Appendix III: Benefit-Cost Analysis Tools

The value that individuals place on policies, goods, or other actions can be difficult to assess as changes in the welfare of individuals cannot be directly observed. Therefore, the BCA analyst must rely on individuals revealing their preferences through the choices they make. For example, if a person chooses to purchase car A over (equally priced) car B, it is reasonable to assume they prefer car A over car B. If a person chooses to not pursue further education when they are able to do so, it is reasonable to assume that they believe the costs of the next period of education exceed the benefits.

BCA should rely on revealed preference, either within the target population, or based on careful research in other contexts. When possible, stated preference (for example, surveys of how much an individual values a particular good or service) should be avoided in arriving at any of the core assumptions of the BCA.

Two examples of tools that high-quality studies employ are: (1) ''willingness-to-pay,'' a measure of the maximum amount individuals are willing to spend to obtain a given benefit; and (2) ''willingness-to-accept,'' the minimum amount individuals are willing to accept to relinquish or forego a given benefit. Market prices provide a valuable starting point for measuring willingness-to-pay and willingness-to-accept, but they can also be estimated through revealed preference or other methods.

Revealed preference methods have the benefit of being based on observable behavior often involving market transactions. These methods can be particularly useful to establish values of certain benefits and costs that are

reflected in observable tradeoffs that people actually make. For example, it is possible to ascertain willingness to pay by observing how much an individual purchases at different prices. Cohen et al. (2016) use a rich data set on Uber rides (a ride sharing app) to assess individuals' willingness to pay for a ride by observing whether they go through with the purchase after observing the price. While such detailed data are rarely available in other contexts, willingness-to-pay calculations can often be made even for outcomes that are never directly priced, such as the value of a statistical life (VSL).[61] Another example is an intervention may try to reduce teenage overdoses through an education program. The primary benefit of such a program would be reduced mortality, and thus the applicant would use existing estimates of the VSL to multiply by the estimated number of lives saved. Existing estimates of the VSL are often calculated by observing how much people are willing to spend to reduce their risk of death in certain contexts. For example, some studies use the additional amount that a firm must pay its employees to induce them to work a relatively riskier job (a compensating differential) to estimate the VSL. Other studies use willingness to pay for car features that will reduce the probability of death in certain types of accidents but cost more than equivalent cars without these features. For further guidance on using VSL estimates in BCA, consult the March 2021 Department of Transportation Guidance, March 2021.[62] BCA may rely on revealed preference, either within the target population, or based on careful research in other contexts.

Laura Feiveson,

Deputy Assistant Secretary for Microeconomics.

[FR Doc. 2023–26174 Filed 11–29–23; 8:45 am]

BILLING CODE 4810–AK–P

[61] Cohen, Peter, Robert Hahn, Jonathan Hall, Steven Levitt, and Robert Metcalfe. *Using big data to estimate consumer surplus: The case of uber.* No. w22627. National Bureau of Economic Research, 2016. *https://www.nber.org/system/files/working_papers/w22627/w22627.pdf.*

[62] Department of Transportation, Treatment of the Value of Preventing Fatalities and Injuries in Preparing Economic Analyses, 2021. *https://www.transportation.gov/sites/dot.gov/files/2021-03/DOT%20VSL%20Guidance%20-%202021%20Update.pdf.*

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0098]

Agency Information Collection Activity Under OMB Review: Dependents' Application for VA Education Benefits

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by clicking on the following link: *www.reginfo.gov/public/do/PRAMain. Select* ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0098.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *Maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0098'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3311 (as amended by Pub. L. 113–146, section 701, effective August 7, 2014), 3513, 3697A, 5113, 5101, 5102, and 5103; 38 CFR 21.3030 and 21.9510.

Title: Dependents' Application for VA Education Benefits, VA Form 22–5490.

OMB Control Number: 2900–0098.

Type of Review: Revision of a currently approved collection.

Abstract: The VA's Veterans Claims Examiners use the information from this collection to help determine whether a claimant qualifies for DEA or Fry Scholarship benefits. The information on the form can be obtained only from the claimant, and an eligibility determination cannot be made without the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 88 FR 67452 on Friday, September 29, 2023, Pages 67452–67453.

Affected Public: Individuals and Households.

Estimated Annual Burden: 48,983 hours.

Estimated Average Burden Time per Respondent: 45 and 25 min., (paper and electronic, respectively).

Frequency of Response: Once.

Estimated Number of Respondents: 83,972.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–26369 Filed 11–29–23; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee Charter Renewals

AGENCY: Department of Veterans Affairs.

ACTION: Notice of advisory committee charter renewals.

In accordance with the provisions of the Federal Advisory Committee Act (FACA) and after consultation with the General Services Administration, the Secretary of Veterans Affairs has determined that the following Federal advisory committee is vital to the mission of the Department of Veterans Affairs (VA) and renewing its charter would be in the public interest. Consequently, the charter for the following Federal advisory committee is renewed for a two-year period, beginning on the dates listed below:

Committee name	Committee description	Charter renewed on
Department of Veterans Affairs Voluntary Service National Advisory Committee.	Provides advice on the coordination and promotion of volunteer activities within VA health care facilities and on other matters relating to volunteerism.	February 28, 2023.
Veterans' Family, Caregiver and Survivor Advisory Committee.	Provides advice with respect to the administration of benefits by VA for services to Veterans' families, caregivers and survivors.	May 4, 2023.

The Secretary has also renewed the charter for the following statutorily authorized Federal advisory committee for a two-year period, beginning on the date listed below:

Committee name	Committee description	Charter renewed on
Research Advisory Committee on Gulf War Veterans' Illnesses.	Provides advice and makes recommendations on proposed research studies, plans and strategies related to understanding and treating the health consequences of military service in the Southwest Asia theater of operations during the 1990–1991 Gulf War (Operations Desert Shield and Desert Storm).	January 11, 2023.
Advisory Committee on Structural Safety of Department of Veterans Affairs Facilities.	Provides advice on all matters of structural safety in the construction and remodeling of VA facilities.	March 3, 2023.
Veterans' Advisory Committee on Education	Provides advice on the administration of education and training programs for Veterans and Service members; Reservists and Guard personnel; and for dependents of Veterans, including programs under Chapters 30, 32, 33, 35 and 36 of title 38, U.S.C. and Chapter 1606 of title 10, U.S.C.	March 13, 2023.
Veterans and Community Oversight and Engagement Board.	Coordinates locally with VA to identify the goals of the community and Veteran partnership; provides advice and recommendations to the Secretary of Veterans Affairs, to improve services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and provides advice and recommendations on the implementation of the Draft Master Plan approved by the Secretary on January 28, 2016, and on the creation and implementation of any other successor master plans.	April 24, 2023.
Advisory Committee on Cemeteries and Memorials.	Provides advice on the administration of VA national cemeteries, Soldiers' lots and plots, the selection of cemetery sites, the erection of appropriate memorials and the adequacy of Federal burial benefits.	May 16, 2023.
Special Medical Advisory Group	Provides advice on the care and treatment of enrolled Veterans and other matters pertinent to the operations of the Veterans Health Administration.	July 7, 2023.
Advisory Committee on Women Veterans	Provides advice on the administration of benefits for women Veterans; reports and studies pertaining to women Veterans; and the needs of women Veterans with respect to health care, rehabilitation benefits, compensation, outreach, and other relevant programs administered by VA.	October 4, 2023.

FOR FURTHER INFORMATION CONTACT: Jeffrey Moragne, Committee Management Officer, Department of Veterans Affairs, Advisory Committee Management Office (00AC), 810 Vermont Avenue NW, Washington, DC 20420; telephone (202) 714–1578; or email at *Jeffrey.Moragne@va.gov.* To view a copy of a VA Federal advisory committee charters, please visit *http://www.va.gov/advisory.*

Dated: November 24, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–26265 Filed 11–29–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226

Endangered and Threatened Species; Designation of Critical Habitat for Five Species of Threatened Indo-Pacific Corals; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226

[Docket No: 231120–0274]

RIN 0648–BJ52

Endangered and Threatened Species; Designation of Critical Habitat for Five Species of Threatened Indo-Pacific Corals

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

ACTION: Proposed rule; withdrawal and reproposal; request for comments.

SUMMARY: On November 27, 2020, we, NMFS, published in the **Federal Register** a proposal to designate 17 island units of critical habitat in the Pacific Islands Region for 7 Indo-Pacific coral species listed under the Endangered Species Act (ESA). Based on public comments and new information regarding the interpretation of the records of the listed corals and application to critical habitat, a substantial revision of the proposed rule is warranted. Accordingly, we are withdrawing the 2020 proposed rule and publishing this new proposed rule. We propose to designate critical habitat for five of the seven coral species that were addressed in the 2020 proposed rule: *Acropora globiceps, Acropora retusa, Acropora speciosa, Euphyllia paradivisa,* and *Isopora crateriformis.* Proposed critical habitat includes 16 island units encompassing approximately 251 square kilometers ((km²); 97 square miles (mi²)) of marine habitat. Several areas are ineligible for critical habitat because of final Department of Defense Integrated Natural Resource Management Plans that we have determined will benefit the listed corals. We have considered economic, national security, and other relevant impacts of the proposed designations, but are not proposing to exclude any areas from the critical habitat designations due to anticipated impacts.

DATES: Comments on this proposal must be received by February 28, 2024.

Public hearings: Public hearings on this proposed rule will be held during the public comment period at dates, times and locations to be announced in a forthcoming **Federal Register** Notice.

ADDRESSES: You may submit comments on this document, identified by the FDMS docket number NOAA–NMFS–2016–0131, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and type NOAA–NMFS–2016–0131 in the Search box (*note:* copying and pasting the FDMS Docket Number directly from this document may not yield search results). Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Lance Smith, Protected Resources Division, NMFS, Pacific Islands Regional Office, NOAA Inouye Regional Center, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Lance Smith, NMFS, Pacific Islands Regional Office (PIRO), 808–725–5131, *lance.smith@noaa.gov;* or, Celeste Stout, NMFS, Office of Protected Resources, 301–427–8436, *celeste.stout@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

We listed 20 reef coral species as threatened under the ESA on September 10, 2014 (79 FR 53851), 15 of which occur in the Indo-Pacific. The remaining five species occur in the Caribbean. On November 27, 2020, we proposed critical habitat for the seven listed Indo-Pacific species that were then considered to occur within U.S. jurisdiction (85 FR 76262) and the five listed Caribbean species (85 FR 76302). All 20 of these listed coral species have undergone some level of population decline and are susceptible to multiple threats, including ocean warming, diseases, ocean acidification, ecological effects of fishing, and land-based sources of pollution. We determined that these species are likely to become endangered throughout their ranges within the foreseeable future as a result of a combination of threats, the most severe of which are related to climate change.

On November 27, 2020, NMFS proposed to designate critical habitat for the seven listed Indo-Pacific corals that were then considered to occur within U.S. jurisdiction (*Acropora globiceps, Acropora jacquelineae, Acropora retusa, Acropora speciosa, Euphyllia paradivisa, Isopora crateriformis,* and *Seriatopora aculeata*) and opened a public comment period (85 FR 76262). In response to multiple requests from the public, the initial 60-day public comment period was extended three times, with the last extension ending on May 26, 2021. Two virtual public hearings were held in January 2021. Approximately 80 public comments were received on the proposed rule.

The coral critical habitat proposed for designation in 2020 (the ''2020 proposed rule'') consisted of substrate and water column habitat characteristics essential for the reproduction, recruitment, growth, and maturation of the seven listed coral species. A total of 17 areas or ''units'' were proposed to be designated as critical habitat, including 4 units in American Samoa (Tutuila and Offshore Banks, Ofu-Olosega, Ta'u, Rose Atoll), 1 unit in Guam, 7 units in the Commonwealth of the Northern Mariana Islands (CNMI; Rota, Aguijan, Tinian, Saipan, Anatahan, Pagan, Maug), and 5 units in the Pacific Remote Islands Areas (PRIA; Howland, Palmyra Atoll, Kingman Reef, Johnston Atoll, Jarvis). Based on the best available information at that time, between 1 and 6 listed coral species were thought to occur within each of these 17 units. Several other areas were also found to be either ineligible for designation as critical habitat, or were proposed to be excluded from the designation due to national security impacts. These areas included the following: A complex of overlapping Navy Surface Danger Zones off of Ritidian Point in Guam, other parts of Guam, parts of Tinian in CNMI, a group of six Navy anchorage berths on Garapan Bank in Saipan in CNMI, all of Farallon de Medinilla in CNMI, and all of Wake Atoll in PRIA.

The ESA defines critical habitat under section 3(5)(A) as the (1) 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 essential to the conservation of the species and 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 by the Secretary of Commerce (Secretary) that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)(A)). Conservation is defined in

section 3(3) of the ESA as to use, and 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 this Act are no longer necessary (16 U.S.C. 1532(3)). Section 3(5)(C) of the ESA provides that, except in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species. ESA implementing regulations provide that critical habitat shall not be designated within foreign countries or in other areas outside U.S. jurisdiction (50 CFR 424.12(g)).

Section 4(a)(3)(B)(i) of the ESA prohibits designating as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DOD) or designated for its use, that are subject to an Integrated Natural Resources Management Plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is designated. Section 4(b)(2) of the ESA requires us to designate critical habitat for threatened and endangered species on the basis of the best scientific data available and after taking into consideration the economic, national security, and any other relevant impact, of specifying any particular area as critical habitat. Pursuant to this section, the Secretary may exclude any area from critical habitat if she determines the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat. However, the Secretary cannot exclude areas if failure to designate them as critical habitat will result in the extinction of the species (16 U.S.C. 1533(b)(2)).

Once critical habitat is designated, section 7(a)(2) of the ESA requires Federal agencies to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify that habitat (16 U.S.C. 1536(a)(2)). This requirement is in addition to the section 7(a)(2) requirement that Federal agencies ensure their actions are not likely to jeopardize the continued existence of ESA-listed species. Specifying the geographic location of critical habitat also facilitates implementation of section 7(a)(1) of the ESA by identifying areas where Federal agencies can focus their conservation programs and use their authorities to further the purposes of the ESA. Critical habitat requirements do not apply to citizens engaged in actions on private land that do not involve a Federal agency. The requirements of section 7(a)(2) to not destroy or adversely modify critical habitat apply only to Federal agencies and do not apply to non-Federal entities on non-Federal land or within non-Federal waters in the absence of a Federal nexus (*e.g.* Federal funding, Federal permit). However, designating critical habitat can help focus the efforts of other conservation partners (*e.g.,* state and local governments, individuals, and non-governmental organizations).

On July 5, 2022, the U.S. District Court for the Northern District of California issued an order vacating the ESA section 4 implementing regulations that were revised or added to 50 CFR part 424 in 2019 (''2019 regulations,'' see 84 FR 45020, August 27, 2019) without making a finding on the merits. On September 21, 2022, the U.S. Court of Appeals for the Ninth Circuit granted a temporary stay of the district court's July 5 order (*Wash. Cattlemen's Ass'n,* No. 22–70194, 2022 WL 4393033). On November 14, 2022, the Northern District of California issued an order granting the government's request for voluntary remand without vacating the 2019 regulations. The District Court issued a slightly amended order two days later on November 16, 2022 (*Ctr. for Biological Diversity* v. *Haaland,* No. 19–cv–05206–JST, 2022 WL 19975245). As a result, the 2019 regulations remain in effect, and we are applying the 2019 regulations here. We also note that, on June 22, 2023, our agency in coordination with the Department of Interior jointly published proposed revisions to the ESA section 4 regulations (88 FR 40764). For purposes of this determination and in an abundance of caution, we considered whether the analysis or its conclusions would be any different under the current, pre-2019, and recently proposed regulations. We have determined that while the analysis differs in some ways, the conclusions presented here would not be any different. We will consider any changes to the section 4 regulations, as appropriate, should they be finalized and become effective prior to completion of a final critical habitat determination.

In this rulemaking, the terms ''occupied area,'' ''specific area,'' and ''critical habitat unit'' each have distinct meanings. The terms ''occupied area'' and ''specific area'' are species-specific, whereas the term ''critical habitat unit'' is not species-specific. The term ''occupied area'' is consistent with the definition of the ''geographical area occupied by the species'' in 50 CFR 424.02 and refers to the area that may generally be delineated around species' occurrences at the time of listing, as determined by the Secretary—*i.e.,* range. Within each occupied area, ''specific areas'' are the areas containing the essential feature of critical habitat for the species. We use the term ''critical habitat unit'' to refer to the cumulative specific areas for one or more species around the 16 islands proposed for designation. Critical habitat units are named according to the particular island or offshore bank around, or on which, the coral habitat is located. For example, overlapping occupied areas for five listed coral species occur around Tutuila Island and its offshore banks, which is thus named the Tutuila and Offshore Banks Unit of coral critical habitat.

Rationale for Withdrawing 2020 Proposed Rule

We evaluated the comments and information received during the public comment period and at the public hearings that were held for the 2020 proposed rule, as well as other new information that has become available, as described in the Critical Habitat Information Report for this proposed rule (NMFS, 2023) and its appendices. Based on our consideration of the comments and information, a substantial revision of the 2020 proposed rule is needed for three main reasons:

1. The initial methodology used to compile existing records of listed coral species in U.S. waters was not exhaustive, resulting in the inadvertent exclusion of some islands within the occupied area for some listed species that should have been included as occupied areas.

2. The initial methodology used to determine which U.S. islands were within the occupied area for each listed coral species at the time of listing (2014) was too simplistic, resulting in the inadvertent inclusion of some islands in the occupied area for some listed species that should not have been included.

3. The initial methodology used to determine the depth range of each listed species on each island within its occupied area used incorrect assumptions, resulting in inaccurate depth ranges for some species in some locations (*i.e.,* some depth ranges were larger than they should have been).

With regard to the compilation of records of listed coral species in U.S. waters, in developing the 2020 proposed rule, we relied on Federal coral reef monitoring programs as the only source of records used for most of the remote

islands. However, as pointed out in the public comments and also as indicated by new information, other records exist for some islands. Specifically, several sources of photo records and expert data records have been published or shared since the 2020 proposed rule published, and some previously unused historical photo records were found to have been mislabeled with the names of unlisted species. As a result, numerous existing records that were not considered in the 2020 proposed rule, including some that provide the only records of any listed coral species on some islands, were considered in developing this proposed rule.

With regard to determining the occupied area within U.S. jurisdiction for each listed coral species for the 2020 proposed rule, we assumed that any expert record of a listed coral species was adequate to conclude that the island was within the occupied area for that species at the time of listing. However, as pointed out in the public comments and also as indicated by new information, for those islands with very few records for a listed coral species, such records may not provide adequate evidence that the island was within the occupied area of the listed species at the time of listing. There are several potential reasons for this, including species misidentifications, old records of species that were no longer present at the time of listing, and the likelihood that a single record of a colony of a listed species represents a vagrant individual. For example, only a single colony of the listed coral *Acropora jacquelineae* has ever been recorded in U.S. waters on Tutuila, an island that has been frequently surveyed by coral experts since that single colony was recorded in 2008, and that record was used as the basis for including *A. jacquelineae* in the 2020 proposed rule. However, as indicated in the public comments and by new information, that record likely represents a vagrant individual of *A. jacquelineae,* and thus Tutuila should not be considered as being occupied by the species at the time of listing. Therefore, the mere existence of an expert record of a listed coral from an island is not necessarily adequate to support a conclusion that the area was within the occupied area of the species at the time of listing.

With regard to the species' depth ranges applied in the 2020 proposed rule, we assumed that the depth range of a listed coral species shown by the records from an extensively surveyed island was similarly representative of that species' depth range on other islands. For example, since the records of *A. globiceps* from Tutuila showed a depth range of 0–20 m on that island, we assumed that the species' depth range was 0–20 m in other locations where we lacked depth distribution data, including islands within (*e.g.,* Rose Atoll) and outside (*e.g.,* Guam) the Samoan Archipelago. However, as indicated in the public comments and by new information, the depth range of a listed coral species can vary from island to island, especially between archipelagos. For example, surveys that became available or were conducted since the 2020 proposed rule between 10 and 20 m on both Tutuila and Guam indicate that *A. globiceps* is commonly found to 20 m on Tutuila in the Samoan Islands but only to 12 m on Guam in the Mariana Islands.

In order to address these issues with the 2020 proposed rule, a systematic methodology was developed and implemented for compilation, assessment, and interpretation of the records of each listed coral species in order to determine its occupied area within U.S. waters at the time of listing in 2014 (*i.e.,* which islands) as well as the depth range of each species on each of those islands. This new methodology resulted in significant changes to the occupied area (*i.e.,* which islands are included or not), as well as depth ranges of critical habitat for most listed coral species. Ultimately, these changes altered which species are considered to occupy areas within U.S. jurisdiction and the location and boundaries of the areas proposed for designation. Specifically, two species included in the 2020 proposed rule, *Acropora jacquelineae* and *Seriatopora aculeata,* are no longer considered to have occupied areas within U.S. jurisdiction at the time of listing, and we cannot designate critical habitat in areas outside U.S. jurisdictions (50 CFR 424.12(g)). In addition, some new areas are being proposed that were not included in the 2020 proposed rule (Alamagan and Uracas in CNMI, French Frigate Shoals in Hawaii). Given these multiple, substantial changes, we concluded it was necessary to withdraw the 2020 proposed rule and publish this proposed rule to provide the public an opportunity to comment on the new methodology and the different areas being proposed as critical habitat.

New Methodology for Determining Occupied Areas and Depth Ranges

The determinations of the occupied areas and depth ranges that inform critical habitat are based on the records of each listed coral species within U.S. waters. However, using the records for critical habitat requires overcoming three major challenges: (1) Finding all the records (compilation); (2) accounting for the high variability in the quality, quantity, age, species identification uncertainty, survey effort, and other factors associated with the records (assessment); and (3) interpreting the records to determine which islands are within the occupied area for each listed species and thus should be included in critical habitat (application). In order to address these challenges and ensure that coral critical habitat is based on the best available information, we conducted exhaustive searches to compile all the available records for each listed coral species around each island within U.S. Pacific Islands jurisdictions, and developed a consistent and transparent methodology for assessing and applying the records. The results are provided in appendix A of the Information Report (NMFS, 2023), hereafter referred to as the Records Document, and provide the foundation for this new proposed rule. The compilation, assessment, and application of the records are summarized from the Records Document below.

Compilation of Records

We compiled the available records for each listed coral species around each island within U.S. Pacific Islands waters via the following steps: (1) Reviewed all relevant NOAA Fisheries files, such as those used for the final coral listing rule and 2020 proposed critical habitat; (2) gathered records from government agencies that have conducted coral reef monitoring within these areas; (3) gathered records from other sources such as research projects, site surveys, area inventories, etc.; (4) conducted an exhaustive virtual search; and (5) consulted with experts from the Territorial Governments (American Samoa, Guam, CNMI) and the Marine National Monuments (Rose Atoll, Pacific Remote Islands, Marianas Trench) to ensure that no records were overlooked. Some of these records were brought to our attention by the public comments that we received during the public comment period in 2021. The search produced records of seven listed coral species (*A. globiceps, A. jacquelineae, A. retusa, A. speciosa, E. paradivisa, I. crateriformis,* and *S. aculeata*) from U.S. Pacific Islands waters (NMFS, 2023, appendix A). This comprehensive compilation process yielded more than twice as many records as were used for the 2020 proposed rule, including historical records that we were unaware of in 2020 as well as new data collected since then.

The records were divided into 45 records groups by island and species.

Throughout this proposed rule and in the supporting documents, we refer to high islands (volcanic, *e.g.,* Guam), atolls (*e.g.,* Rose Atoll), stand-alone reefs (*e.g.,* Kingman Reef), shoals (*e.g.,* French Frigate Shoals (FFS)), and pinnacles (*e.g.,* Gardner Pinnacles) as ''islands.'' The 45 records groups included a total of 24 such islands, 4 of which were in American Samoa (Tutuila and Offshore Banks, Ofu-Olosega, Ta'u, Rose Atoll), 1 in Guam (Guam), 9 in CNMI (Rota, Aguijan, Tinian, Saipan, Farallon de Medinilla (FDM), Alamagan, Pagan, Maug Islands, Uracas), 7 in PRIA (Howland, Baker, Palmyra Atoll, Kingman Reef, Johnston Atoll, Wake Atoll, Jarvis), and 3 in the Northwestern Hawaiian Islands (FFS, Maro Reef, Gardner Pinnacles) in Hawaii, as shown in table 2 of appendix A. We found no records of any listed species in any of the Main Hawaiian Islands (NMFS, 2023, appendix A).

Assessment of Records

We assessed each of the 45 records groups (*i.e.,* all records of a listed species from an island) in terms of the multiple factors, including (1) quality of records, (2) quantity of records, (3) age of records, (4) species identification uncertainty, and (5) survey effort. We addressed the quality of records by organizing the records into three mutually-exclusive categories: ''photo records,'' ''expert data records,'' or ''other records.'' Because of species identification uncertainty, photo records are ideal, as long as the location and date of the photo are known, and the photo clearly shows colony and branch morphology. However, many records of coral species are in the form of data sheets or species lists, and lack photos. Any such record collected by a recognized Indo-Pacific reef-building coral species expert is considered an expert data record. Records that do not meet the criteria for photo records or expert data records are considered other records (*e.g.,* personal communications). We confirmed all records via direct communication with the experts who took the records, or with experts who were able to vouch for the records. Our determinations of whether the island was within the occupied area for a listed species at the time of listing relied almost entirely upon photo records and expert data records. However, other records provided valuable information for some islands or parts thereof. For example, records that do not meet the criteria for photo or expert data records (*i.e.,* exact dates and locations not available) provide information on depth and habitat distributions (NMFS, 2023, appendix A).

Although we did not specify a particular quantity of records necessary to support a determination that a particular island was within the occupied area for a listed species at the time of listing, the more photo records and expert data records we have for a species from an island, the greater the likelihood that the island was within the occupied area for a listed species at the time of listing. Islands with a single photo record or expert data record of a listed species may or may not have been within the occupied area of that species at the time of listing (2014), depending on other factors (NMFS, 2023, appendix A).

Older records are not necessarily lower quality, thus age of records was not a consideration for determining the quality of a record. However, the more that a record predates listing, the less relevance it had to our determination of whether the island was within the occupied area for a listed species at the time of listing (NMFS, 2023, appendix A).

Species identification uncertainty is substantial for most of the 15 listed Indo-Pacific reef coral species, even for experts. For listed coral species that are consistently distinct from similar species and frequently observed, species identification uncertainty has decreased since listing, as survey effort and expertise have increased. This is the case with *A. globiceps* and *I. crateriformis.* In addition, *E. paradivisa* and *S. aculeata* are consistently distinct from similar species, although they are very infrequently observed within U.S. waters. For these four listed species, identification uncertainty is relatively low at this point in time for coral species experts based in the U.S. Pacific Islands. In contrast, for listed species that are very similar to other species, the increase in survey effort since listing in 2014 has emphasized the difficulty in distinguishing them. This is the case with *A. retusa,* especially in the Marianas and PRIA. The combination of high colony morphological variability and low numbers of records from the Marianas (*i.e.,* Guam and CNMI) and PRIA is such that we have low confidence in these records, even though they are expert data records. Even more challenging are those listed species that are very similar to other species but are very infrequently observed, such as *A. jacquelineae* and *A. speciosa.* For these three listed species, identification uncertainty is relatively high at this point in time, even for coral species experts who focus on the U.S. Pacific Islands (NMFS, 2023, appendix A).

A particular species identification uncertainty problem is the apparent variability in colony morphology of *A. retusa* and related species between the American Samoa, Guam-CNMI, and PRIA archipelagos. The combination of high colony morphological variability and low numbers of records in Guam-CNMI and PRIA is such that we have low confidence in these records, even though they are expert data records. However, in American Samoa, there is apparently lower colony morphological variability and higher numbers of records for *A. retusa,* thus we have high confidence in these records.

Survey effort refers to the amount of expert coral species surveys that have been conducted on an island. Historical survey effort has been highly variable from island to island, potentially influencing the interpretation of the records. However, all islands in this document except FDM in CNMI have been included in the Pacific Islands Fisheries Science Center's (PIFSC) species-level standardized coral reef monitoring surveys at least one time since listing in 2014, and some islands have also been included in standardized surveys by other agencies. PIFSC's surveys are quite extensive around each island, including a large number of transects and covering wide depth ranges (appendix A). The Department of the Navy (DON) restricts access to FDM, hence PIFSC does not survey there. However, the Navy periodically conducts species-level coral surveys at FDM by recognized Indo-Pacific reef-building coral species experts, thus numerous surveys have been conducted on FDM both around and since the time of listing. All islands have been subject to extensive species-level surveys (*i.e.,* the PIFSC and DON surveys) around or since the time of listing, including within the depth ranges and habitat types of all listed coral species (NMFS, 2023, appendix A).

Several other factors were taken into consideration in assessing the records, including taxonomic issues, morphological variability across archipelagos, and habitat preferences. Taxonomic issues include confusion of *A. globiceps* with *A. humilis,* and the name change from *Acropora crateriformis* to *Isopora crateriformis,* both of which affected how we treated historical records. Finally, some types of coral reef habitats are surveyed more than others, mainly because of accessibility and safety. Of the surveys that produced the records in this document, the majority took place on forereefs (AKA reef slopes) between about 5 and 20 m of depth, and some surveys included reef slopes of 20–30 m

depth. Fewer surveys were done in backreef habitats, such as pools, lagoons, and reef flats, raising the possibility that the records may not be representative of species' distributions across habitats. However, for some of the more frequently surveyed islands, habitat-specific information is available, as noted in the species-island sections (NMFS, 2023, appendix A).

Based on the assessment factors, we developed a 10-category system for rating the level of evidence provided by each records group (*i.e.,* all records of a listed species from an island) that the island was within the occupied area for the listed species at the time of listing in 2014, from the least to the most evidence (table 1). Then we interpreted the rating results of each records group to determine whether the island was within the occupied area for the listed species at the time of listing, and thus should be included in critical habitat. For islands within the occupied area of a listed species, we also used the records to determine the depth range of that species on the island.

TABLE 1—RATING SYSTEM FOR EVIDENCE PROVIDED BY EACH OF THE RECORDS GROUPS THAT THE ISLAND WAS WITHIN THE OCCUPIED AREA FOR THE LISTED SPECIES AT THE TIME OF LISTING IN 2014, AND THE RESULTING RATINGS OF THE 45 RECORDS GROUPS

[NMFS, 2023, appendix A, tables 1 and 2]

Rating	Species ID uncertainty	Evidence category for records groups	Ratings results for the 45 records groups
1	High	Up to a few pre-listing photo or expert data records are available, but no post-listing records are available.	10 records groups: *A. jacquelineae* from Tutuila; *A. retusa* from Ta'u, Guam, Rota, Tinian, Howland, Kingman Reef, and Johnston Atoll; and *A. speciosa* from Guam and Kingman Reef.
2	Low	″ ″ ″	7 records groups: *A. globiceps* from Howland, Baker, Kingman Reef, Maro Reef, and Gardner Pinnacles; and *S. aculeata* from Guam and Saipan.
3	High	Up to a few post-listing photo or expert data records are available, but post-listing standardized monitoring surveys have not detected colonies.	1 records group: *A. retusa* from Jarvis.
4	Low	″ ″ ″	2 records groups: *A. globiceps* from Alamagan and Uracas.
5	High	More than a few post-listing photo or expert data records are available, but post-listing standardized monitoring surveys have not detected colonies.	2 records groups: *A. retusa* from Wake Atoll; and *A. speciosa* from Tutuila.
6	Low	″ ″ ″	7 records groups: *A. globiceps* from Ta'u, Rose Atoll, FDM, Palmyra Atoll, Johnston Atoll, and FFS; and *E. paradivisa* from Tutuila.
7	High	More than a few post-listing photo or expert data records are available, and post-listing standardized monitoring surveys have detected colonies.	1 records group: *A. retusa* from Ofu-Olosega.
8	Low	″ ″ ″	6 records groups: *A. globiceps* from Ofu-Olosega, Aguijan, Pagan, Maug Islands, and Wake Atoll; and *I. crateriformis* from Ta'u.
9	High	At least dozens of post-listing photo and expert data records are available, and post-listing standardized monitoring surveys have detected colonies at multiple sites over multiple years.	2 records groups: *A. retusa* from Tutuila and Rose Atoll.
10	Low	″ ″ ″	7 records groups: *A. globiceps* from Tutuila, Guam, Rota, Tinian, and Saipan; and *I. crateriformis* from Tutuila and Ofu-Olosega.

We interpreted the ratings of the records groups in terms of the likelihood that the island was within the occupied area for the listed species at the time of listing in 2014. We considered record groups with ratings of 1–3 as providing inadequate evidence that the island was within the occupied area for the listed species at the time of listing. Eighteen of the 45 records groups were rated as 1–3 (table 1). The rationales for why these records groups provide inadequate evidence for the species being within the occupied area at the time of listing are summarized below from the Records Document (NMFS, 2023, appendix A).

One *A. jacquelineae* records group was rated as 1 (Tutuila), a species with high species identification uncertainty even for trained experts. This record consists of photos of a single colony of *A. jacquelineae* on Tutuila taken in 2008. Since then, hundreds of expert surveys have been conducted on Tutuila within the habitat and depth range of the species, including at the location of the original record, but no other records have been documented. The regulatory definition of an occupied area does not include habitats used solely by vagrant individuals (*i.e.,* waifs). Waifs are a single individual or small group of individuals found outside of its normal range, presumably advected by unusual currents or weather conditions (Johnson *et al.,* 2000), which are common among reef corals (Turak and DeVantier, 2019). Based on the fact that no other colonies of *A. jacquelineae* have been observed before or since 2008 on Tutuila despite extensive expert surveys, there is considerable likelihood that the single observed colony of *A. jacquelineae* on Tutuila was a waif colony. Since occupied areas do not include habitats used solely by vagrant individuals (*i.e.,* waifs), this record provides inadequate evidence that Tutuila was within the occupied area of *A. jacquelineae* at the time of listing in 2014 (NMFS, 2023, appendix A).

Seven *A. retusa* records groups were rated as 1 (Ta'u, Guam, Rota, Tinian, Howland, Kingman Reef, Johnston Atoll), a species with high species identification uncertainty even for trained experts. All seven records groups consist of one or two records collected at least several years before listing (2004—2010). Five of the records groups each consist of one or two photo records that all appear to be of closely-related but undescribed species. The other two records groups (Ta'u, Rota) each consist of a single expert data record but because of species identification uncertainty and lack of photos, identifications could not be confirmed. Because these records groups each consist of only one or two ambiguous records collected at least several years before listing, and expert surveys of all seven islands since listing have not recorded any *A. retusa*

colonies, these records groups provide inadequate evidence that any of the seven islands were within the occupied area of *A. retusa* at the time of listing in 2014 (NMFS, 2023, appendix A).

Two *A. speciosa* records groups were rated as 1 (Guam, Kingman Reef), a species with high species identification uncertainty even for trained experts. The Guam records group consists of several photos of a single colony in Apra Harbor of Guam taken in 2010. Definitive species identification requires examination of a skeletal sample, but no sample was taken. Many subsequent expert dives and surveys were conducted in the area in the following years, but neither the original colony nor any other colonies resembling *A. speciosa* were recorded. The Kingman Reef records group consists of a single expert data record collected between 2004 and 2006 with no photos or skeletal sample. Because these records groups each consist of only a single ambiguous colony recorded at least several years before listing, and expert surveys of both islands since listing have not recorded any *A. speciosa* colonies, these records groups provide inadequate evidence that either island was within the occupied area of *A. speciosa* at the time of listing in 2014 (NMFS, 2023, appendix A).

Five *A. globiceps* records were groups rated as 2 (Howland, Baker, Kingman Reef, Maro Reef, Gardner Pinnacles), a species with low species identification uncertainty for trained experts. All five records groups consist of one or two photo records collected at least several years before listing (2000–2006). The three records groups from PRIA (Howland, Baker, Kingman Reef) each consist of one or two photo records taken between 2004 and 2006 and identified by an expert at that time but that are clearly not *A. globiceps,* and thus provide no evidence that these three islands were within the occupied area of *A. globiceps* at the time of listing in 2014. The two records groups from NWHI (Maro Reef, Gardner Pinnacles) are a photo of a single colony from 2004 (Maro Reef) and photos of a group of colonies in close proximity from 2000 (Gardner Pinnacles). Because these records groups each consist of only a single colony or group of colonies (*i.e.,* likely clones) collected many years before listing, multiple expert surveys conducted at Maro Reef and Gardner Pinnacles through 2008 did not record any *A. globiceps* colonies, and an expert survey of both islands since listing did not record any *A. globiceps* colonies, these records groups provide inadequate evidence that either island was within the occupied area of *A. globiceps* at the time of listing in 2014 (NMFS, 2023, appendix A).

Two *S. aculeata* records groups were rated as 2 (Guam, Saipan), a species with low species identification uncertainty for trained experts. The Guam records group consists of three photo records (two from the 1970s and one from 2010), while the Saipan records group consists of an expert data record of a cluster of colonies in close proximity (*i.e.,* likely clones) from 2011. Since 2010 and 2011, hundreds of expert surveys have been conducted on Guam and Saipan within the habitat and depth range of *S. aculeata,* but no additional records have been documented. Since the most recent of these records were collected in 2010 (Guam) and 2011 (Saipan), there have been sharp declines in coral cover throughout Guam and Saipan, especially of branching corals such as *S. aculeata,* due to a multitude of disturbances. There are several reasons why these records groups provide inadequate evidence that either island was within the occupied area of *S. aculeata* at the time the species was listed in 2014. First, each records group consists of only a few records collected between the 1980s and 2010. Second, hundreds of expert surveys have been conducted on Guam and Saipan since listing in 2014 but did not record any additional *S. aculeata* colonies. Third, there have been sharp declines in the coral cover of branching corals such as *S. aculeata* on Guam and Saipan that started at least several years before listing in 2014 (NMFS, 2023, appendix A).

One *A. retusa* records group was rated as 3 (Jarvis), a species with high species identification uncertainty even for trained experts. This records group consists of a single photo taken in 2018 although the photo does not clearly show branch and colony morphology. Like the other *A. retusa* photo records from PRIA, the colony could only be identified as possible *A. retusa* colonies because of a combination of species identification uncertainty and taxonomic ambiguity. Because *A. retusa* has high species identification uncertainty especially in PRIA, the records group consists of only one poor quality and ambiguous photo record, and post-listing standardized monitoring surveys in 2015 and 2018 at Jarvis did not detect any *A. retusa* colonies, this records group does not provide adequate evidence that Jarvis was within the occupied area of *A. retusa* at the time of listing in 2014 (NMFS, 2023, appendix A).

We considered record groups with ratings of 4–10 to provide adequate evidence that the island was within the occupied area for the listed species at the time of listing. Twenty-seven of the 45 records groups were rated as 4–10 (table 1), and the rationales for why these records groups provide adequate evidence for the species being within the occupied area at the time of listing are summarized below from the Records Document (NMFS, 2023, appendix A).

Two *A. globiceps* records groups were rated as 4 (Alamagan, Uracas), a species with low species identification uncertainty for trained experts. These records groups consist of one (Alamagan) and two (Uracas) photo records, all taken in 2017. No expert surveys have been conducted on either island since then, except PIFSC's standardized monitoring survey in 2022, details for which are not yet available. Because *A. globiceps* has low species identification uncertainty, and these records consist of photo records taken in 2017, these records groups provide adequate evidence that the two islands were within the occupied area of *A. globiceps* at the time of listing in 2014 (NMFS, 2023, appendix A).

Two records groups were rated as 5, *A. retusa* from Wake Atoll, and *A. speciosa* from Tutuila. Both species have high species identification uncertainty even for trained experts. The *A. retusa*/Wake records group consists of many photo and expert data records since listing in 2014, although standardized monitoring surveys have not detected the species on Wake. The *A. speciosa*/Tutuila records group consists of several photo and expert data records before and after listing in 2014, including two from 2016 that were confirmed with skeletal samples, and one record from a standardized monitoring survey that was not confirmed with a skeletal sample. Although both species have high species identification uncertainty even for trained experts, the *A. retusa*/Wake records group consists of many photo and expert data records since listing, and the *A. speciosa*/Tutuila records group includes multiple post-listing records that were confirmed with skeletal samples. Thus the records groups provide adequate evidence that Wake Atoll was within the occupied area of *A. retusa,* and that Tutuila was within the occupied area of *A. speciosa,* at the time of listing in 2014 (NMFS, 2023, appendix A).

Seven records groups were rated as 6, six for *A. globiceps* (Ta'u, Rose Atoll, FDM, Palmyra Atoll, Johnston Atoll, FFS), and one for *E. paradivisa* from Tutuila. Both species have low species identification uncertainty for trained experts. Each of the seven records

groups include several records collected before and after listing in 2014. Because both species have low species identification uncertainty, multiple records are available for all seven islands, and records were collected after listing, these records groups provide adequate evidence that the six islands were within the occupied area of *A. globiceps,* and that Tutuila was within the occupied area of *E. paradivisa,* at the time of listing in 2014 (NMFS, 2023, appendix A).

One *A. retusa* records group was rated as 7 (Ofu-Olosega), a species with high species identification uncertainty even for trained experts. This records group consists of several records collected before and after listing in 2014. Although *A. retusa* generally has high species identification uncertainty, colonies of the species have a typical and distinct appearance in American Samoa. Because multiple records are available, some of which were collected after listing, this records group provides adequate evidence that Ofu-Olosega was within the occupied area of *A. retusa* at the time of listing in 2014 (NMFS, 2023, appendix A).

Six records groups were rated as 8, five for *A. globiceps* (Ofu-Olosega, Aguihan, Pagan, Maug Islands, Wake Atoll), and one for *I. crateriformis* from Ta'u. Both species have low species identification uncertainty for trained experts. Each of the six records groups consist of many records collected after listing in 2014. Because both species have low species identification uncertainty, and many records are available for all six islands since listing, these records groups provide adequate evidence that the five islands were within the occupied area of *A. globiceps,* and that Ta'u was within the occupied area of *I. crateriformis,* at the time of listing in 2014 (NMFS, 2023., appendix A).

Two *A. retusa* records groups were rated as 9 (Tutuila, Rose Atoll), a species with high species identification uncertainty even for trained experts. These records groups each consist of dozens of records collected after listing in 2014. Although *A. retusa* generally has high species identification uncertainty, colonies of the species have a typical and distinct appearance in American Samoa. Because dozens of records are available from after listing for both islands, these records groups provide adequate evidence that Tutuila and Rose Atoll were within the occupied area of *A. retusa* at the time of listing in 2014 (NMFS, 2023, appendix A).

Seven records groups were rated as 10, five for *A. globiceps* (Tutuila, Guam, Rota, Tinian, Saipan), and two for *I. crateriformis* (Tutuila, Ofu-Olosega). Both species have low species identification uncertainty for trained experts. Each of the seven records groups consist of dozens to hundreds of records collected after listing in 2014. Because both species have low species identification uncertainty, and many records are available for all seven islands since listing, these records groups provide adequate evidence that the five islands were within the occupied area of *A. globiceps,* and that Tutuila and Ofu-Olosega were within the occupied area of *I. crateriformis,* at the time of listing in 2014 (NMFS, 2023, appendix A).

Summary of Results for Occupied Areas and Depth Ranges

In summary, and based on the new methodology for identifying occupied areas and depth ranges as described above and in the Records Document (NMFS, 2023, appendix A), 18 records groups each provide inadequate evidence that the island where the records were collected was within the occupied area of the listed species at the time of listing, while 27 records groups each provide adequate evidence that the island was within the occupied area of the listed species at the time of listing. These 27 records groups were from 18 islands for *A. globiceps,* 4 islands for *A. retusa,* 1 island each for *A. speciosa* and *E. paradivisa,* and 3 islands for *I. crateriformis* (table 2).

In addition, the 27 records groups were used to determine the depth ranges of each listed species around each island. For *A. globiceps,* the depth ranges are 0–20 m (3 islands), 0–12 m (10 islands), and 0–10 m (5 islands). For the other 4 species, the depth ranges are 0–20 m for *A. retusa* (4 islands) and *I. crateriformis* (3 islands), and 20–50 m for *A. speciosa* and *E. paradivisa* (table 2).

TABLE 2—DEPTH RANGES (IN METERS) OF THE LISTED SPECIES AROUND EACH OF THE ISLANDS CONSIDERED TO BE OCCUPIED AT THE TIME OF LISTING BASED ON APPLICATION OF THE RECORDS ASSESSMENT METHODOLOGY

[NMFS, 2023, appendix A]

Island	*A. globiceps*	*A. retusa*	*A. speciosa*	*E. paradivisa*	*I. crateriformis*
Tutuila and Offshore Banks	0–20	0–20	20–50	20–50	0–20
Ofu-Olosega	0–20	0–20			0–20
Ta'u	0–20				0–20
Rose Atoll	0–10	0–20			
Guam	0–12				
Rota	0–12				
Aguijan	0–12				
Tinian	0–12				
Saipan	0–12				
Farallon de Medinilla	0–12				
Alamagan	0–12				
Pagan	0–12				
Maug Islands	0–12				
Uracas	0–12				
Palmyra Atoll	0–10				
Johnston Atoll	0–10				
Wake Atoll	0–10	0–20			
French Frigate Shoals	0–10				

Changes From the 2020 Proposed Rule

Application of the records assessment methodology described above led to substantive changes from the 2020 proposed rule: (1) a reduction in the number of listed corals whose occupied areas occurred within U.S. jurisdiction at the time of listing from seven to five species; (2) changes in the numbers of islands included within the occupied areas for most of the listed species; and (3) changes in the depth ranges for all of the listed species. These substantive changes led to other changes in this proposed rule, including refinement of critical habitat boundaries, and elimination of all proposed exclusions from critical habitat under 4(b)(2). Changes between this and the 2020 proposed rule are summarized in table 3 and described in further detail below.

TABLE 3—COMPARISON OF 2020 AND NEW PROPOSED RULES

	2020 Proposed rule	New proposed rule
Listed Coral Species With Occupied Areas*.	7 species: *A. globiceps, A. jacquelineae, A. retusa, A. speciosa, E. paradivisa, I. crateriformis, S. aculeata.*	5 species: *A. globiceps, A. retusa, A. speciosa, E. paradivisa, I. crateriformis.*
Considered for Coral Critical Habitat (*i.e.,* Islands Within Occupied Areas**).	19 island units: Tutuila & Offshore Banks, Ofu-Olosega, Ta'u, Rose Atoll, Guam, Rota, Aguijian, Tinian, Saipan, FDM, Anatahan, Pagan, Maug Islands, Howland, Palmyra Atoll, Kingman Reef, Johnston Atoll, Wake Atoll, Jarvis.	18 island units: Tutuila & Offshore Banks, Ofu-Olosega, Ta'u, Rose Atoll, Guam, Rota, Aguijan, Tinian, Saipan, FDM, Alamagan, Pagan, Maug Islands, Uracas, Palmyra Atoll, Johnston Atoll, Wake Atoll, FFS.
Jurisdictions With Occupied Areas.	4 jurisdictions: American Samoa, Guam, CNMI, PRIA	5 jurisdictions: American Samoa, Guam, CNMI, PRIA, Hawaii.
Combined Depth Ranges***	0–10 m (3 units), 0–20 m (12 units), 0–40 m (4 units)	0–10 m (3 units), 0–12 m (10 units), 0–20 m (4 units), 0–50 m (1 unit).
Mapping of Specific Areas	All areas within depth ranges around all islands included	Only suitable substrates within depth ranges included.
4(a)(3) Ineligible Areas	All of FDM and Wake, most of Tinian, part of Guam	No changes.
4(b)(2) National Security Exclusions.	7 areas excluded: 6 Navy anchorages off of Saipan, 1 Navy area off of Ritidian Point on Guam.	No areas excluded.
Proposed for Coral Critical Habitat.	17 island units: The 19 island units within the occupied areas of the listed species, except FDM and Wake Atoll, which are ineligible because of 4(a)(3) INRMPs.	16 island units: The 18 island units within the occupied areas of the listed species, except FDM and Wake Atoll, which are ineligible because of 4(a)(3) INRMPs.

*These are the listed Indo-Pacific coral species whose occupied areas include islands within U.S. jurisdiction. The islands within the occupied area for each listed coral species are shown in table 2.

**These are the areas for which coral critical habitat was considered, most of which is proposed, for all of the listed coral species combined.

***These are the depth ranges around a given island for all of the listed species found on that island. The depth ranges of each listed species on each island are shown in table 2.

Changes to the Occupied Areas

Application of the new methodology for determining the occupied area for each listed species (NMFS, 2023, appendix A) resulted in changes to the numbers of islands included within the occupied areas at the time of listing (2014) for five of the seven listed species in the 2020 proposed rule. For *A. globiceps,* some new islands were added while some islands that were included in the 2020 proposed rule were removed. For *A. jacquelineae, A. retusa, A. speciosa,* and *S. aculeata,* some islands that were included in the 2020 proposed rule were removed. No changes to the islands included within the occupied areas were made for *E. paradivisa* or *I. crateriformis.*

For *A. globiceps,* four islands were added to the occupied area that were not in the 2020 proposed rule: Alamagan and Uracas in CNMI, Johnston Atoll in PRIA, and French Frigate Shoals in Hawaii. Also, two islands from the 2020 proposed rule were removed, Anatahan in CNMI and Kingman Reef in PRIA. Since 16 islands were within the occupied area for *A. globiceps* in the 2020 proposed rule, and 4 new islands have been added while 2 have been removed, this proposed rule includes 18 islands within the occupied area for *A. globiceps.* These 18 islands are in 5 jurisdictions, including 4 in American Samoa, 1 in Guam, 9 in CNMI, 3 in PRIA, and 1 in Hawaii (table 2).

For *A. jacquelineae,* one island from the 2020 proposed rule was removed, Tutuila and Offshore Banks in American Samoa. Since that was the only island within the occupied area for this species, the range of *A. jacquelineae* is considered to be entirely outside of U.S. waters.

For *A. retusa,* eight islands from the 2020 proposed rule were removed: Ta'u in American Samoa, Guam, Tinian in CNMI, and Howland, Kingman Reef, Johnston Atoll, Wake Atoll, and Jarvis in PRIA. Since 11 islands were within the occupied area for *A. retusa* in the 2020 proposed rule, and 8 have been removed, this proposed rule includes 3 islands within the occupied area for *A. retusa,* all of which are in American Samoa (table 2).

For *A. speciosa,* one island from the 2020 proposed rule was removed, Kingman Reef in PRIA. Since two islands were within the occupied area for *A. speciosa* in the 2020 proposed rule, and one has been removed, this proposed rule includes one island within the occupied area for *A. speciosa,* Tutuila and Offshore Banks in American Samoa (table 2).

For *S. aculeata,* two islands from the 2020 proposed rule were removed: Guam and Saipan in CNMI. Since these were the only islands within the occupied area for this species, the range of *S. aculeata* is considered to be entirely outside of U.S. waters.

In conclusion, based on the results of the new methodology, the islands within the occupied areas changed, and therefore the geographical areas occupied by five of the seven listed species have been revised accordingly from the 2020 proposed rule, including: *A. jacquelineae, A. globiceps, A. retusa, A. speciosa,* and *S. aculeata.* Since the occupied areas for two of the listed species, *A. jacquelineae* and *S. aculeata,* do not include any areas within U.S. jurisdiction, those two species have been removed from this proposed rule. A total of 18 islands are within the occupied area for at least one listed species, including 5 islands with multiple listed species, Tutuila and Offshore Banks (5 species), Ofu-Olosega (3 species), and Ta'u, Rose Atoll, and Wake Atoll (2 species each). The other 13 islands are within the occupied area for *A. globiceps* only (table 2).

Changes to the Depth Ranges

The records compiled via the new methodology for determining the occupied area for each listed species (NMFS, 2023, appendix A) also provided new depth range information for all five listed species in this proposed rule. Depth ranges were determined for each listed species around each island within its occupied area.

For *A. globiceps,* depth ranges were 0–20 m around all 16 islands considered for this species in the 2020 proposed rule. Based on the updated records, the depth ranges of *A. globiceps* around the 18 islands within its occupied area are now 0–20 m (3 islands), 0–12 m (10 islands), and 0–10 m (5 islands) (table 2).

For *A. retusa,* depth ranges were 0–10 m around all 11 islands considered for this species in the 2020 proposed rule. Based on the updated records, the depth ranges of *A. retusa* around the four islands within its occupied area are now 0–20 m (table 2).

For *A. speciosa,* depth ranges were 12–40 m around the two islands considered for this species in the 2020 proposed rule. Based on the updated records, the depth range of *A. speciosa* around the one island within its occupied area is now 20–50 m (table 2).

For *E. paradivisa,* depth range was 2–40 m around the one island considered for this species in the 2020 proposed rule. Based on the updated records, the depth range of *E. paradivisa* around the one island within its occupied area is now 20–50 m (table 2).

For *I. crateriformis,* depth ranges were 0–12 m around the three islands considered for this species in the 2020 proposed rule. Based on the updated records, the depth ranges of *I. crateriformis* around the three islands within its occupied area are now 0–20 m (table 2).

Changes to the Specific Areas

In this proposed rule, we refined the boundaries of the specific areas (*i.e.,* areas containing the essential feature of critical habitat for a species) for all species and islands. As a result of additional records collected to develop the proposed critical habitat designation, we obtained new information on habitat preferences indicating that the listed coral species are found entirely or predominantly on certain types of hard substrates but not others. We used that new information along with benthic maps showing the types of hard substrates throughout the occupied areas and depth ranges to delineate the boundaries of the specific areas for each of the listed corals. That is, we used detailed island-scale benthic habitat maps illustrating the variety of hard substrates that occur within the depth ranges of the listed species, together with habitat preference information showing that the listed species occur entirely or predominantly on certain hard substrate types but not on others. Thus, the benthic substrate maps, the habitat preferences, and other site-specific sources of substrate and water quality information were used to delineate the boundaries of the specific areas around each island within the listed species' occupied areas and depth ranges, as described further in the Specific Areas section.

Changes to Areas Excluded From Designation

Section 4(b)(2) of the ESA requires that we consider the economic impact, impact on national security, and any other relevant impact, of designating any particular area as critical habitat. The 4(b)(2) analyses in this proposed rule have been updated with new information and data on national security and economic impacts. In particular, the Navy's exclusion request for six anchorage berths in the Saipan Unit, which was granted in the 2020 proposed rule, is now moot because the depth range of proposed critical habitat is 0–12 m in this unit instead of 0–40 m as in the 2020 proposed rule. That is, the deepest point of critical habitat in this proposed rule in the Saipan Unit is shallower than the shallowest point within any of these six anchorage berths. One national security exclusion request remains in this proposed rule at the Navy's Ritidian Point Surface Danger Zone Complex on Guam. A full description of the 4(b)(2) analyses is provided in the Application of ESA section 4(b)(2) section of this document.

Critical Habitat Identification and Designation

In the following sections, we describe the relevant definitions and requirements in the ESA and our implementing regulations, and the key information and criteria used to prepare this proposed critical habitat designation for the five listed corals (*A. globiceps, A. retusa, A. speciosa, E. paradivisa,* and *I. crateriformis*). In accordance with section 4(b)(2) of the ESA and our implementing regulations (50 CFR 424.12), this proposed rule is based on the best scientific information available.

Our five-step process for identifying critical habitat areas for the threatened corals was to determine the following: (1) the geographical areas occupied by the listed corals at the time of listing (*i.e.,* occupied areas, as well as depth ranges for the listed corals within the occupied areas); (2) the physical or biological features essential to the conservation of the listed corals (*i.e.,* essential feature); (3) whether the physical or biological features within these geographical areas may require special management considerations or protection; (4) the specific areas within each of the occupied areas where the essential features occur (this step consists of four sub-steps); and (5) whether any unoccupied areas are essential to the conservation of any of the corals. Our evaluation and determinations are described in detail in the Information Report (NMFS, 2023) and are summarized below.

Geographical Area Occupied by the Species (Occupied Area)

The process for determining the occupied areas for the listed corals species is described in the preceding sections. The islands within the occupied area for each of the five listed species are listed in table 2, which include marine habitat around: 18 islands for *A. globiceps,* 4 islands for *A. retusa,* 3 islands for *I. crateriformis,* and 1 island each for *A. speciosa* and *E. paradivisa.*

The occupied area for each listed species is further defined by its depth range around each island within its occupied area, also shown in table 2. For *A. globiceps,* the depth ranges are 0–20 m (3 islands), 0–12 m (10 islands), and 0–10 m (5 islands). For the other 4 species, the depth ranges are 0–20 m for *A. retusa* (4 islands) and *I. crateriformis* (3 islands), and 20–50 m for *A. speciosa* and *E. paradivisa* (1 island each).

The occupied areas for the 5 listed species include a total of 18 islands, 5 of which include overlapping occupied areas for multiple listed species (*Tutuila and Offshore Banks, Ofu-Olosega, Ta'u, Rose Atoll, and Wake Atoll*).

Physical or Biological Features Essential for Conservation

Within the occupied areas, critical habitat consists of specific areas in which are found those physical and biological features (PBFs) essential to the conservation of the species and that may require special management considerations or protection. PBFs essential to the conservation of the species are defined as the features that occur in specific areas and that are essential to support the life-history needs of the species, including water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity (50 CFR 424.02).

Based on the best scientific information available, we identify the following physical feature essential to the conservation of the five corals.

Reproductive, recruitment, growth, and maturation habitat. Sites that support the normal function of all life stages of the corals, including reproduction, recruitment, and maturation. These sites are natural, consolidated hard substrate or dead coral skeleton, which is free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape (all the visible features of an area of reef) with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

With regard to the first and second attributes, reef-building corals, including the listed species, require exposed natural consolidated hard substrate for the settlement and recruitment of larvae or asexual fragments. Substrate provides the physical surface and space necessary for settlement of coral larvae, a stable environment for metamorphosis of the larvae into the primary polyp, growth of juvenile and adult colonies, and re-attachment of fragments. A number of attributes have been shown to influence coral larval settlement. Positive cues include the presence of crustose coralline algae, biofilms, and cryptic habitat such as crevices and holes. Attributes that negatively affect settlement include presence of sediment and algae (NMFS, 2023).

With regard to the third and fourth attributes, reef-building corals, including the listed species, require seawater temperature, aragonite saturation, nutrients, and water clarity conditions within suitable ranges to enable coral growth, reproduction, and recruitment. Corals may tolerate and survive in conditions outside these suitable ranges, depending on the local conditions to which they have acclimatized and the intensity and duration of deviations outside the suitable ranges. Extended deviations from suitable ranges result in direct negative effects on all life stages. The listed corals thrive in warm, clear, nutrient-poor marine waters with calcium carbonate concentrations that allow for symbiont photosynthesis, coral physiological processes and skeleton formation. This water must also have low to no levels of contaminants that would interfere with normal functions of all life stages (NMFS, 2023).

Some new information relevant to the essential feature was provided during the public comment period for the 2020 proposed rule or has become available since then, and has been added to the description of the essential feature in the Information Report (NMFS, 2023). The new information did not, however, result in any changes to the definition of the essential feature from the 2020 proposed rule.

Need for Special Management Considerations or Protection

As described in the Information Report (NMFS, 2023), we determined that the essential feature may require special management considerations or protection throughout the species' ranges because threats to this feature exist within these areas. Such threats include global and local threats, especially ocean warming, ocean acidification, coral disease, land-based sources of pollution, and fishing. There were no public comments on this section of the Draft Information Report or 2020 proposed rule, nor has any relevant new information become available that would alter our conclusion regarding the potential need for special management considerations or protection.

Specific Areas Containing the Essential Feature Within the Geographical Areas Occupied by the Species

As described under *Geographical Area Occupied by the Species (Occupied Area)* and shown in table 2, we identified 18 island units that we considered for proposed coral critical habitat. Each island unit includes occupied habitat for at least one listed coral species. Within each occupied area in each island unit, we delineated more specific areas that contain the essential feature using a 4-step process: (1) general information was used to delineate soft vs. hard substrates; (2) for the hard substrate areas identified in Step 1, specific substrate information was used to delineate unsuitable vs. suitable hard substrates; (3) for the suitable hard substrate areas identified in Step 2, we used water quality information to further delineate suitable vs. unsuitable areas; and (4) from the suitable areas identified in Steps 1–3, we removed any overlapping artificial substrates and managed areas. The 4 steps were implemented for each of the 18 units as follows:

(1) For Step 1, we used comprehensive substrate maps developed by PIFSC (PIFSC, 2021) to delineate soft vs. hard substrates, leaving only hard substrate areas within the combined depth ranges of all listed species in each unit, except for Wake Atoll and FFS, for which PIFSC (2021) did not produce maps. For Wake Atoll, we used the substrate map from the Pacific Islands Benthic Habitat Mapping Center (PIBHMC) (PIBHMC 2021). For French Frigate Shoals, we used the geomorphological structure component of the maps developed by National Centers for Coastal and Ocean Sciences (NCCOS) (NCCOS, 2003).

(2) For Step 2, we started with the hard substrate areas identified in Step 1, then distinguished unsuitable vs. suitable hard substrates. Many hard substrates are unsuitable because: (1) highly-fluctuating physical conditions cause frequent and extreme environmental changes (*e.g.,* high tide surge vs. low tide sun exposure on many reef flat substrates); (2) water motion continuously mobilizes sediment (*e.g.,* pavement with sand channels) or unstable substrate (*e.g.,* rubble); or (3) flat, low-relief areas provide poor settlement and growth habitat (*e.g.,* pavement). Removal of these areas left suitable hard substrates, including spur-and-groove, individual patch reef, aggregate reef, aggregated patch reef, scattered coral/rock, and rock/boulder. For this step, primary information sources were Brainard *et al.* (2008, 2012, 2019), NCCOS (2003, 2005, 2010), PIBHMC (2021), PIFSC (2021), the detailed public comment letters from the Territories (AS DMWR 2021, Guam DOAG 2021, CNMI DLNR 2021), and the American Samoa, Guam, CNMI, PRIA, and Northwestern Hawaiian Islands (NWHI) chapters in Waddell and Clarke (2008). Additional sources for individual units are cited in the unit sections in the Information Report (NMFS, 2023).

(3) For Step 3, starting with the suitable hard substrate areas identified in Step 2, we used water quality information to further delineate suitable vs. unsuitable areas. Unsuitable areas are those with water quality conditions that chronically fall outside of suitable

ranges. For example, some of the areas identified in Step 2 are nearly constantly exposed to pollution such as excessive nutrients, excessive sediment (*i.e.,* more than a thin veneer), or contaminants, making them unsuitable. Generally, such areas occur in enclosed lagoons and inner harbors where there is high runoff and limited water circulation. Outside of such areas, point and non-point sources of pollution generally do not overlap with suitable hard substrates because wastewater outfalls are located on soft substrates beyond the reef slopes, and stormwater and freshwater discharges occur primarily on soft substrates (sand or mud) or unsuitable hard substrates (pavement or rubble) along or near shorelines. For this step, primary information sources were Brainard *et al.* (2008, 2012, 2019), EPA (2021a–f), the detailed public comment letters from the Territories (AS DMWR, 2021, Guam DOAG, 2021, CNMI DLNR, 2021), Territory water quality assessments (AS EPA, 2020, CNMI BECQ, 2018), and sources for individual units cited in the Information Report (NMFS, 2023).

(4) For Step 4, from the suitable areas identified via the above three steps, we removed any artificial substrates and managed areas, because they do not provide the essential feature. ''Managed areas,'' for the purposes of this proposed rule, are specific areas where the substrate has been persistently disturbed by planned management authorized by local, state, or Federal governmental entities at the time of critical habitat designation, and expectations are that the areas will continue to be periodically disturbed by such management. Examples include, but are not necessarily limited to, all harbors and their entrance channels, navigation channels, turning basins, and berthing areas that are periodically dredged or maintained. This only applies to existing artificial substrates and managed areas, not proposed or planned artificial substrates and managed areas.

The resulting specific areas are where we consider the essential feature to be distributed currently within each island unit and depth range, based on the best available information. However, on smaller spatial scales, there are likely locations within the specific areas that lack the essential feature, and the exact locations with and without the essential feature are likely to change somewhat over time in response to changing conditions. Thus, the specific areas described below are intended to delineate areas containing the essential feature, rather than areas made up completely and permanently of the essential feature. As described in detail in the Information Report (NMFS, 2023), these 4 steps were applied to each of the 18 units to delineate the specific areas of proposed coral critical habitat in more detail than in the 2020 proposed rule.

Unoccupied Critical Habitat Areas

Section 3(5)(A)(ii) of the ESA authorizes the designation of specific areas outside the geographical area occupied by the species (referred to here as ''unoccupied areas''), if those areas are determined to be essential for the conservation of the species. Our regulations at 50 CFR 424.12(b)(2) require that we first evaluate areas occupied by the species, and only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species.

To evaluate unoccupied areas that may qualify as critical habitat, we first considered the ranges at the time of listing of the five coral species that occur in areas under U.S. jurisdiction (NMFS 2023). The best available data provides no evidence that those occupied areas have been reduced from the historical ranges for any of the five listed species. Areas within U.S. jurisdiction that are outside the occupied ranges and that could serve as habitat for these species represent <1% of the area of each of their current ranges. Because these species still occupy their historical ranges, the feature essential to their conservation is present in these areas, and the unoccupied areas represent a very small amount of potential habitat, we find the occupied areas adequate to ensure the conservation of the species (NMFS, 2023). Thus, we are not proposing to designate any unoccupied areas within U.S. jurisdiction as critical habitat. The impacts of global climate change-related threats (especially ocean warming and ocean acidification) to the listed corals and their habitats are projected to substantially worsen in the foreseeable future, which may result in range shifts for some or all of the 5 listed coral species, as well as the other 10 species of corals that occur outside U.S. jurisdiction. For the five species occurring within U.S. waters, the areas outside their occupied ranges mostly occur along the northern edges of their ranges, thus ocean warming could make the ocean temperatures of these areas more suitable for the listed species in the foreseeable future. In contrast, ocean acidification is likely to have the opposite effect, causing ocean pH levels along the northern fringes of the species' ranges to become less suitable (Brainard et al. 2011, NMFS 2014). However, it is not possible to determine where such changes are likely to happen, and how they would affect any of the listed species' habitat.

We also considered whether these conclusions would differ under the regulations that were in effect prior to the revisions to the regulations in 50 CFR 424.12(b)(2) in 2019 (see 84 FR 45020, August 27, 2019). We conclude that while our analysis would necessarily differ, the decision not to propose designating any unoccupied areas would not be any different. Because the five coral species each still occupy their historical ranges, the feature essential to their conservation is present in these areas, and unoccupied areas represent a very small amount of potential habitat, we cannot conclude that any unoccupied areas are essential to their conservation.

Application of ESA Section 4(a)(3)(B)(i) (INRMPs)

Section 4(a)(3)(B)(i) of the ESA prohibits designating as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DOD), or designated for its use, that are subject to an Integrated Natural Resources Management Plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary of Commerce determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

Two INRMPs are applicable to the proposed coral critical habitat: (1) The Navy's Joint Region Marianas INRMP (JRM INRMP), finalized and signed in 2019 (DON, 2019a); and (2) the Air Force's INRMP for Wake Island Air Field, Wake Atoll, Kokee Air Force Station, Kauai, Hawaii, and Mt. Kaala Air Force Station, Oahu, Hawaii (Wake INRMP), finalized and signed in 2023 (USAF, 2023a). The JRM INRMP is a composite of management plans for many distinct DOD-controlled areas in the Mariana Islands, including areas in Guam, Tinian, and FDM (DON, 2019a).

Summaries of the analyses in the Information Report (NMFS, 2023) of whether these two INRMPs are likely to benefit the ESA-listed corals or their habitat in Guam and CNMI (JRM INRMP) and Wake (Wake INRMP) are provided below. The analyses address the four considerations outlined in our implementing regulations at 50 CFR 424.12(h). These four considerations are: (1) the extent of the area and essential feature present in the area; (2) The type and frequency of use of the area by the listed species; (3) The

relevant elements of the INRMP in terms of management objectives, activities covered, and best management practices, and the certainty that the relevant elements will be implemented; and (4) The degree to which the relevant elements of the INRMP will protect the habitat (essential feature) from the types of effects that would be addressed through a destruction-or-adverse-modification analysis under section 7 of the ESA.

JRM INRMP—Guam

In Guam, the JRM INRMP encompasses three marine areas (hereafter ''INRMP marine areas'') that include potential proposed coral critical habitat for the one listed coral that occurs in the Mariana Islands, *A. globiceps:* (1) Naval Base Guam—Main Base (NBG Main Base) Submerged Lands; (2) Naval Base Guam—Telecommunications Site (NBG TS) Submerged Lands; and (3) Andersen Air Force Base (AAFB) Submerged Lands. A summary of the analyses of whether the INRMP is likely to benefit the habitat of *A. globiceps* in each of these three INRMP marine areas is provided below, from the full analyses in the Information Report (NMFS, 2023).

With regard to the extent of the area and essential feature present: (1) the NBG Main Base Submerged Lands cover approximately 30,000 acres (12,100 hectares) along the coastline from Orote Peninsula to Asan (described in the JRM INRMP, section 5.3, DON, 2019a); (2) the NBG TS Submerged Lands cover approximately 19,500 acres on the northwestern side of Guam (described in the JRM INRMP, section 8.3, DON, 2019a); and (3) AAFB Submerged Lands cover approximately 26,500 acres (10,700 hectares) of Submerged Lands on the northern side of Guam (described in the JRM INRMP, section 9.3, DON, 2019a). Each of the three INRMP marine areas include extensive habitat for *A. globiceps* (NMFS, 2023). The potential critical habitat within the three INRMP marine areas includes both the substrate and water quality components of the essential feature of coral critical habitat (*i.e.,* characteristics of substrate and water quality to support coral life history, including reproduction, recruitment, growth, and maturation), based on information provided in the Guam section of the Information Report (NMFS, 2023) and the INRMP (DON, 2019a).

With regard to the relevant elements of the INRMP, and the certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant elements of the JRM INRMP for each INRMP marine area include: (1) for the NBG Main Base Submerged Lands, the INRMP includes a Coral Habitat Enhancement Plan (section 5.4.2.1), consisting of eight specific actions in three categories (three monitoring and adaptive management actions, three collaboration with local partners actions, and two reduction of vessel impacts actions); (2) for NBG TS Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan (section 8.4.2.1), consisting of a similar set of eight specific actions as for NBG Main Base; and (3) for AAFB Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan (section 9.4.2.1), consisting of a similar set of seven specific actions as for NBG Main Base, except that there is less focus on reduction in vessel impacts because of the much lower vessel traffic there. The actions, projects, and updates through the end of 2023 are described in detail in the Information Report (NMFS, 2023).

NMFS concludes that the Navy will implement the relevant elements of the JRM INRMP for the previously described three INRMP marine areas for three reasons:

(1) Clear and Recent Documentation—the 2019 JRM INRMP includes Coral Habitat Enhancement plans for INRMP marine areas in Guam, with clear strategies and actions that address the habitat conservation needs of ESA-listed corals within these areas. The JRM INRMP's appendix D also includes annual reports describing how coral conservation efforts had been implemented in the years leading up to the 2019 final INRMP. These coral habitat conservation plans, as well as progress reports from the most recent years (DON, 2019b, 2020, 2021a,b,c,d, 2023), clearly articulate how the Navy is conserving coral habitat within the INRMP marine areas in Guam, and how it is planning to do so in the future.

(2) Demonstration of Good Faith Efforts for Listed Corals—the Navy has already implemented coral habitat conservation projects that are beneficial to ESA-listed corals within some INRMP marine areas in Guam, as described in the INRMP itself and its appendix D (DON, 2019b), as well as progress reports (DON, 2019b, 2020, 2021a,b,c,d, 2023). Many of these projects have been ongoing for several years and are proactive, in that they were not required of the Navy by the ESA.

(3) History of Strong Conservation Work—in our experience working with the Navy on the development of the marine resource components of its 2013 and 2019 final INRMPs (DON, 2013, 2019a), we have found the Navy to be successful at carrying out marine habitat conservation work on Guam, and that it often takes the initiative on conservation efforts whether requested by NMFS or not. For example, many of the coral habitat conservation projects in the 2019 JRM INRMP (DON, 2019a) and progress reports (DON, 2019b, 2020, 2021a,b,c,d, 2023) had already been started by the Navy before corals were listed in 2014, and were being done to improve conservation of marine resources on the island, regardless of whether they were required by Federal statute or not.

The coral habitat enhancement elements of the JRM INRMP described previously are expected to substantially reduce the types of effects within the three INRMP marine areas in Guam that would be addressed through the destruction-or-adverse-modification analysis. The Navy would accomplish this primarily by using the results of its own monitoring program to develop and implement management measures to minimize the impacts of the Navy's actions in Guam on coral habitat within the INRMP marine areas. Thus, implementation of the JRM INRMP is likely to provide substantial protection to the essential feature of coral critical habitat (reproductive, recruitment, growth, and maturation habitat) within the Guam INRMP marine areas from the types of effects that would be addressed through critical habitat consultation (DON, 2021a,b,d, 2023).

JRM INRMP—CNMI

In CNMI, the JRM INRMP encompasses two marine areas that include potential proposed coral critical habitat for the one listed coral that occurs in the Mariana Islands, *A. globiceps:* (1) the Tinian Marine Lease Area (Tinian MLA) Submerged Lands; and (2) the Farallon de Medinilla (FDM) Submerged Lands (DON, 2019a). A summary of the analyses of whether the INRMP is likely to benefit the habitat of *A. globiceps* in each of these two INRMP marine areas is provided below, from the full analyses in the Information Report (NMFS, 2023).

With regard to the extent of the area and essential feature present: (1) the Tinian MLA Submerged Lands cover approximately 47,500 acres (19,200 hectares) surrounding the northern portion of Tinian (described in the JRM INRMP, section 11.3, DON, 2019a); (2) the FDM Submerged Lands consists of approximately 25,000 acres (10,100 hectares) surrounding FDM (described in the JRM INRMP, section 12.3, DON, 2019a). Most or all of the potential critical habitat within the two INRMP marine areas includes both the substrate and water quality components of the

essential feature of coral critical habitat (*i.e.,* characteristics of substrate and water quality to support coral life history, including reproduction, recruitment, growth, and maturation), based on information provided in the Tinian and FDM sections of the Information Report (NMFS, 2023) and the INRMP (DON, 2019a).

With regard to the relevant elements of the INRMP, and the certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant elements of the JRM INRMP for each INRMP marine area include: (1) for the Tinian MLA Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan, consisting of three specific actions to enhance coral habitat by monitoring health and acute impacts (section 11.4.2.1; DON, 2019a); and (2) for the FDM Submerged Lands, the INRMP includes marine habitat management actions, consisting of surveys and mapping of ESA-listed corals, coral reef, and other marine habitats within the area (section 12.4.2; DON, 2019a). The INRMP also includes an assessment of ESA-listed corals, as required by the 2015 biological opinion on the Navy's Mariana Islands Testing and Training program (section 12.4.2.2; DON, 2019a). The actions, projects, and updates through the end of 2021, are described in detail in the Information Report (NMFS, 2023).

NMFS concludes that the Navy will implement these relevant elements of the JRM INRMP for three reasons:

(1) Clear and Recent Documentation—the 2019 JRM INRMP includes Coral Habitat Enhancement plans for INRMP marine areas in CNMI (Tinian MLA, FDM Submerged Lands), with clear strategies and actions that address the habitat conservation needs of ESA-listed corals within these areas. The JRM INRMP's appendix D also includes annual reports describing how coral conservation efforts had been implemented in the years leading up to the 2019 final INRMP. These coral habitat conservation plans, as well as progress reports from the most recent years (DON, 2019b, 2020, 2021a,b,c,d, 2023), clearly articulate how the Navy is conserving coral habitat within the INRMP marine areas in CNMI, and how it will do so in the future.

(2) Demonstration of Good Faith Efforts for Listed Corals—the Navy has already implemented coral projects that have the potential to benefit the habitat of ESA-listed corals within INRMP marine areas in CNMI (Tinian MLA, FDM Submerged Lands). For example, coral species presence and abundance surveys were conducted within the Tinian MLA in 2013 (Tetra Tech, 2014) and 2017 (DON, 2017), and around FDM in 2012 (Smith and Marx, 2016), 2017 (Carilli *et al.,* 2018), and 2022 (DON 2023). These surveys have the potential to benefit the habitat of ESA-listed corals by providing the information needed to better protect these areas in the future.

(3) History of Strong Conservation Work—the Navy has a long history of carrying out successful marine habitat conservation work in the Mariana Islands and often takes the initiative on conservation efforts whether requested by NMFS or not. For example, many of the coral habitat conservation projects in the 2019 JRM INRMP (DON 2019a) and progress reports (DON, 2019b, 2020, 2021a,b,c,d, 2023) had already been started by the Navy before corals were listed in 2014. These projects were conducted to improve the conservation of marine resources on the island, regardless of whether they were required by Federal statute or not. While the majority of these projects have been implemented in Guam rather than CNMI, the JRM INRMP includes many plans for CNMI (as noted above), and the same Navy command (Joint Region Marianas) is responsible for carrying out such work in both Guam and CNMI.

The coral habitat enhancement elements of the JRM INRMP described above will substantially reduce the types of effects within the INRMP marine areas in CNMI that would be addressed through the destruction-or-adverse-modification analysis. The Navy would accomplish this primarily by using the results of its own monitoring program to develop and implement management measures to minimize the impacts of the Navy's actions in CNMI on coral habitat within the INRMP marine areas. Thus, implementation of the JRM INRMP is likely to provide substantial protection to the essential feature of coral critical habitat (reproductive, recruitment, growth, and maturation habitat) within the CNMI INRMP marine areas from the types of effects that would be addressed through critical habitat consultation (DON 2021a,c,d, 2023).

Wake INRMP

On Wake Atoll, the Wake INRMP (USAF, 2023a) encompasses the entire area considered for coral critical habitat for the two listed corals on the atoll, *A. globiceps* and *A. retusa,* as described in the Information Report (NMFS, 2023). A summary of the analyses of whether the INRMP is likely to benefit the habitat of ESA-listed corals in this INRMP marine area is provided below, from the full analyses in the Information Report (NMFS, 2023).

With regard to the extent of the area and essential feature present, the Wake INRMP marine area includes nearly 500,000 acres (202,300 hectares) of Submerged Lands and waters within the lagoon and surrounding the atoll out to 12 nautical miles (22.2 km) from the mean low water line (USAF, 2023a), and thus includes all reef-building corals and coral reefs associated with the atoll. Most or all of the potential critical habitat within the INRMP marine area includes both the substrate and water quality components of the essential feature of coral critical habitat (*i.e.,* reproductive, recruitment, growth, and maturation habitat provided by suitable substrate and suitable water quality), based on information provided in the Wake section of the Information Report (NMFS, 2023) and the INRMP (USAF, 2023a).

With regard to the relevant elements of the INRMP, and the certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant element of the Wake INRMP is the coral conservation component that was added to the INMRP in 2017 (Appendix K, Coral Conservation Actions at Wake Atoll; USAF, 2023a), which is made up of four groups of actions, each of which includes multiple projects: Water quality improvements (six projects), education and outreach (two projects), fisheries management (four projects), and physical DOD presence on Wake Atoll (three projects; USAF, 2023a). The actions, projects, and updates through the end of 2021, are described in detail in the Information Report (NMFS, 2023).

NMFS concludes that the Air Force will implement these relevant elements of the Wake INRMP for three reasons:

(1) Clear and Recent Documentation—the Wake INRMP includes a coral conservation plan (USAF, 2023a) with a 4-pronged strategy (water quality improvement, outreach and education for Wake-based staff, fisheries management, and physical DOD presence on Wake Atoll, *i.e.,* restriction of access and overall natural resource management) that comprehensively addresses the conservation needs of ESA-listed corals on Wake Atoll. This coral conservation plan clearly articulates how U.S. Air Force (USAF) is conserving corals on Wake, and how it will do so in the future. The ongoing implementation of the Wake INRMP is reported via progress updates and reviews (USAF, 2018, 2019, 2021a,b, 2023b).

(2) Demonstration of Good Faith Efforts for Listed Corals—In the years

leading up to the final Wake INRMP (USAF, 2023a), USAF implemented projects on Wake related to each of its 4-pronged coral conservation strategy, as explained in appendix S of the Wake INRMP. For water quality improvement, in 2016 USAF began implementation of both the stormwater pollution prevention and invasive plant control projects. For outreach and education, in 2016 USAF revised the Wake Island Dive Club Charter to further reduce the potential impacts of recreational activities on corals. For fisheries management, in 2017 USAF updated its fishing rules, which are part of the Wake Island Operating Guidance, to prohibit the use of (1) cast nets on the exterior of the atoll, (2) anchoring on coral reef habitat, and (3) and trolling over coral reef habitat. For physical DOD presence on Wake Atoll, in 2016 USAF funded and provided logistical support for a Fish and Wildlife Service (FWS) coral survey that documented two ESA-listed corals on the atoll for the first time. Since 2017, USAF has implemented projects on Wake for each of its 4-pronged coral conservation strategy, as noted above in the 2021 updates, and detailed in the progress updates and reviews (USAF, 2018, 2019, 2021a,b, 2023b).

(3) History of Strong Conservation Work—USAF has a long history of carrying out successful conservation work on Wake and often takes the initiative on conservation efforts whether requested by NMFS or not. For example, many of the projects in the INRMP's coral conservation strategy had already been started by USAF before corals were listed in 2014, and were being done to improve the conservation of marine and terrestrial resources on the atoll, regardless of whether they were required by Federal statute or not. Likewise, in 2016, USAF funded and supported the FWS coral survey of the atoll, leading to the discovery that the two ESA-listed corals occur on the atoll. In addition, USAF has historically been a strong conservation partner with NMFS, supporting a wide variety of marine and terrestrial conservation projects, and actively engaging both agencies in the INRMP planning and implementation process, as described in the progress updates and reviews (USAF, 2018, 2019, 2021a,b, 2023b).

The coral conservation component of the Wake INRMP (Appendix K, Coral Conservation Actions at Wake Atoll; USAF, 2023a) is expected to reduce both direct and indirect impacts to listed corals via minimization or avoidance of recreational impacts (fishing, diving, anchoring), and terrestrial impacts (*i.e.,* run-off from land-based activities), thereby addressing two of the primary threats to listed corals (fishing and land-based sources of pollution). That is, the coral conservation elements of the Wake Atoll INRMP described previously are expected to substantially reduce the types of effects at Wake Atoll that would be addressed through the destruction-or-adverse-modification analysis. Based on the fact that the Wake INRMP's coral conservation strategy is well-designed to reduce impacts to listed corals, and also that recent progress updates and reviews (USAF, 2018, 2019, 2021a,b, 2023b) demonstrate substantial progress with the implementation of the strategy, we determined that the Wake INRMP provides a benefit to listed corals, and their critical habitat (reproductive, recruitment, growth, and maturation habitat).

Conclusion Regarding Areas Subject to INRMPs

Based on the analyses summarized previously and provided in the Information Report (NMFS, 2023), we conclude both the JRM INRMP (DON, 2019a) and the Wake INRMP (USAF, 2023a) provide a conservation benefit to the listed corals and their habitats within all INRMP marine areas on Guam, CNMI, and Wake. Thus, the potential coral critical habitat areas within the INRMP marine areas on Guam, Tinian, FDM, and Wake are ineligible for designation as critical habitat.

Application of ESA Section 4(b)(2)

Section 4(b)(2) of the ESA requires that we consider the economic impact, impact on national security, and any other relevant impact, of designating any particular area as critical habitat. Additionally, the Secretary has the discretion to consider excluding any area from critical habitat if they determine that the benefits of exclusion (that is, avoiding some or all of the impacts that would result from designation) outweigh the benefits of designation based upon the best scientific and commercial data available. The Secretary may not exclude an area from designation if exclusion will result in the extinction of the species.

The following sub-sections summarize the economic, national security, and other relevant impacts analyses in the Information Report (NMFS, 2023) that we projected would result from proposed coral critical habitat. We considered these impacts when deciding whether to exercise our discretion to exclude particular areas from the designation. Both positive and negative impacts were identified and considered (these terms are used interchangeably with benefits and costs, respectively). Impacts were evaluated in quantitative terms where feasible, but qualitative appraisals were used where that is more appropriate.

The primary impacts of a critical habitat designation result from the ESA section 7(a)(2) requirement that Federal agencies ensure that their actions are not likely to result in the destruction or adverse modification of critical habitat and that they consult with NMFS in fulfilling this requirement. The impacts of designating coral critical habitat are only those that would be in addition to the impacts of listing (*i.e.,* incremental impacts). The distribution of listed corals within critical habitat strongly influences the extent of incremental impacts. That is, the more colonies of listed corals that are distributed throughout coral critical habitat, the lower the proportion of Federal actions that would affect critical habitat but not listed corals, and thus the lower the incremental impacts of critical habitat designation. As described in section 3.3.19 of the Information Report (NMFS, 2023), colonies of listed corals are generally distributed throughout the specific areas being considered for proposed coral critical habitat, thus the incremental impacts are expected to be quite low.

Summaries of the economic, national security, and other relevant impact analyses in the Information Report (NMFS, 2023) are provided below. The analyses follow the guidance for 4(b)(2) analyses provided in our 2016 policy (81 FR 7226, February 11, 2016) and regulations at 50 CFR 424.19.

4(b)(2) Economic Impact Analysis

The economic impacts of designating the areas identified as coral critical habitat are analyzed in the full 4(b)(2) Economic Impact Analysis document, completed in late 2021, which is appendix C of the Information Report (NMFS, 2023). Economic impacts are projected for the 10-year period 2022–2031, and uncertainty is accounted for by using low-end and high-end scenarios to estimate incremental impacts. The Economic Impact Analysis Report (NMFS, 2023, appendix C) presents economic impacts in terms of present value versus annualized costs. For example, table 17 of the report summarizes the low-end estimated cost of coral critical habitat as $373,171 in terms of the present value of the total cost over the 10-yr period of 2022–2031, with an estimated annualized cost of $53,131 over that 10-yr period. Present value over the 10-year period is not

simply 10 times the annualized cost because present value represents the sum of a series of past or future cash flows discounted at a specified discount rate (in this case, 7 percent) and expressed in constant dollars, whereas annualized cost provides a comparison of impacts across activities with varying forecast periods (NMFS, 2023, appendix C).

For the low-end scenario, total incremental costs over the 10-year period are estimated at $373,171 for all jurisdictions combined or $53,131 annualized. These are entirely administrative costs since the low-end scenario assumes that no project modifications would be required. For the high-end scenario, total incremental costs over the 10-year period are estimated at $6,815,860 for all jurisdictions combined or $970,425 annualized. Of these costs, 95 percent are derived from project modifications because, for purposes of this analysis, the high-end scenario assumes that 100 percent of section 7 consultations will be formal consultations that result in the need for project modifications to avoid destruction or adverse modification of the critical habitat. The jurisdiction with the highest economic impacts in both scenarios is Guam, due to the relatively high number of expected consultations there (NMFS, 2023).

While the low-end vs. high-end scenarios are useful for illustrating the range of potential economic impacts, the following points are relevant to interpreting the results:

(1) Both scenarios assumed that proposed coral critical habitat would be 0–50 m depth around all island units considered in proposed coral critical habitat; however, proposed coral critical habitat is 0–50 m depth on just one island (Tutuila) and 0–20 m, 0–12 m, and 0–10 m on the others.

(2) Colonies of listed corals occur within all specific areas being considered for proposed coral critical habitat (NMFS, 2023, appendix A), thus reducing incremental impacts. That is, since colonies of listed corals occur in all specific areas of proposed coral critical habitat, there would be a low proportion of future Federal actions that would affect critical habitat but not listed corals. As the proposed coral critical habitat will not include extensive areas where listed coral colonies are absent, the incremental impacts of proposed coral critical habitat are likely to be quite low, which minimizes economic impacts.

(3) A comparison of projected vs. actual consultations in 2016–2019 was included in the economic analysis done for the 2020 proposed coral critical habitat rule (NMFS 2020, appendix B), which showed that three times more formal consultations were projected in the high-end scenario than actually occurred. That is, the reality of consultations was more similar to the low-end scenario than the high-end scenario.

For these reasons, it is reasonable to conclude that the actual economic impacts are likely to be much closer to those projected in the low-end scenario than the high-end scenario. In addition, economic benefits would be relatively high in the high-end scenario (because project modifications would provide better protection of coral reef ecosystems, which produce economic benefits, as described in section 5.1.6 of the Information Report (NMFS, 2023), but lower in the low-end scenario (because there would be no project modifications, and thus no increased protection of coral reef ecosystems).

4(b)(2) National Security Impact Analysis

We received a request from the Department of the Navy (Navy) to exclude one site based on national security impacts: The portion of the Navy's Ritidian Point Surface Danger Zone (SDZ) Complex outside of DOD Submerged Lands on Guam. For this site, we weighed the national security impacts of designating the site as critical habitat against the conservation benefits to the listed corals of designating the site as critical habitat. If impacts to national security outweigh the benefits of including an area in the designation, the Secretary may exercise her discretion to exclude that particular area from critical habitat. If the benefits of including the area in the designation outweigh the impacts to national security, however, the site cannot be considered for exclusion from critical habitat (81 FR 7226, February 11, 2016).

The Ritidian Point SDZ complex overlaps with a small area of forereef identified for potential designation as coral critical habitat. The area is 0–12 m of depth and consists primarily of spur-and-groove and aggregate reef that provides high quality coral habitat. A species-level coral survey conducted in 2021 at this site indicated that *A. globiceps* was present, finding a total of four colonies along eight 50-m transects at 6 m depth within forereef habitat at the site. In contrast, a species-level coral survey conducted in 2006 at this site did not find any *A. globiceps* colonies along a different set of eight 50-m transects between 1 and 20 m within forereef and reef flat habitat (NMFS, 2023).

National security impacts depend on the additional section 7 requirements that would result from the coral critical habitat, above and beyond those already required to avoid jeopardizing the continued existence of any listed species or avoid destruction or adverse modification of other, designated critical habitats (*i.e.* incremental impacts). The Navy noted that the Ritidian Point SDZ complex supports training at the Marine Corps Live Fire Training Range Complex (LFTRC) at AAFB, and construction of new facilities (*e.g.,* range administration building, range maintenance building, and observation towers) at AAFB, to meet the individual weapons training/qualification requirements of the Marine Corps. This SDZ is expected to be operational for 32 weeks per year and extends approximately 2 miles over open water in the event stray bullets go over the berm and into the ocean. If this occurs, the bullets will settle on the seafloor (NMFS, 2023).

The Navy stated that designation of the marine component of this site as coral critical habitat would result in limitations on live fire training at LFTRC. The Navy explained that such limitations would occur because limited staff time and resources would be diverted to preparing additional documents required to implement activities in critical habitat areas from work required on other vital environmental items. In 2021 and 2022, the Navy confirmed that this information is still applicable to the site. Because many training and construction activities are planned at LFTRC adjacent to this marine area, the listed coral *A. globiceps* occurs there, and the planned activities have the potential to affect this listed species, ESA section 7 consultations would likely be necessary whether critical habitat is designated or not. That is, the additional consultation requirement above and beyond what would already be required by the fact that listed corals occur at the site is not expected to be substantial. Also, the additional consultation for critical habitat would be for activities that are planned in advance, and thus the additional section 7 consultation workload would not be unpredictable but rather could be anticipated and managed ahead of time.

The Navy noted that the individual live fire training for Marine Corps personnel at the LFTRC on Guam is a prerequisite for conducting unit level and combined level training. The Navy further explained that without the qualification of these live fire training events, individuals and small teams are not capable of conducting larger unit

collective events, and that the LFTRC provides the necessary foundation for which training progression is built upon. Plans are in place to considerably expand LFTRC in anticipation of growing Marine Corps training needs. No other facility on Guam or elsewhere in the Mariana Islands provides this type of training. In 2021 and 2022, the Navy confirmed that this information is still applicable to the site (NMFS, 2023).

In determining benefits to the conservation of ESA-listed corals we considered whether designation of critical habitat at the particular site would lead to additional conservation of the species beyond what is already provided by the species' listing. The potential for additional conservation at a given site is a function of the listed corals' use of the area, the level of protection already provided by existing management (*e.g.,* the site is entirely within Guam National Wildlife Refuge), and the likelihood of non-DOD actions that are likely to affect the area and that are subject to the consultation requirements of section 7.

As elsewhere on Guam, the coral reef habitat within the area being considered for proposed coral critical habitat is made up of forereef from 0—12 m depth, consisting primarily of spur-and-groove and aggregate reef. As noted above, *A. globiceps* occurs at this site. However, colonies of the species may die off in response to natural disturbances and not reappear for a few years, which may be why the 2021 survey found *A. globiceps* there but the 2006 survey did not despite surveying within the same habitat and depth range. Such mortality and recovery and associated disappearance and reappearance of coral populations at any given site is a normal response to natural disturbance. Critical habitat protects the essential feature whether colonies of the listed coral species occur at the site at the time of consultation or not.

The area being considered for potential designation as coral critical habitat is entirely within U.S. Fish and Wildlife Service (USFWS) Submerged Lands, which forms the marine component of the Guam National Wildlife Refuge (NWR), and is managed according to the Guam NWR Comprehensive Conservation Plan. The plan includes Strategies to Restore, Protect, and Maintain Native Marine Communities, such as marine debris removal and area closures. The site is also entirely within Essential Fish Habitat (EFH) for coral reef ecosystems, but EFH protections are not mandatory (NMFS, 2023).

It is possible that non-DOD Federal actions will be proposed within this site that could affect the essential feature (*e.g.,* actions proposed by USFWS), but that would no longer be subject to the critical habitat provision if the particular area were excluded from the designation. When the site is not closed by the SDZ, non-DOD actions could potentially occur there, for example those permitted or carried out by USFWS. Although such actions would presumably be consistent with the Guam NWR Comprehensive Conservation Plan (USFWS 2009), they may affect the essential feature (NMFS, 2023).

Based on the considerations described above, we conclude that the impacts to national security of including this area within critical habitat do not outweigh the conservation benefits to the listed corals, and thus do not propose to exclude the Ritidian Point SDZ complex from proposed coral critical habitat designation. The most important factors supporting this recommendation are: (1) the national security impacts of coral critical habitat are unlikely to be either substantial or unpredictable because listed corals are known to occur at this site at least some of the time, meaning that the Navy would already be conducting section 7 consultations on listed corals for any of their activities that may affect listed corals at this site even without critical habitat, resulting in little additional consultation work; and (2) the conservation benefits of coral critical habitat could be considerable because critical habitat would provide additional protection of the high quality essential feature that is found throughout the area from future proposed Federal actions (NMFS, 2023).

Other Relevant Impacts

Other relevant impacts include the benefits of critical habitat designation and impacts on governmental or private entities that are implementing existing management plans that provide benefits to the listed species. The three main types of benefits of critical habitat designation are increased protection of the essential feature from Federal actions, ecosystem service benefits of coral reef conservation, and education and awareness.

Critical habitat is habitat needed to support recovery of listed species. That is, the most direct benefits of the critical habitat designation stem from the increased protection of the essential feature from Federal actions. While listed corals are generally distributed throughout the specific areas, there are still many locations within the specific areas that lack colonies of listed corals at any given point in time due to natural spatial and temporal fluctuations of coral colony presence. That is, individual colonies of listed corals may decrease or disappear from particular locations in response to local disturbances, then return and increase as local conditions improve. Such dynamic spatial and temporal fluctuations in the distribution of colonies of listed corals within the specific areas is a natural process. Critical habitat thus protects the essential feature in locations and during times when specific areas lack colonies of listed corals and Federal actions are proposed at that location (NMFS, 2023).

Overall, coral reef ecosystems, including those comprising populations of the listed corals, provide important ecosystem services of value to individuals, communities, and economies. These include recreational opportunities (and associated tourism spending in the regional economy), habitat and nursery functions for recreationally and commercially valuable fish species, shoreline protection in the form of wave attenuation and reduced beach erosion, and climate stabilization via carbon sequestration. As of 2021, the total economic value of coral reefs in the three U.S. Pacific Islands jurisdictions where the great majority of critical habitat is being proposed is (1) American Samoa—$13.4 million/year, (2) Guam—$165.0 million/year, and (3) CNMI—$60.4 million/year (NMFS, 2023). Efforts to conserve the listed corals also benefit the broader reef ecosystems, thereby preserving or improving these ecosystem services and values (NOAA Coral Reef Conservation Program, 2013). While we cannot quantify the precise economic benefits of designating critical habitat, providing these values gives an indication of the value of conserving coral habitat.

There is the potential for education and awareness benefits arising from the critical habitat designation, stemming from entities that engage in section 7 consultations, and from members of the general public interested in coral conservation. Entities that engage in section 7 consultations may alter their activities to benefit the species or essential feature because they were made aware of the critical habitat designation through either the section 7 consultation process or the original listings. Members of the public may engage in similar efforts because they learned of the critical habitat designation through outreach materials (NMFS, 2023).

Impacts may also occur to governmental or private entities that are

implementing existing management plans that provide benefits to the listed species, although such potential impacts would be limited to actions that have a Federal nexus and affect critical habitat.

There are a large number of Federal marine protected areas in American Samoa, Guam, CNMI, PRIA, and NWHI where coral critical habitat is being proposed, and many of these jurisdictions have draft or proposed management plans (NMFS, 2023). Impacts of critical habitat designation on the agencies responsible for natural resource management planning of these areas (*e.g.,* the National Park Service, USFWS, and Territorial natural resources management agencies), depend on the type and number of section 7 consultations that may result from the designation in the areas covered by those plans, as well as any potential project modifications recommended by these consultations. Negative impacts to these entities could result if the critical habitat designation interferes with these agencies' ability to provide for the conservation of the species, or otherwise hampers the management of these areas.

Existing or proposed management plans in the marine protected areas and their associated regulations protect existing coral reef resources, but they may not specifically protect the substrate and water quality components of the essential feature for purposes of increasing listed coral abundance and eventual recovery. However, section 7 consultations on the implementation of these Federal marine protected area plans over the next 10 years are not expected to result in incremental project modifications, thus any section 7 impacts will likely be limited to administrative costs (NMFS, 2023, appendix C).

Conclusions for Section 4(b)(2)

We are not exercising our discretion to exclude any areas from the proposed coral critical habitat based on economic or national security impacts. As summarized in the *4(b)(2) Economic Impact Analysis* section, the economic impacts of the proposed coral critical habitat are likely to be low, even on the islands with concentrated economic activity (Tutuila, Guam, Saipan). Since these are the three units where most future proposed Federal actions that could affect critical habitat are expected (NMFS, 2023, appendix C), the conservation benefits of critical habitat are the greatest in these three units. Thus, economic impacts do not outweigh conservation benefits. Likewise, as summarized in the *4(b)(2) National Security Impact Analysis* section, the national security impacts of the proposed coral critical habitat on the one requested exclusion site, the Navy's Ritidian Point Surface Danger Zone complex in Guam, are not expected to outweigh the conservation benefits of designating critical habitat.

Proposed Critical Habitat Designations

We are proposing to designate critical habitat for 5 listed coral species around 16 islands in 5 U.S. Pacific Islands jurisdictions. For *A. globiceps,* specific areas around all 16 islands are proposed, including 4 in American Samoa, 1 in Guam, 9 in CNMI, 3 in PRIA, and 1 in Hawaii. The depth ranges of the specific areas for *A. globiceps* are 0–20 m (3 islands), 0–12 m (9 islands), and 0–10 m (4 islands). For *A. retusa,* specific areas around three islands are proposed, all of which are in American Samoa. The depth ranges of the specific areas for *A. retusa* are 0–20 m on all three islands. For *A. speciosa* and *E. paradivisa,* specific areas around Tutuila and its offshore banks in American Samoa are proposed. The depth ranges of the specific areas for *A. speciosa* and *E. paradivisa* are 20–50 m. For *I. crateriformis,* specific areas around three islands are proposed, all of which are in American Samoa. The depth ranges of the specific areas for *I. crateriformis* are 0–20 m on all three islands (table 4). The 4(a)(3)(B)(i) INRMP analyses found that the entire areas around FDM and Wake Atoll, several areas off of Guam, and most of Tinian are ineligible for proposed coral critical habitat. Maps of the proposed critical habitat for each of the listed species around each of the 16 islands are provided at the end of this rulemaking (table 4).

TABLE 4—THE 16 ISLAND UNITS THAT CONTAIN PROPOSED CRITICAL HABITAT FOR THE 5 LISTED CORAL SPECIES

[For each species, depth ranges in meters and figure numbers ("Fig.") for the maps are shown. Maps showing areas that were deemed ineligible for designation of critical habitat by the 4(a)(3)(B)(i) INRMP analyses are also noted.]

Island (unit)	*A. globiceps*		*A. retusa*		*A. speciosa*		*E. paradivisa*		*I. crateriformis*		4(a)(3)(B)(i)
	Depth	Fig.	Depth	Fig.	Depth	Fig.	Depth	Fig.	Depth	Fig.	Fig.
Tutuila and Offshore Banks	0–20	1	0–20	1	20–50	2	20–50	2	0–20	1	
Ofu-Olosega	0–20	3	0–20	3					0–20	3	
Ta'u	0–20	4							0–20	4	
Rose Atoll	0–10	5	0–20	5							
Guam	0–12	6									6
Rota	0–12	7									
Aguijan	0–12	8									
Tinian	0–12	9									9
Saipan	0–12	10									
Alamagan	0–12	11									
Pagan	0–12	12									
Maug Islands	0–12	13									
Uracas	0–12	14									
Palmyra Atoll	0–10	15									
Johnston Atoll	0–10	16									
FFS	0–10	17									

Effects of Critical Habitat Designations

Section 7(a)(2) of the ESA requires Federal agencies, including NMFS, to ensure that any action authorized, funded, or carried out by the agency does not jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat. When a species is listed or critical habitat is designated, Federal agencies must consult with NMFS on any agency actions to be conducted in an area where the species is present and that may affect the species or its critical habitat. During formal consultation, NMFS would evaluate the agency's action to determine whether the action may adversely affect listed species or designated critical habitat and issue its

findings in a biological opinion. If NMFS concludes in the biological opinion that the proposed agency action would likely result in the destruction or adverse modification of designated critical habitat, NMFS would identify any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives are defined in 50 CFR 402.02 as alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. If NMFS concludes in the biological opinion that the proposed agency action would not likely result in the destruction or adverse modification of designated critical habitat, NMFS may provide discretionary conservation recommendations.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinitiate consultation on previously reviewed actions in instances in which (1) critical habitat is subsequently designated, or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of consultation or to conference with NMFS on actions for which formal consultation has been completed, if those actions may adversely modify or destroy designated critical habitat or adversely modify or destroy proposed critical habitat, respectively.

Activities That May Be Affected

Section 4(b)(8) of the ESA requires that we describe briefly, and evaluate in any proposed or final regulation to designate critical habitat, those activities that may adversely modify such habitat or that may be affected by such designation. A wide variety of Federal activities may require ESA section 7 consultation because they may affect the essential feature of critical habitat (*i.e.,* suitable substrate and suitable water quality). Specific future activities would need to be evaluated with respect to their potential to destroy or adversely modify critical habitat, in addition to their potential to affect and jeopardize the continued existence of listed species. For example, activities may adversely modify the essential feature by removing or altering the substrate or reducing water clarity through turbidity. These activities would require ESA section 7 consultation when they are authorized, funded, or carried out by a Federal agency. Non-Federal entities may also be affected by these proposed critical habitat designations if they are undertaking a project that requires a Federal permit or receives Federal funding. Categories of activities that may be affected by the designations include in-water and coastal construction, dredging and disposal, water quality and discharges, fishery management, military activities, shipwreck and marine debris removal, scientific research and monitoring, aquaculture, protected area management, and beach nourishment/shoreline protection. Further information is provided in the Economic Impact Analysis in our Information Report (NMFS, 2023, appendix C). Questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat should be directed to us (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Public Comments Solicited

We request that interested persons submit comments, information, and suggestions concerning this proposed rule during the comment period (see **DATES**). We are soliciting comments or suggestions from the public, other concerned governments and agencies, the scientific community, industry, or any other interested party concerning this proposed rule, including any foreseeable economic, national security, or other relevant impact resulting from the proposed designations. We are seeking comments on the changes in this proposed rule from the 2020 proposed rule, including the following: (1) development of the methodology for using records of listed coral species to determine their occupied areas for critical habitat; (2) changes to the occupied areas for the listed coral species; (3) changes to the depth ranges for the listed coral species; and (4) other changes including refinement of critical habitat boundaries. These changes are summarized in the Summary of Changes From the 2020 Proposed Rule above and described in detail in the Information Report (NMFS, 2023). You may submit your comments and materials concerning this proposal by any one of several methods (see **ADDRESSES**). Copies of the proposed rule and supporting documentation are available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* or upon request (see **FOR FURTHER INFORMATION CONTACT**). We will consider all comments pertaining to this designation received during the comment period in preparing the final rule. Accordingly, the final designation may differ from this proposal.

References Cited

A complete list of all references cited in this rulemaking is available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* or upon request (see **FOR FURTHER INFORMATION CONTACT**). In addition, PDF copies of all cited documents are available upon request from the NMFS Pacific Islands Regional Office in Honolulu, HI (see **ADDRESSES**).

Information Quality Act and Peer Review

The data and analyses supporting this action have undergone a predissemination review and have been determined to be in compliance with applicable information quality guidelines implementing the Information Quality Act (section 515 of Pub. L. 106–554). On December 16, 2004, OMB issued its Final Information Quality Bulletin for Peer Review (Bulletin). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664), and went into effect on June 16, 2005. The primary purpose of the Bulletin is to improve the quality and credibility of scientific information disseminated by the Federal Government by requiring peer review of ''influential scientific information'' and ''highly influential scientific information'' prior to public dissemination. ''Influential scientific information'' is defined as information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The Bulletin provides agencies broad discretion in determining the appropriate process and level of peer review. Stricter standards were established for the peer review of highly influential scientific assessments, defined as information whose dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.

The information in the Critical Habitat Information Report (NMFS, 2023) and its appendices was

considered influential scientific information and subject to peer review. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the the Critical Habitat Information Report (NMFS, 2023) and its appendices. The resulting Peer Review Reports are available on our website *https://www.noaa.gov/information-technology/endangered-species-act-critical-habitat-designation-for-7-indo-pacific-corals-information-report.*

Classification

Takings (Executive Order 12630)

Under E.O. 12630, Federal agencies must consider the effects of their actions on constitutionally protected private property rights and avoid unnecessary takings of private property. A taking of property includes actions that result in physical invasion or occupancy of private property and regulations imposed on private property that substantially affect its value or use. In accordance with E.O. 12630, this proposed rule would not have significant takings implications, because it does not include, occupy or invade private property or otherwise affect the value or use of private property to qualify as a taking. A takings implication assessment is not required.

Regulatory Planning and Review (E.O.s 12866, 14094, 13563)

This rulemaking has been determined to be significant for purposes of E.O. 12866 as amended by Executive Order 14094. Executive Order 14094, which amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O 13563, states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). 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 have developed this proposed rule in a manner consistent with these requirements.

A draft economic impact analysis report, which has been prepared as part of the Information Report (see appendix C of NMFS, 2023), considers the economic costs and benefits of this proposed critical habitat designation and alternatives to this rulemaking as required under E.O. 12866. Based on the impact analysis report, low-end total incremental costs over the 10-year period are estimated at $373,171 for all jurisdictions combined or $53,131 annualized. These are 100 percent administrative costs since the low-end scenario assumes that no project modifications will be required. For the high-end, total incremental costs over the 10-year period are estimated at $6,815,860 for all jurisdictions combined or $970,425 annualized. Of these costs, 95 percent are derived from project modifications since the high-end scenario assumes that 100 percent of section 7 consultations will be formal. The jurisdiction with the highest economic impacts in both scenarios is Guam, due to the relatively high number of expected consultations there (NMFS, 2023, appendix C).

As explained under the *4(b)(2) Economic Impact Analysis,* we find that the actual economic impacts are likely to be much closer to the low-end scenario's projections than the high-end scenario's projections. In addition, economic benefits would be relatively high in the high-end scenario (because project modifications would provide better protection of coral reef ecosystems, which produce economic benefits), but non-existent in the low-end scenario (because there would be no project modifications, and thus no increased protection of coral reef ecosystems). We conclude that the economic impacts of the proposed coral critical habitat are likely to be much closer to those projected by the low-end scenario than the high-end scenario, and also that there would be low economic benefits. That is, we find that the economic analysis and IRFA support the conclusion that the proposed coral critical habitat would have low economic effects on small entities. A proposed Economic Impact Analysis Report (appendix C of the Information Report; NMFS, 2023) and Final ESA section 4(b)(2) Report (*i.e.,* the 4(b)(2) section of the Information Report; NMFS, 2023) have been prepared to support the exclusion process under section 4(b)(2) of the ESA and our consideration of alternatives to this rulemaking. These supporting documents are available at the link provided in **ADDRESSES**, or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Federalism (E.O. 13132)

The E.O. on Federalism, Executive Order 13132, requires agencies to take into account any federalism impacts of regulations under development. It includes specific consultation directives for situations in which a regulation may preempt State law or impose substantial direct compliance costs on State and local governments (unless required by statute). Pursuant to E.O. 13132, we determined that this proposed rule does not have significant federalism effects and that a federalism assessment is not required. In keeping with Department of Commerce policies and consistent with ESA regulations at 50 CFR 424.16(c)(1)(ii), we requested information for this rulemaking from the appropriate marine resources agencies in American Samoa, Guam, CNMI, PRIA, and Hawaii. The designation may have some benefit to State and local resource agencies in that the rule more clearly defines the physical and biological feature essential to the conservation of the species and the areas in which that feature is found. While this designation would not alter where and what non-federally sponsored activities may occur, it may assist local governments in long-range planning (rather than waiting for case-by-case ESA section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests only on the Federal agency.

Energy Supply, Distribution, and Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking an action expected to lead to the promulgation of a final rule or regulation that is a significant regulatory action under E.O. 12866 and is likely to have a significant adverse effect on the supply, distribution, or use of energy. OMB Guidance on Implementing E.O. 13211 (July 13, 2001) states that significant adverse effects could include any of the following outcomes compared to a world without the regulatory action under consideration: (1) reductions in crude oil supply in excess of 10,000 barrels per day; (2) reductions in fuel production in excess of 4,000 barrels per day; (3) reductions in coal production in excess of 5 million tons (4.5 million metric tons) per year;

(4) reductions in natural gas production in excess of 25 million cubic feet (708,000 cubic meters) per year; (5) reductions in electricity production in excess of 1 billion kilowatt-hours per year or in excess of 500 megawatts of installed capacity; (6) increases in energy use required by the regulatory action that exceed any of the thresholds previously described; (7) increases in the cost of energy production in excess of 1 percent; (8) increases in the cost of energy distribution in excess of 1 percent; or (9) other similarly adverse outcomes. A regulatory action could also have significant adverse effects if it (1) adversely affects in a material way the productivity, competition, or prices in the energy sector; (2) adversely affects in a material way productivity, competition, or prices within a region; (3) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency regarding energy; or (4) raises novel legal or policy issues adversely affecting the supply, distribution or use of energy arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866 and 13211.

The economic impacts of this rulemaking are analyzed in the full 4(b)(2) Economic Impact Analysis, which is appendix C of the Information Report (NMFS, 2023). Based on the results of that analysis, the economic impacts on energy supply, distribution, and use would either be non-existent or far below the above thresholds. Thus, we have determined that this rulemaking will not have a significant adverse effect on the supply, distribution, or use of energy. Therefore, we have not prepared a Statement of Energy Effects.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

We prepared an Initial Regulatory Flexibility Analysis (IRFA) pursuant to section 603 of the Regulatory Flexibility Act (RFA). The IRFA analyzes the impacts to small entities that may be affected by the proposed designation and is included as appendix D of the Information Report (NMFS, 2023), which is available at the link provided in **ADDRESSES**, or upon request (see **FOR FURTHER INFORMATION CONTACT**). We welcome public comment on the IRFA, which is summarized below, as required by section 603 of the RFA.

The IRFA uses the best available information to identify the potential impacts of designating critical habitat on small entities. However, uncertainty regarding the extent to which impacts of the proposed designation would be allocated between large and small entities complicates quantification of impacts specifically borne by small entities. Absent specific knowledge regarding which small entities may be involved in consultations with NMFS over the next ten years, this analysis relies on industry- and location-specific information on small businesses with North American Classification System (NAICS) codes that were identified as relevant to the major activity categories considered in the economic analysis and which operate within counties or territories that share a coastline with the proposed critical habitat. Activities considered in the draft economic report and the IRFA include in-water and coastal construction, dredging and disposal, water quality and discharges, fishery management, military activities, shipwreck and marine debris removal, scientific research and monitoring, aquaculture, protected area management, and beach nourishment/shoreline protection.

Information presented in section 4.0 of the Economic Impact Analysis Report demonstrates the lack of third-party involvement in consultations on the effects of Federal fishery management, protected area management, shipwreck removal, scientific research and monitoring, and military activities on ESA-listed marine species within the island units considered for proposed coral critical habitat in the five jurisdictions. Unlike consultations on in-water and coastal construction and dredging projects, these consultations are conducted directly between NMFS and the Federal action agency with no third-party involvement. Each of these five categories of consultation is represented in the consultations completed in 2005–2020 that were reviewed for the economic impact analysis, and third parties were not involved in any of them. As discussed in the IRFA and section 6 Economic Impact Analysis Report, consultations on water quality management include inter-agency consultations on regional water quality standards, which do not involve third parties, and project-specific consultations regarding point source water pollution, such as National Pollutant Discharge Elimination System (NPDES) permits issued to third parties in American Samoa, Guam, and CNMI. The third parties issued NPDES permits are either businesses or territorial or commonwealth governments that do not qualify as small entities. In addition, because no section 7 consultations on beach nourishment and shoreline protection projects occurred within the historical time frame selected for the economic impact analysis, no section 7 consultations on such projects were projected over the next ten years. As a result, no incremental costs are assigned to small entities for these activities. While consultations on aquaculture projects have the potential to involve third parties, the potential economic impacts to third parties are considered *de minimis.* Moreover, all of the historical aquaculture projects that resulted in consultations considered in the economic impact analysis were sponsored by public entities, none of which qualify as small entities.

Consultations on in-water and coastal construction and dredging and disposal (as determined by the 4(b)(2) Economic Impact Analysis Report, which is appendix C of the Information Report (NMFS, 2023)), all have the potential to involve third parties, such as recipients of Clean Water Act section 404 permits. These activities were combined into one broad industry category that may experience impacts to small entities: In-Water and Coastal Construction and Dredging. NAICS industries that are relevant to in-water and coastal construction and dredging activities include:

- Water and Sewer Line and Related Structures Construction (NAICS 237110).
- Highway, Street, and Bridge Construction (NAICS 237310).
- Other Heavy and Civil Engineering Construction (237990).
- Dredging and Surface Cleanup (NAICS 237990).

The IRFA relies on the estimated incremental impacts resulting from the proposed critical habitat designation, as described in section 6.0 of the Economic Impact Analysis Report. To be consistent with this analysis, the IRFA provides low-end and high-end estimates of the impacts to small entities. The IRFA estimates the impacts of the proposed coral critical habitat in terms of the percentage of revenues per small entity, which ranged from 0.20 percent under the low-end (IRFA, table 1) to 36.9 percent under the high-end (IRFA, table 2). These impacts are anticipated to be borne by the small entities engaged in in-water and coastal construction and dredging that consult with NMFS regarding the listed Indo-Pacific coral species critical habitat in the next 10 years. Impacts are presented in the IRFA for each of the three U.S. Pacific jurisdictional areas where one or more of the listed coral species occur and where small businesses engaged in the relevant activities have been identified—American Samoa, Guam, and CNMI. According to section 6.0 of the Economic Impact Analysis Report, two or fewer consultations on in-water

and coastal construction projects are forecasted to occur in both the NWHI and the PRIA. However, because no businesses are located in either the NWHI or the PRIA, it is not possible to determine what small entities, if any, would be affected. In any case, given that few consultations are expected to occur and that these consultations are likely to be informal, the potential costs to small entities associated with in-water and coastal construction projects in the NWHI and the PRIA are anticipated to be negligible.

The low-end estimate assumes no incremental project modifications occur because baseline permit conditions/regulations would provide sufficient protection to avoid adverse modification of critical habitat. Impacts to small entities are thus assumed to be due solely to the additional administrative costs of considering the potential for adverse effects to critical habitat during section 7 consultations. In addition, the low-end estimate assumes that trends in the frequency of informal consultations over the next 10 years will resemble those of the past 10 years (section 6.0 of the Economic Impact Analysis Report). The low-end estimate of total annualized impacts to small entities is $4,675 (IRFA, table 1).

The high-end estimate of the impacts to small entities assumes that all future projects related to in-water and coastal construction and dredging will require formal consultations and that there will be incremental project modification costs for all these future projects (section 6.0 of the Economic Impact Analysis Report). In order to present a conservative estimate of the impacts to small entities (*i.e.,* an estimate more likely to overstate impacts than understate them), the IRFA assumes that all project modification costs are borne by third parties. The high-end estimate of total annualized impacts to small entities is $872,331 (IRFA, table 1).

Given the uncertainty regarding which small entities in a given industry will need to consult with NMFS, this analysis estimates impacts to small entities under two different scenarios for both the low-end and high-end estimates. These scenarios are intended to reflect the range of uncertainty regarding the number of small entities that may be affected by the designation and the potential impacts of critical habitat designation on their annual revenues.

Under Scenario 1, the IRFA assumes that all third parties involved in future consultations are small entities and that incremental impacts for each territory or commonwealth (American Samoa, Guam, and CNMI) are distributed evenly across all of the entities in the respective territory or commonwealth. Scenario 1 accordingly reflects a high estimate of the number of potentially affected small entities (14 for both the low-end and high-end estimates) and a low estimate of the potential effect in terms of percent of revenue, except for American Samoa, where it is estimated that only one entity is conducting construction activities in the areas considered for critical habitat. The assumption under Scenario 1 is that 14 small entities will be involved in consultation annually reflects the forecast that approximately 14 consultations will occur annually on construction activities involving third parties. This assumes that each consultation on construction activities involves a unique small entity, including 1 small entity in American Samoa, 10 small entities in Guam, and 3 small entities in CNMI. For the low-end estimate, this analysis anticipates that approximately 14 small entities will incur $4,675 in annualized costs under Scenario 1, including $1,244 in costs to the America Samoa-based small entity, $281 in costs per Guam-based small entity, and $235 in costs per CNMI-based small entity. Annualized impacts of the rulemaking are estimated to make up less than 1 percent of average annual revenues of approximately $2.36 million for each affected small entity.[1] For the high-end estimate, this analysis anticipates that 14 small entities will incur $872,331 in annualized costs under Scenario 1, including $254,356 in costs to the America Samoa-based small entity, $48,953 in costs per Guam-based small entity, and $47,751 in costs per CNMI-based small entity. Annualized impacts of the rulemaking are estimated to make up 17.0 percent of average annual revenues of $1.5 million for the American Samoa-based entity, 2.1 percent of average annual revenues of approximately $2.37 million for Guam-based small entities, and 1.9 percent of average annual revenues of $2.47 million for CNMI-based small entities.

Under Scenario 2, this analysis assumes that all third parties participating in future consultations are small and that costs associated with each consultation action are borne each year by a single small entity within the potentially impacted construction industries. This method likely understates the number of small entities affected and overstates the likely impacts on the impacted small entity. For the low-end estimate, this analysis anticipates that a single small entity will bear $4,675 in annualized costs. These annualized impacts make up less than 1 percent of estimated average annual revenues of $2.36 million for the impacted small entity. For the high-end estimate, this analysis anticipates that a single small entity will bear $872,331 in annualized costs. These impacts represent approximately 37 percent of estimated average annual revenues for the impacted small entity.

As explained under *4(b)(2) Economic Impact Analysis,* we conclude that the actual economic impacts are likely to be much closer to the low-end scenario's projections than the high-end scenario's projections. In addition, economic benefits would be relatively high in the high-end scenario (because project modifications would provide better protection of coral reef ecosystems, which produce economic benefits), but non-existent in the low-end scenario (because there would be no project modifications, and thus no increased protection of coral reef ecosystems). Moreover, while Scenario 1 and Scenario 2 present a range of potentially affected entities and the associated revenue effects, we expect the actual number of small entities affected and revenue effects will be somewhere in the middle. In other words, some subset of the small entities in American Samoa, Guam, and CNMI greater than 2 and up to 14 will participate in section 7 consultations on Indo-Pacific coral critical habitat and bear associated impacts annually. We conclude that the economic impacts of the proposed coral critical habitat are likely to be much closer to those projected by the low-end scenario than the high-end scenario, and also that there would be low economic benefits. That is, we find that the economic analysis and IRFA support the conclusion that the proposed coral critical habitat would have low economic effects on small entities.

There are no record-keeping requirements associated with the rulemaking. Similarly, there are no reporting requirements.

No Federal laws or regulations duplicate or conflict with this proposed rule. However, the protection of listed species and habitat under critical habitat may overlap other sections of the ESA. For instance, listing of the threatened Indo-Pacific corals under the ESA already requires Federal agencies to consult with NMFS to avoid jeopardy to the species. However, this analysis only examines the incremental impacts to small entities from the proposed critical habitat rule.

The RFA requires consideration of alternatives to the proposed rule that

[1] Average annual revenues were calculated based on company-specific revenue data sourced from the Dun & Bradstreet Hoovers database.

would minimize significant economic impacts to small entities. We considered the following alternatives when developing the proposed critical habitat rule.

Alternative 1: No Action Alternative

Under the no action alternative, we would not designate critical habitat for the listed corals. The alternative of not designating critical habitat was considered in this IRFA but rejected because, in this case, it would violate the legal requirements of the ESA. Moreover, we have determined that the physical feature forming the basis for critical habitat designation is essential to the corals' conservation, and conservation for these species will not succeed without this feature being available. Thus, the lack of protection of the critical habitat feature from adverse modification could result in continued declines in abundance of the listed corals, and loss of associated economic and other values these corals provide to society, such as recreational and commercial fishing and diving services, and shoreline protection services. Small entities engaged in some coral reef-dependent industries would be adversely affected by the continued declines in the listed corals. Thus, the no action alternative is not necessarily a ''no cost'' alternative for small entities.

Alternative 2: Preferred Alternative

Under this alternative, the areas designated are waters ranging from 0 to 10 m deep to 0 to 50 m deep in the 15 units located in American Samoa, Guam, CNMI, the NWHI, and the PRIA. As noted in the Critical Habitat Information Report, the following areas are ineligible for proposed critical habitat: parts of Guam, parts of Tinian all of Farallon de Medinilla, and all of Wake Atoll. An analysis of the costs and benefits of the preferred alternative designation is presented in appendix C of the Information Report. Relative to the no action alternative, this alternative will likely involve an increase in administrative and project modification costs for those section 7 consultations required to avoid adverse impacts to critical habitat, above and beyond those required due to the corals' listing alone. We have determined that no categories of activities would require consultation, and no categories of project modifications would be required, in the future solely due to this rulemaking and the need to prevent adverse modification of critical habitat. Similarly, all categories of activities have similar potential to adversely impact corals and critical habitat, and the same project modifications would remedy both sets of adverse effects. However, in some areas of proposed coral critical habitat, there may be locations with no colonies of listed corals, especially after a natural disturbance event (*e.g.,* coral bleaching or crown-of-thorns starfish outbreak). For future Federal actions that have small action areas within such locations, costs to small entities could occur, and would represent an incremental impact of this rulemaking. On the other hand, because projects with larger or more diffuse action areas are more likely to impact both the listed corals and their critical habitat, consultation and project modification costs associated with those projects would more likely be coextensive with the coral listings or another regulatory requirement. The preferred alternative was selected because it best implements the critical habitat provisions of the ESA by including the well-defined environmental features essential to the species' conservation, and due to the important conservation benefits that will result from this alternative relative to the no action alternative.

Alternative 3: Designating a Subset of Areas

A third alternative was considered that would have excluded from designation those areas in which, on economic or national security bases, the benefits of exclusion outweigh the benefits of inclusion. No areas, other than those excluded in the Preferred Alternative on the basis of national security impacts, were identified where it was determined that the benefits of exclusion outweigh the conservation value of designation to the species. In addition, the public did not submit comments on the benefits of exclusion and inclusion in general, nor were comments submitted on those benefits as they relate to specific areas. Thus, we rejected this alternative because it would lessen the conservation value to the species.

Coastal Zone Management Act (16 U.S.C. 1451 et seq.)

Under section 307(c)(1)(A) of the Coastal Zone Management Act (CZMA) and its implementing regulations (15 CFR part 923), each Federal activity within or near coastal zones that has reasonably foreseeable effects on any land or water use or natural resource of the coastal zone shall be carried out in a manner which is consistent to the maximum extent practicable with the enforceable policies of approved State coastal management programs. Upon publication of the proposed rule (85 FR 76262, November 27, 2020), we determined that the proposed designation of critical habitat for the listed corals would have no reasonably foreseeable effects on the enforceable policies of Guam's, CNMI's, and American Samoa's approved Coastal Zone Management Programs, and submitted our determinations to each of the responsible Territorial agencies.

CNMI and Guam formally objected to our determinations on February 12, 2021, and March 26, 2021, respectively. Both Territories stated that there were reasonably foreseeable coastal effects of coral critical habitat for several reasons, including administrative burdens, economic impacts, and third-party impacts. CNMI requested a consistency determination and identified specific enforceable policies to be addressed. Guam interpreted our determination as a consistency determination, and requested a new consistency determination that addressed specific enforceable policies. In response to these objections and concerns expressed informally by American Samoa, we held a meeting with the three Territorial CZM Programs (American Samoa, Guam, and CNMI) on July 27, 2021. We explained the basis for our determinations at the July meeting and scheduled follow-up meetings with representatives of CNMI and Guam CZM Programs to review their objections in detail.

On September 2, 2021, and September 7, 2021, we held meetings with CNMI's and Guam's CZM Programs, respectively, and the NOAA Office of Coastal Management, to review the Territories' objections to our determinations. The Territories explained why they find that coral critical habitat, as proposed in 2020, would result in administrative burdens, economic impacts, and third-party impacts. The Territorial representatives stated that they believe incomplete biological and economic data were used in the 2020 proposed rule, resulting in the habitat needs of the listed corals being overstated, and the extent of economic impacts of critical habitat being understated in the proposed rule. Subsequently, the Territories requested that NMFS work with their experts to obtain more thorough and recent biological and economic data to inform the proposed coral critical habitat rule. On September 30, 2021, and October 28, 2021, NMFS held meetings with biologists based in American Samoa, CNMI, Guam, and Honolulu to review records of listed corals in the Territories, which contributed to the development of appendix A in the Information Report (NMFS, 2023). On September 23, 2021, and September 25,

2021, Guam and CNMI submitted letters to NMFS with updated economic data, which was used in section 5.1.7 of the Information Report (NMFS, 2023).

In making revisions to the 2020 proposed critical habitat, in addition to considering other public comments received, we considered the comments submitted by each of the Territories regarding their respective concerns about the proposed critical habitat. With the withdrawal of the 2020 proposed rule, we also withdraw the November 27, 2020, CZMA determinations for the American Samoa, Guam, and CNMI CZM Programs. Consistent with the CZMA, we will determine how to proceed for the critical habitat now being proposed and coordinate accordingly with the responsible agencies in American Samoa, Guam, CNMI, and Hawaii.

Paperwork Reduction Act (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new or revised collection of information, defined by the Paperwork Reduction Act of 1995. 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.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

This proposed rule will not produce a Federal mandate. The designation of critical habitat does not impose a legally-binding duty on non-Federal government entities or private parties. The only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7 of the ESA. Non-Federal entities that receive Federal funding, assistance, permits, or otherwise require approval or authorization from a Federal agency for an action may be indirectly affected by the designation of critical habitat, but the Federal agency has the legally binding duty to avoid destruction or adverse modification of critical habitat.

We do not anticipate that this proposed rule will significantly or uniquely affect small governments. Therefore, a Small Government Action Plan is not required.

Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, Executive orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal Government.

This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States towards Indian Tribes and with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities, lands have been retained by Indian Tribes or have been set aside for tribal use. These lands are managed by Indian Tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests. The proposed critical habitat designations for threatened Indo-Pacific corals are located in U.S. Pacific Islands and therefore do not have tribal implications in accordance with Executive Order 13175.

Environmental Justice and Racial Equity (E.O.s 12898, 14096, 14019, 13985)

The designation of critical habitat is not expected to have a disproportionately high effect on minority populations or low-income populations. The purpose of this rulemaking is to protect and conserve ESA-listed species through the designation of critical habitat and is expected to help promote a healthy environment; thus, we do not anticipate minority populations or low-income populations to experience disproportionate and adverse human health or environmental burdens. The designation of critical habitat is not expected to disproportionately affect minority populations, low-income populations, or populations otherwise adversely affected by persistent poverty or inequality. Further, it is not expected to create any barriers to opportunity for underserved communities.

List of Subjects and Maps

50 CFR Part 223

Endangered and threatened species, Exports, Imports, Transportation.

50 CFR Part 226

Endangered and threatened species.

Dated: November 21, 2023.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, we propose to amend 50 CFR parts 223 and 226 as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531 1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102(e), in the table, under the heading ''Corals'' revise the entries for ''*Acropora globiceps,*'' ''*Acropora retusa,*'' ''*Acropora speciosa,*'' ''*Euphyllia paradivisa,*'' and ''*Isopora crateriformis*'' to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
Corals					
Coral, [no common name]	*Acropora globiceps*	Entire species	79 FR 53852, Sept. 10, 2014	*226.230*	NA.
*	*	*	*	*	*
Coral, [no common name]	*Acropora retusa*	Entire species	79 FR 53852, Sept. 10, 2014	*226.230*	NA.
*	*	*	*	*	*
Coral, [no common name]	*Acropora speciosa*	Entire species	79 FR 53852, Sept. 10, 2014	*226.230*	NA.

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
Coral, [no common name]	*Euphyllia paradivisa*	Entire species	79 FR 53852, Sept. 10, 2014	*226.230*	NA.
*	*	*	*	*	*
Coral, [no common name]	*Isopora crateriformis*	Entire species	79 FR 53852, Sept. 10, 2014	*226.230*	NA.
*	*	*	*	*	*

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

PART 226—DESIGNATED CRITICAL HABITAT

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

■ 4. Add § 226.231 to read as follows:

§ 226.231 Critical habitat for Acropora globiceps, Acropora retusa, Acropora speciosa, Euphyllia paradivisa, and Isopora crateriformis.

Critical habitat is designated in the following jurisdictions for the following species as depicted in the maps below and described in paragraphs (a) through (e) of this section. The maps can be viewed or obtained with greater resolution (available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals*) to enable a more precise inspection of the proposed critical habitat for *A. globiceps, A. retusa, A. speciosa, E. paradivisa,* and *I. crateriformis.*

(a) *Critical habitat locations.* Critical habitat is designated for the following species in the following jurisdictions:

TABLE 1 TO PARAGRAPH (a)

Species	State—counties (or other jurisdiction)
Acropora globiceps	American Samoa (AS), Guam (Gu), Commonwealth of the Northern Mariana Islands (CNMI), Pacific Remote Island Areas (PRIA), Hawaii (HI).
Acropora retusa	AS, PRIA.
Acropora speciosa	AS.
Euphyllia paradivisa	AS.
Isopora crateriformis	AS.

(b) *Critical habitat boundaries.* Except as noted in paragraph (d) of this section, critical habitat for the five species includes all specific areas depicted in the maps below.

(c) *Essential feature.* The feature essential to the conservation of *A. globiceps, A. retusa, A. speciosa, E. paradivisa* and *I. crateriformis* is: Sites that support the normal function of all life stages of the corals, including reproduction, recruitment, and maturation. These sites are natural, consolidated hard substrate or dead coral skeleton, which is free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

(d) *Areas not included in critical habitat.* Critical habitat does not include the following particular areas where they overlap with the areas described in paragraphs (a) through (c) of this section:

(1) Pursuant to ESA section 4(a)(3)(B)(i), all areas subject to the 2017 Wake Island and 2019 Joint Region Marianas Integrated Natural Resources Management Plans;

(2) Managed areas that do not provide the quality of substrate essential for the conservation of the five Indo-Pacific corals are defined as particular areas whose consistently disturbed nature renders them poor habitat for coral growth and survival over time. These managed areas include specific areas where the substrate has been disturbed by planned management authorized by local, territorial, State, or Federal governmental entities at the time of critical habitat designation, and will continue to be periodically disturbed by such management. Examples include, but are not necessarily limited to, dredged navigation channels, shipping basins, vessel berths, and active anchorages. A comprehensive list of managed areas is provided in appendix B of the Information Report (NMFS, 2023);

(3) Existing artificial substrates including but not limited to: fixed and floating structures, such as aids-to-navigation (AToNs), seawalls, wharves, boat ramps, fishpond walls, pipes, submarine cables, wrecks, mooring balls, docks, aquaculture cages. A comprehensive list of artificial substrates is provided in appendix B of the Information Report (NMFS, 2023).

(e) *Critical habitat maps.* The specific areas of critical habitat within the 16 island units for the 5 listed coral species are shown on the following 24 maps. These black and white maps are based

on the maps in the Information Report (NMFS, 2023) that are color-coded for the listed coral species. Multiple substrate data sources were used for the maps, as cited in the island sub-sections in section 3.4 of the Information Report (NMFS, 2023).

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Figure 1 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Tutuila and Offshore Banks.

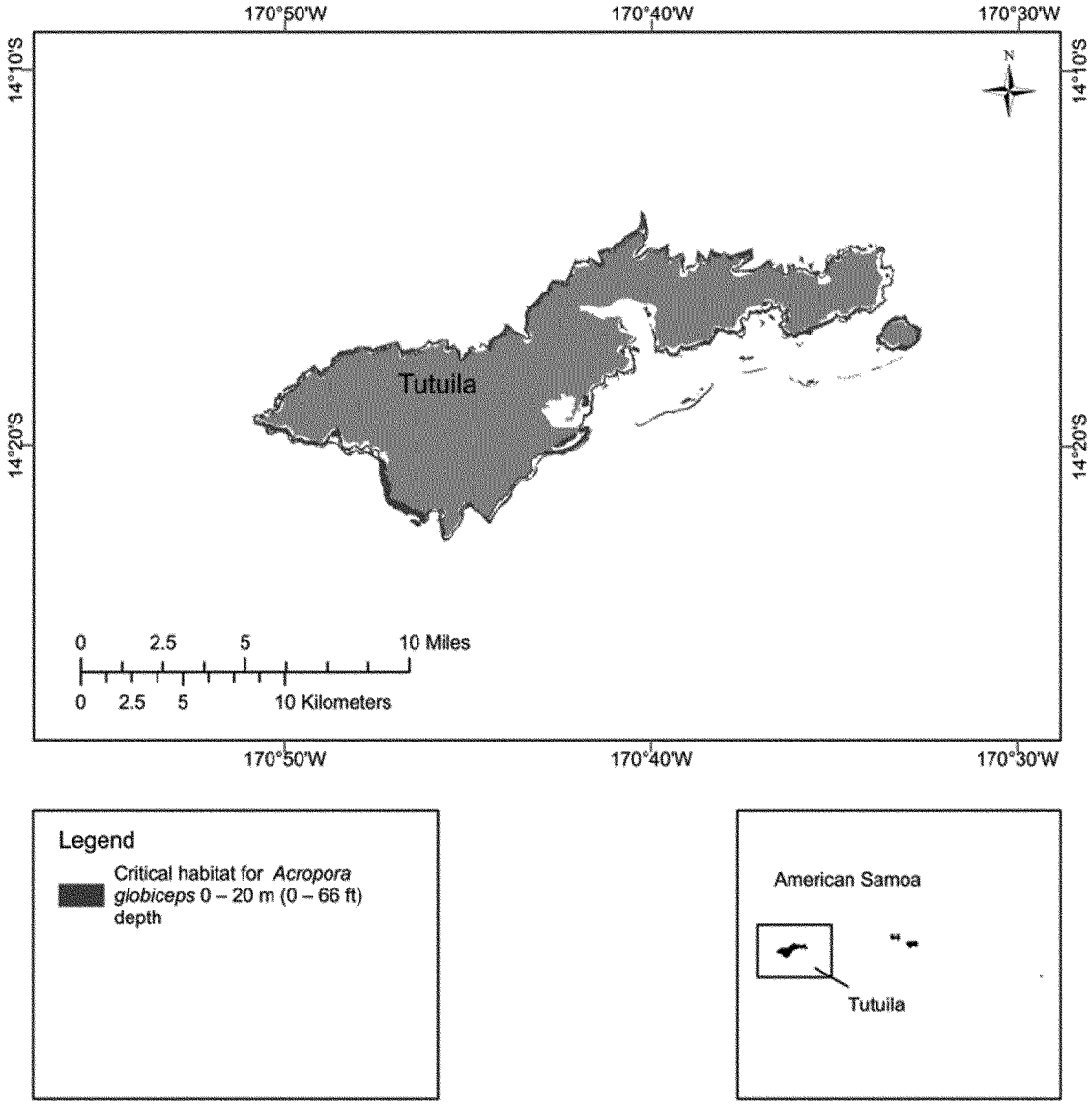


Figure 2 to paragraph (e). Proposed critical habitat for *Acropora retusa*, Tutuila and Offshore Banks.

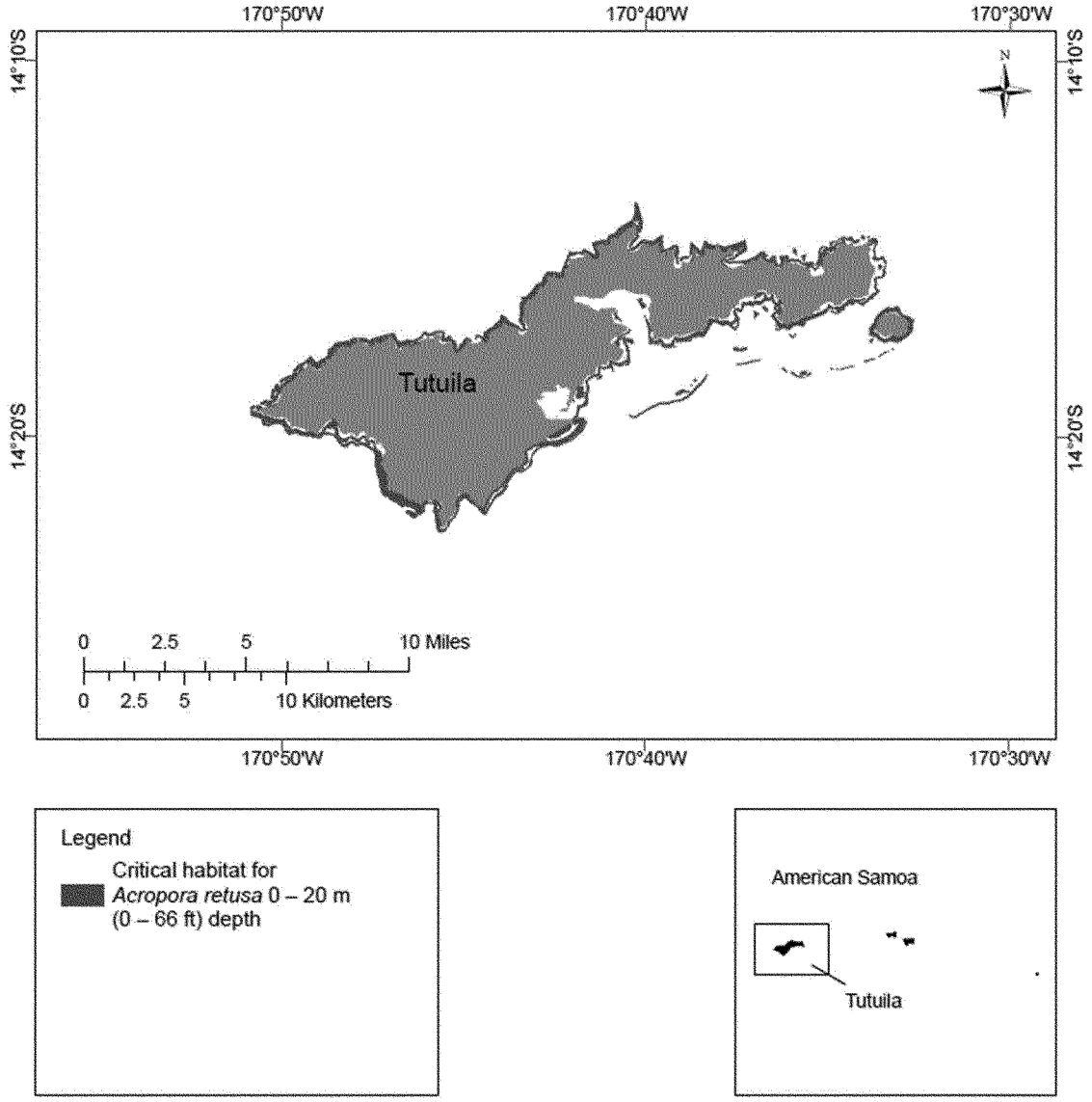


Figure 3 to paragraph (e). Proposed critical habitat for *Acropora speciosa*, Tutuila and Offshore Banks.

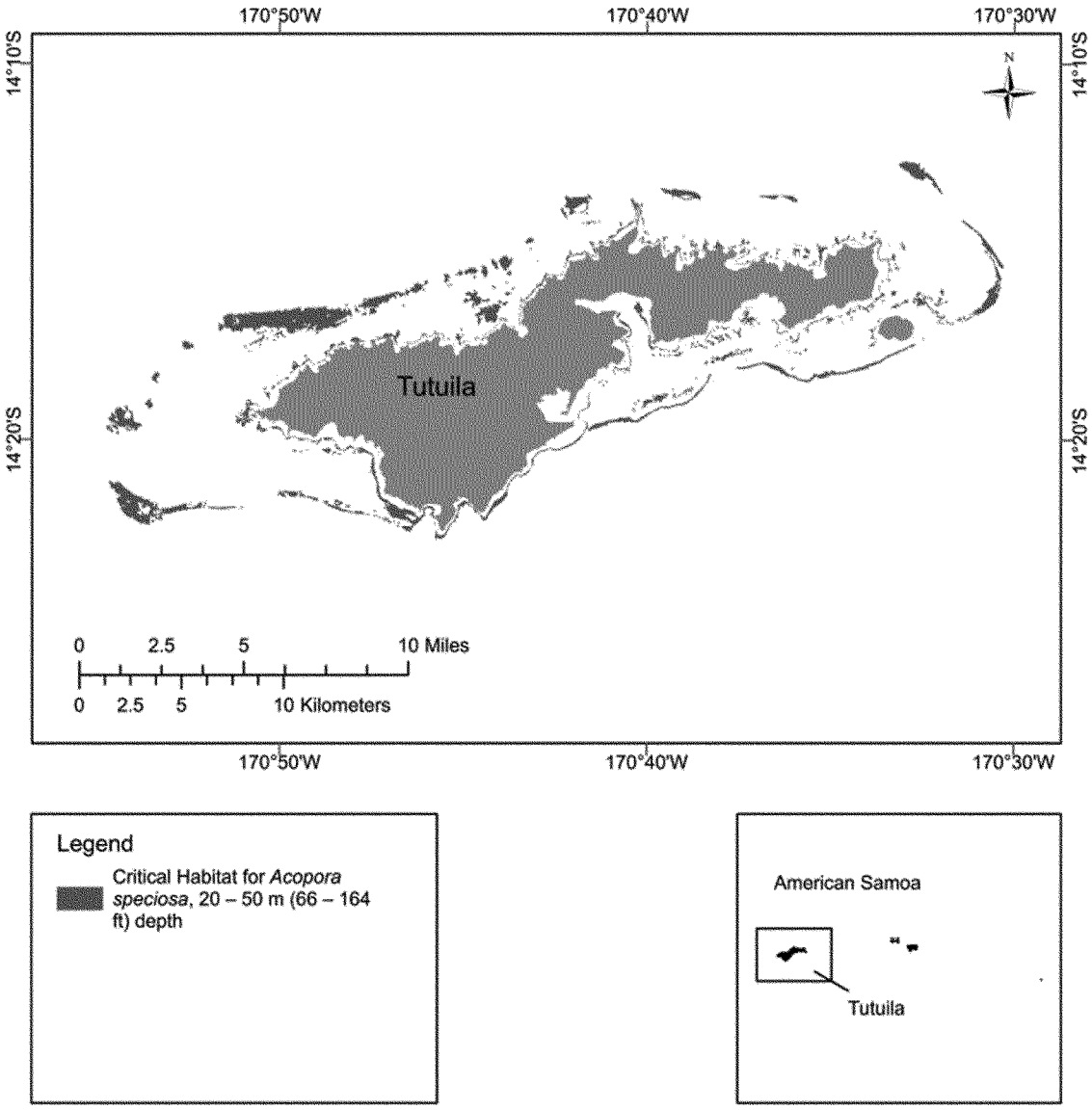


Figure 4 to paragraph (e). Proposed critical habitat for *Euphyllia paradivisa*, Tutuila and Offshore Banks.

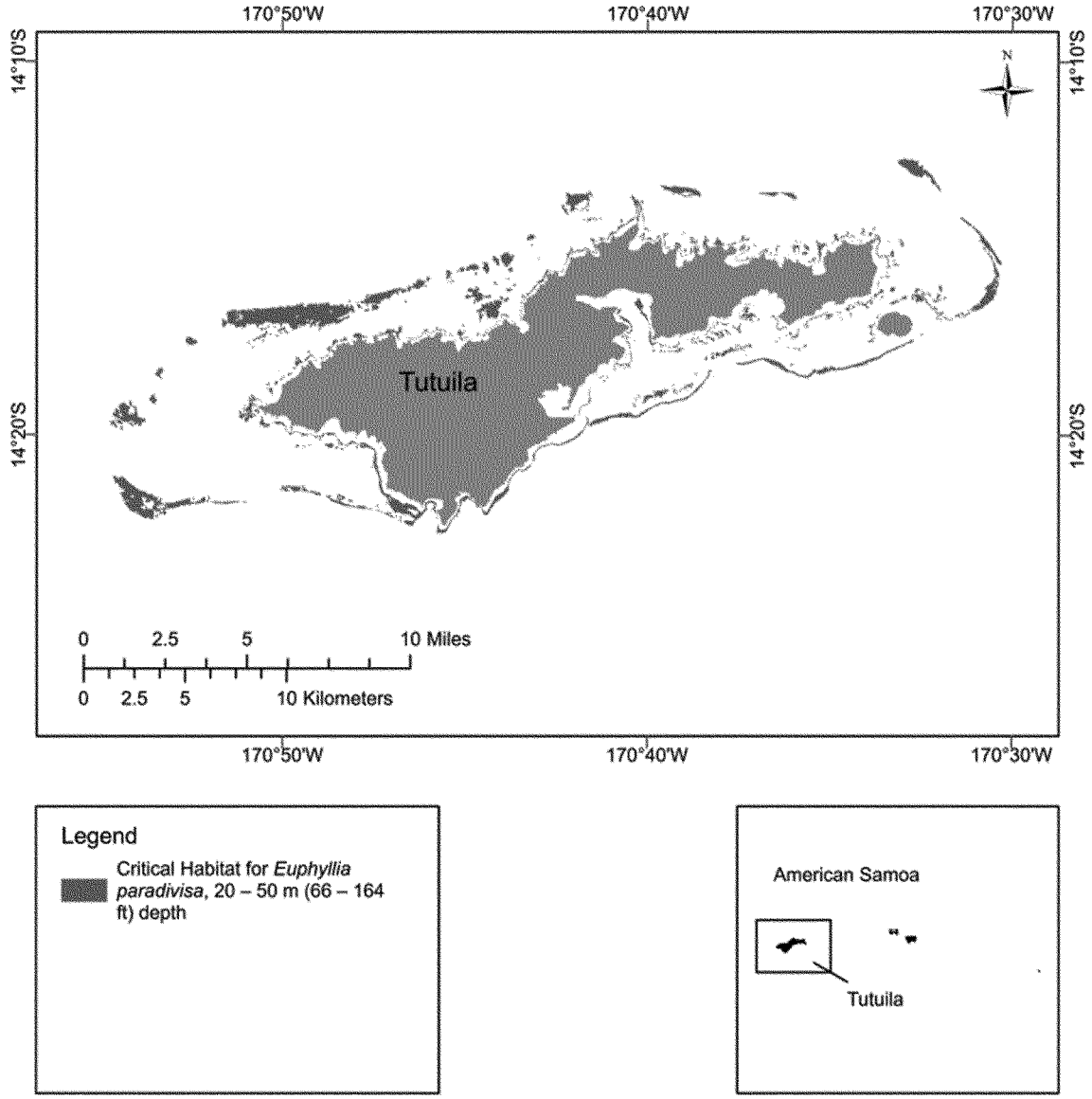


Figure 5 to paragraph (e). Proposed critical habitat for *Isopora crateriformis*, Tutuila and Offshore Banks.

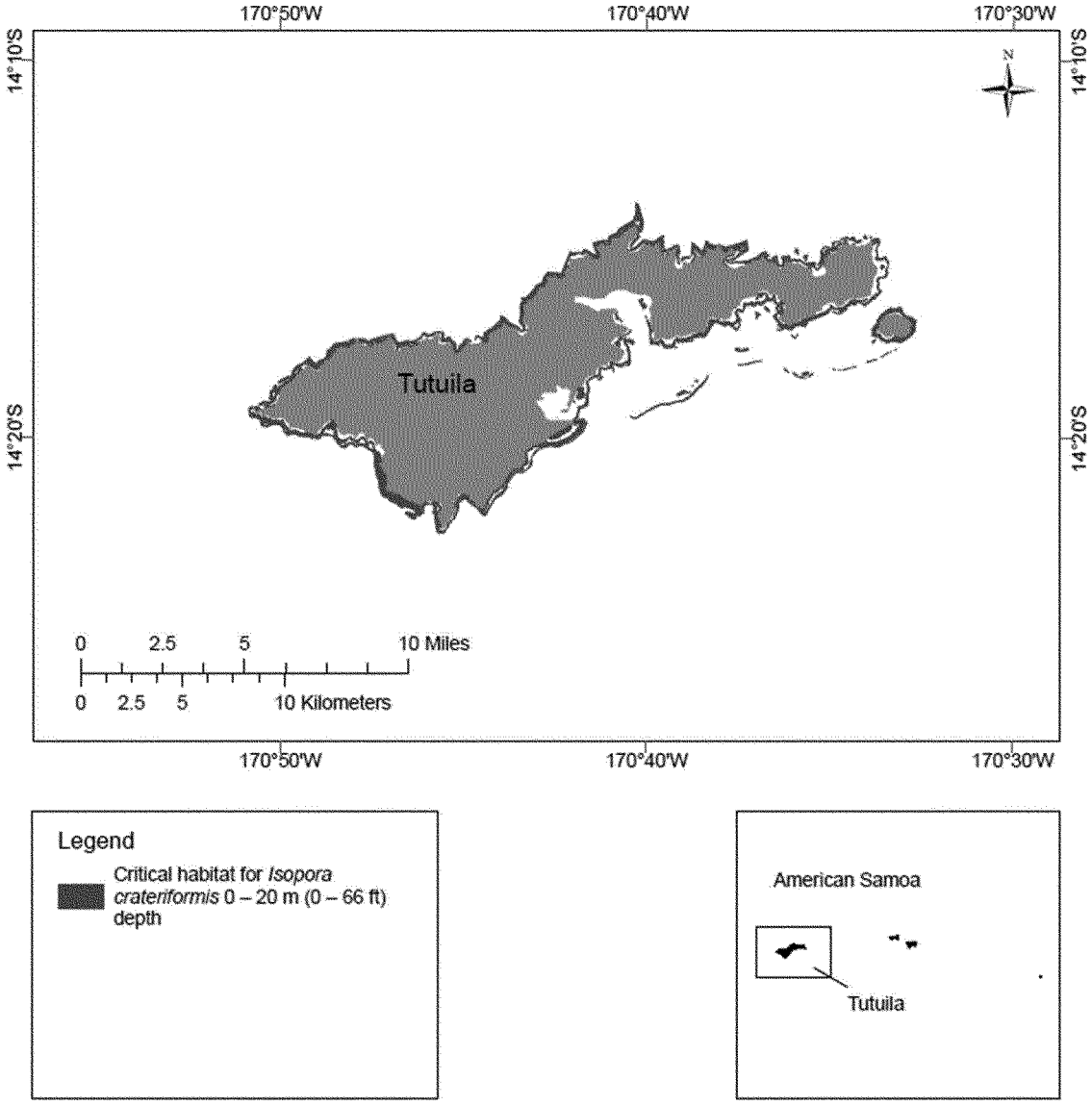


Figure 6 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Ofu-Olosega.

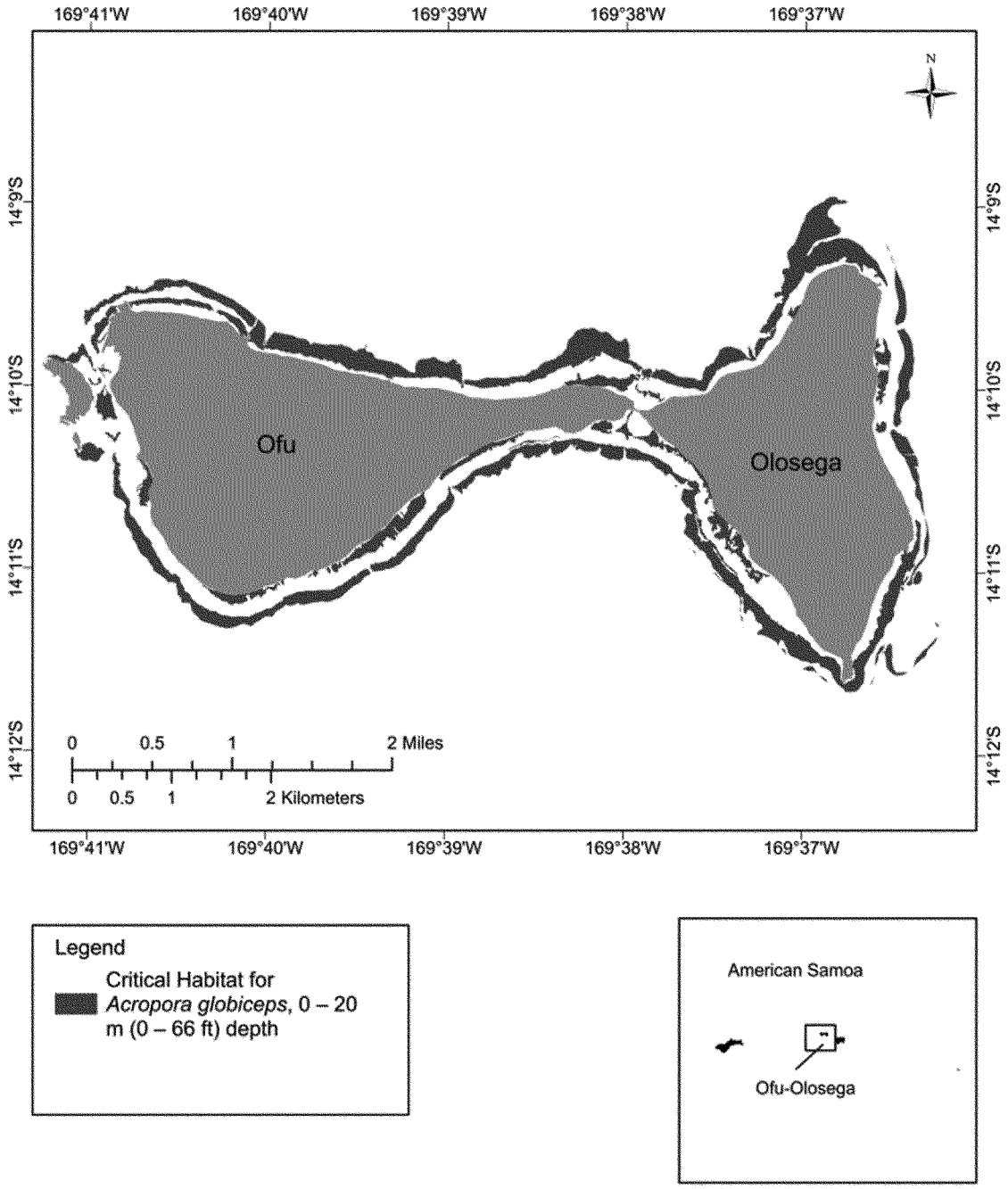


Figure 7 to paragraph (e). Proposed critical habitat for *Acropora retusa*, Ofu-Olosega.

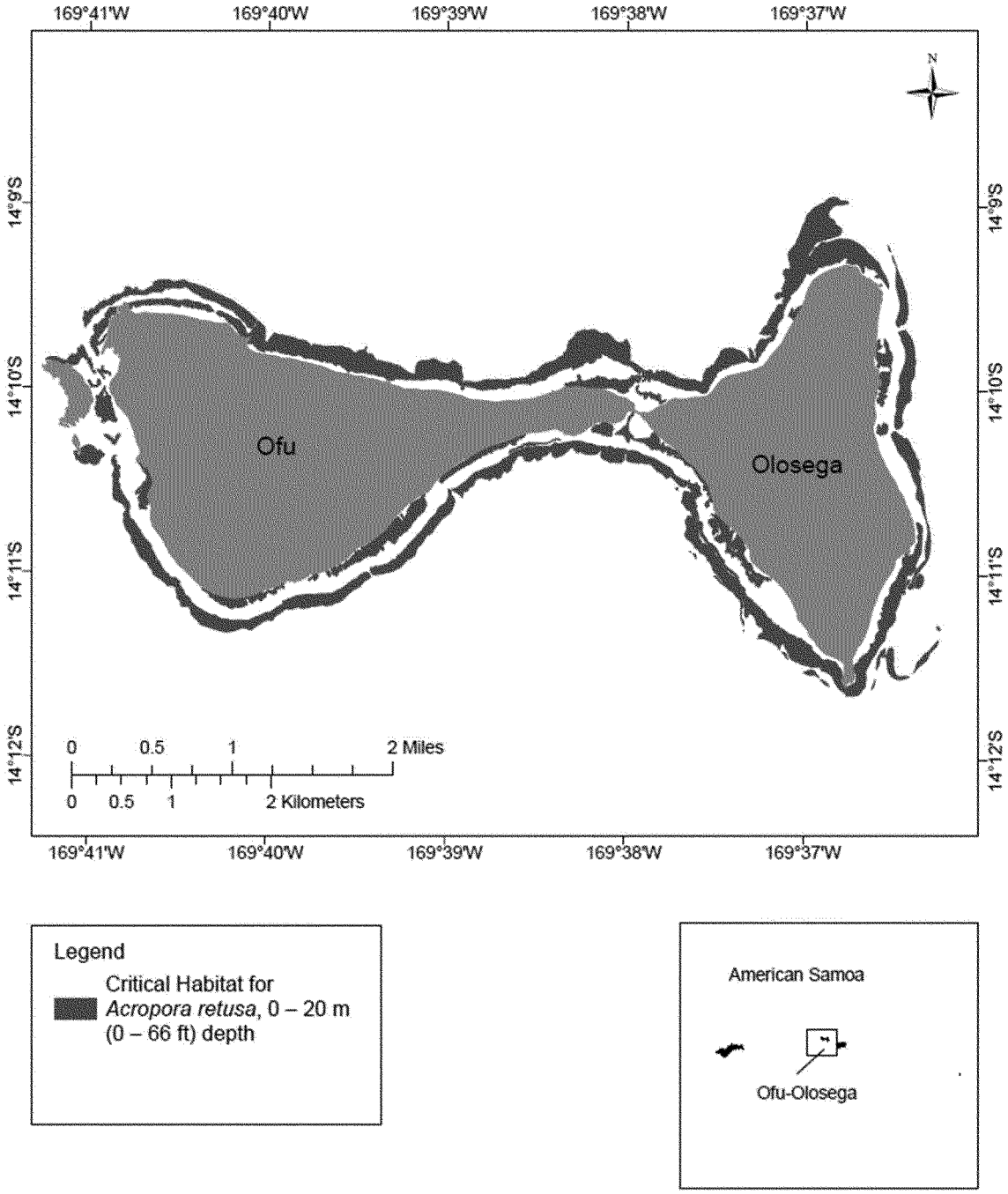


Figure 8 to paragraph (e). Proposed critical habitat for *Isopora crateriformis*, Ofu-Olosega.

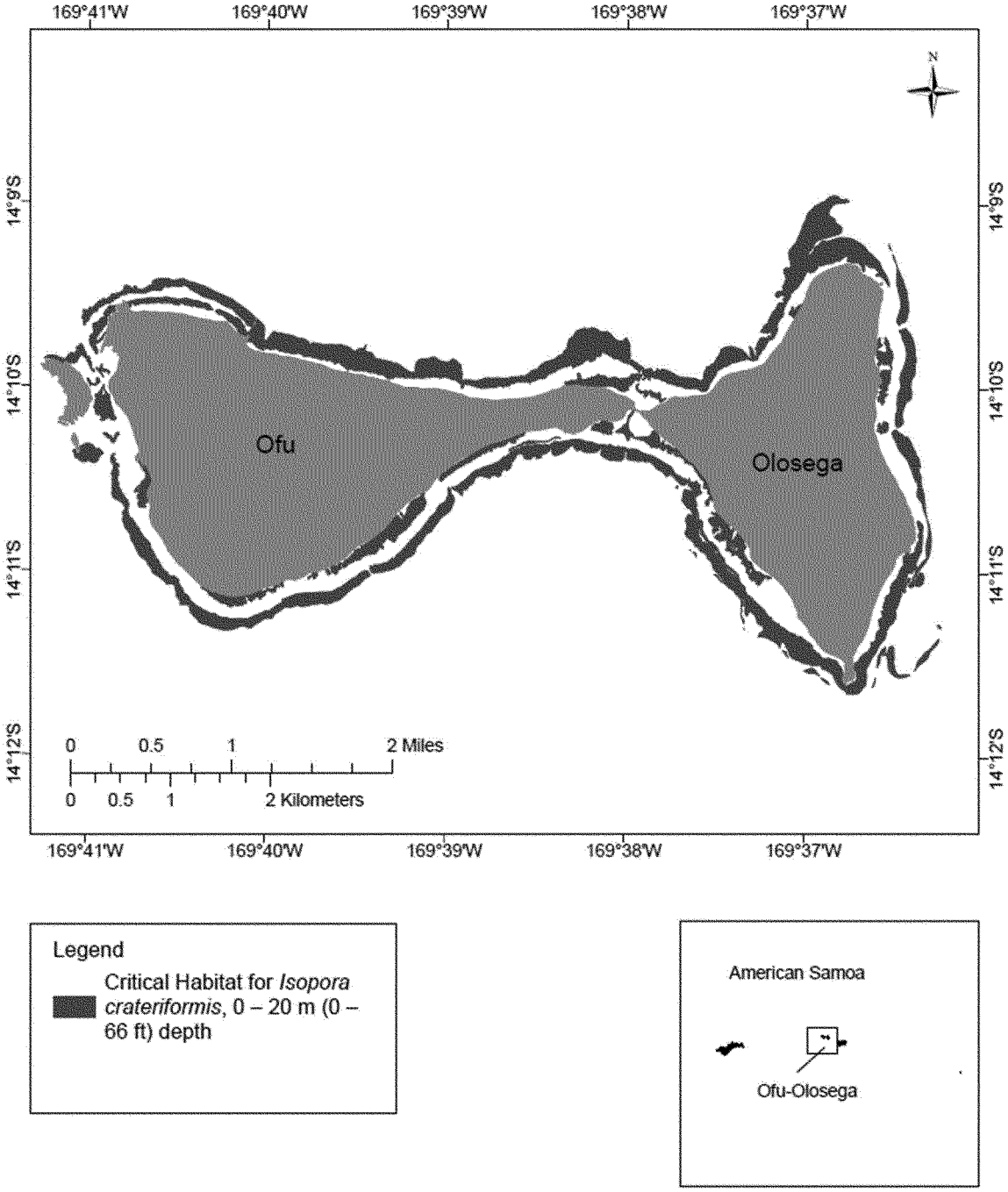


Figure 9 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Ta'u.

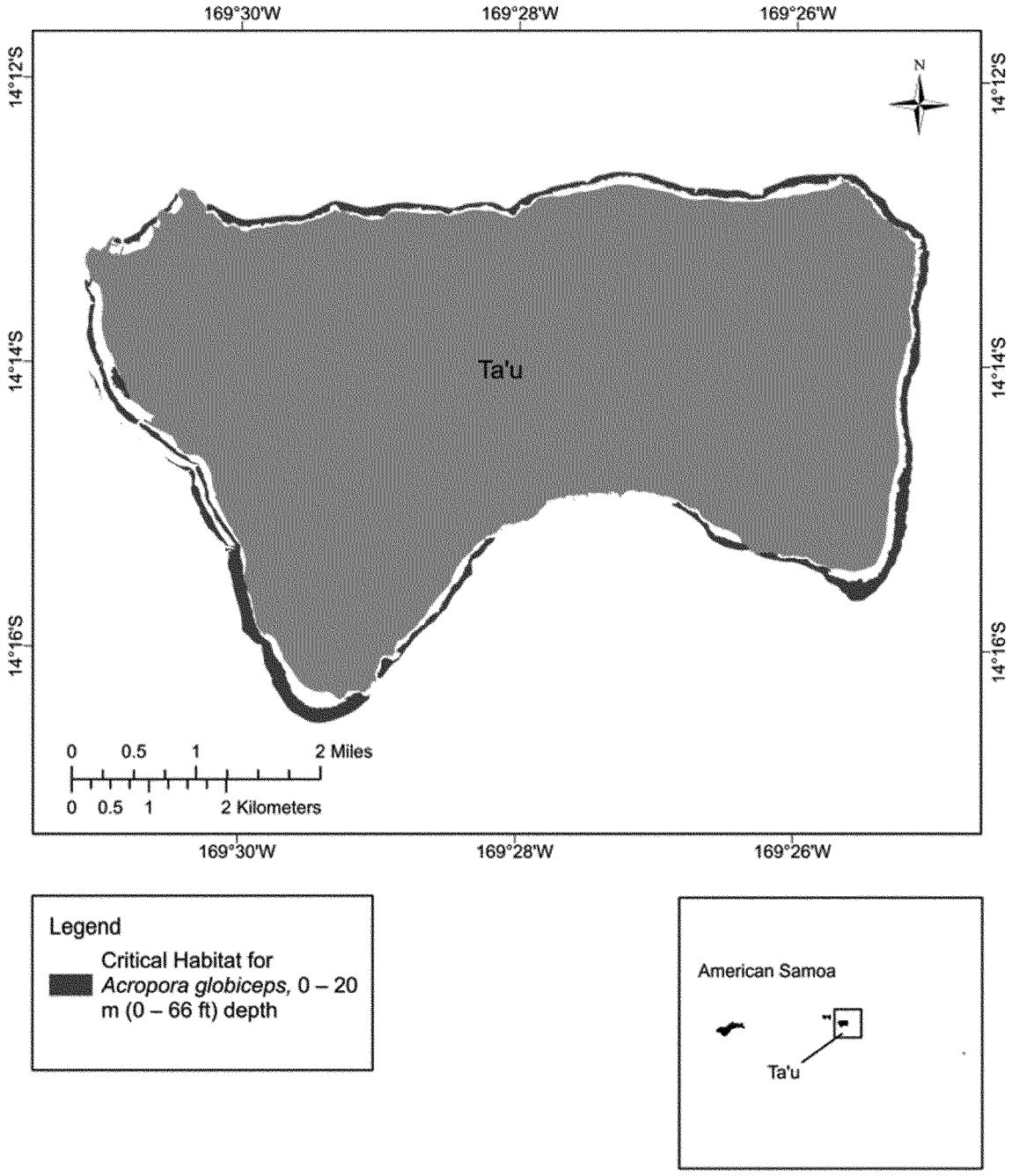


Figure 10 to paragraph (e). Proposed critical habitat for *Isopora crateriformis*, Ta'u.

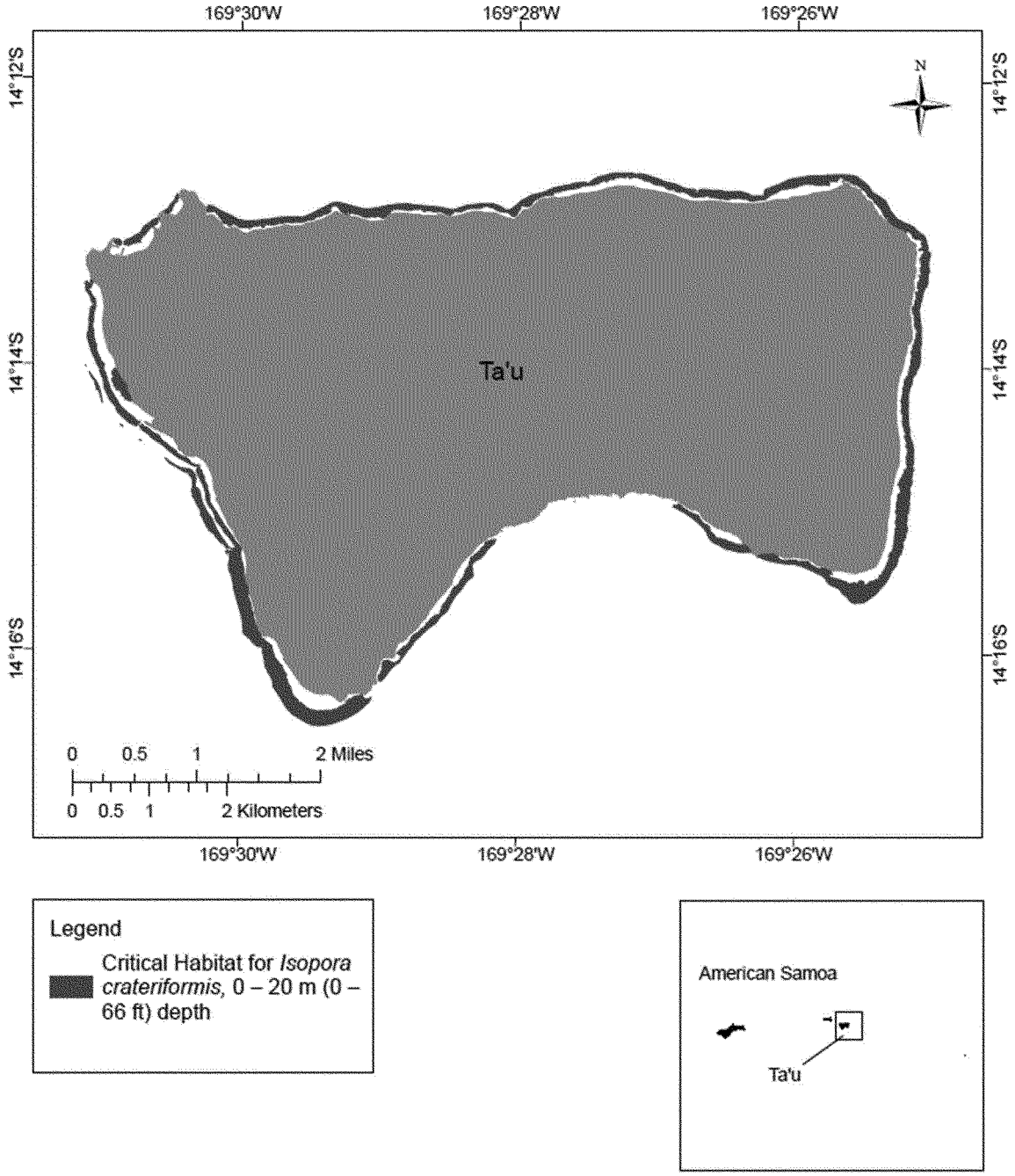


Figure 11 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Rose Atoll.

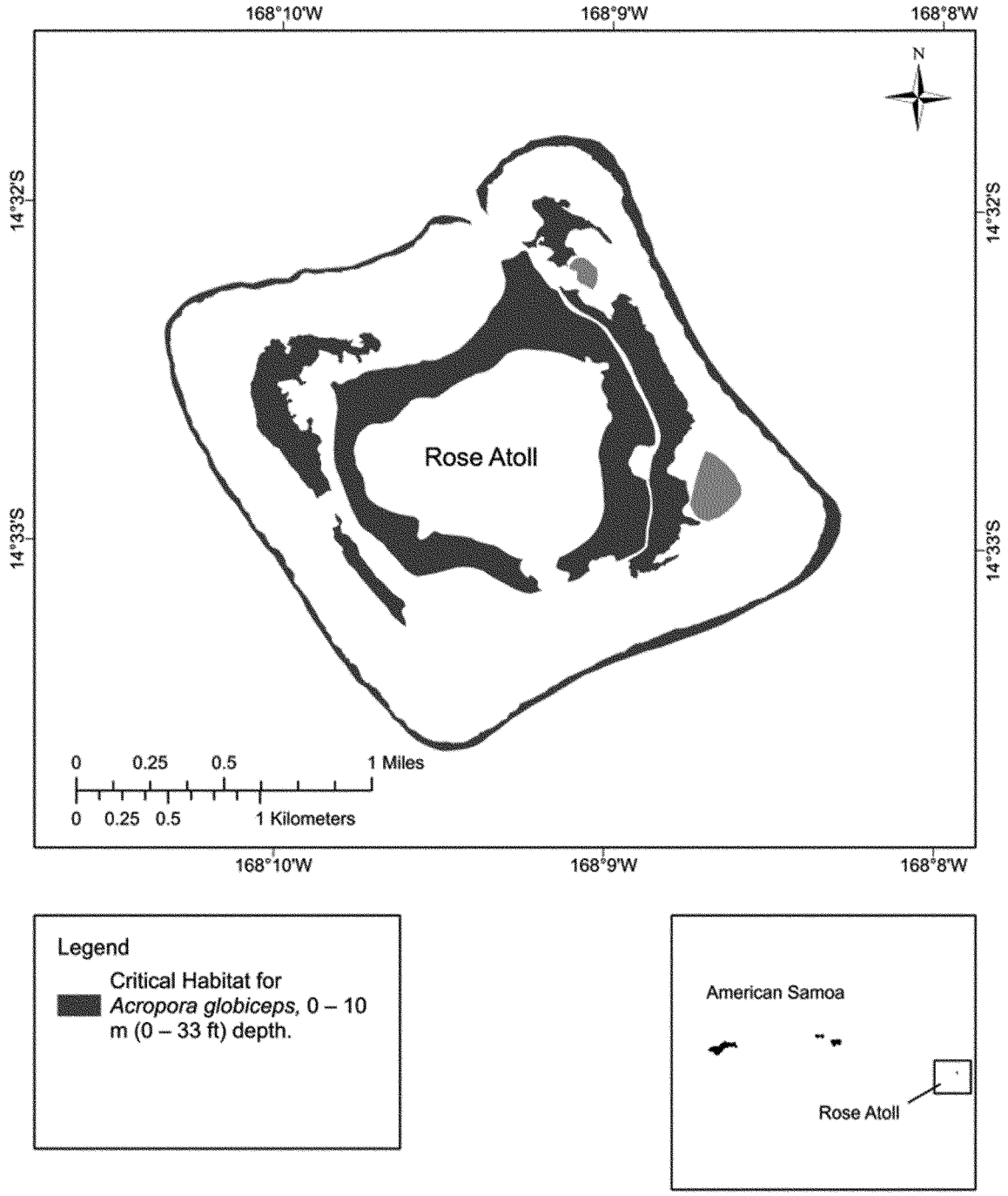


Figure 12 to paragraph (e). Proposed critical habitat for *Acropora retusa*, Rose Atoll.

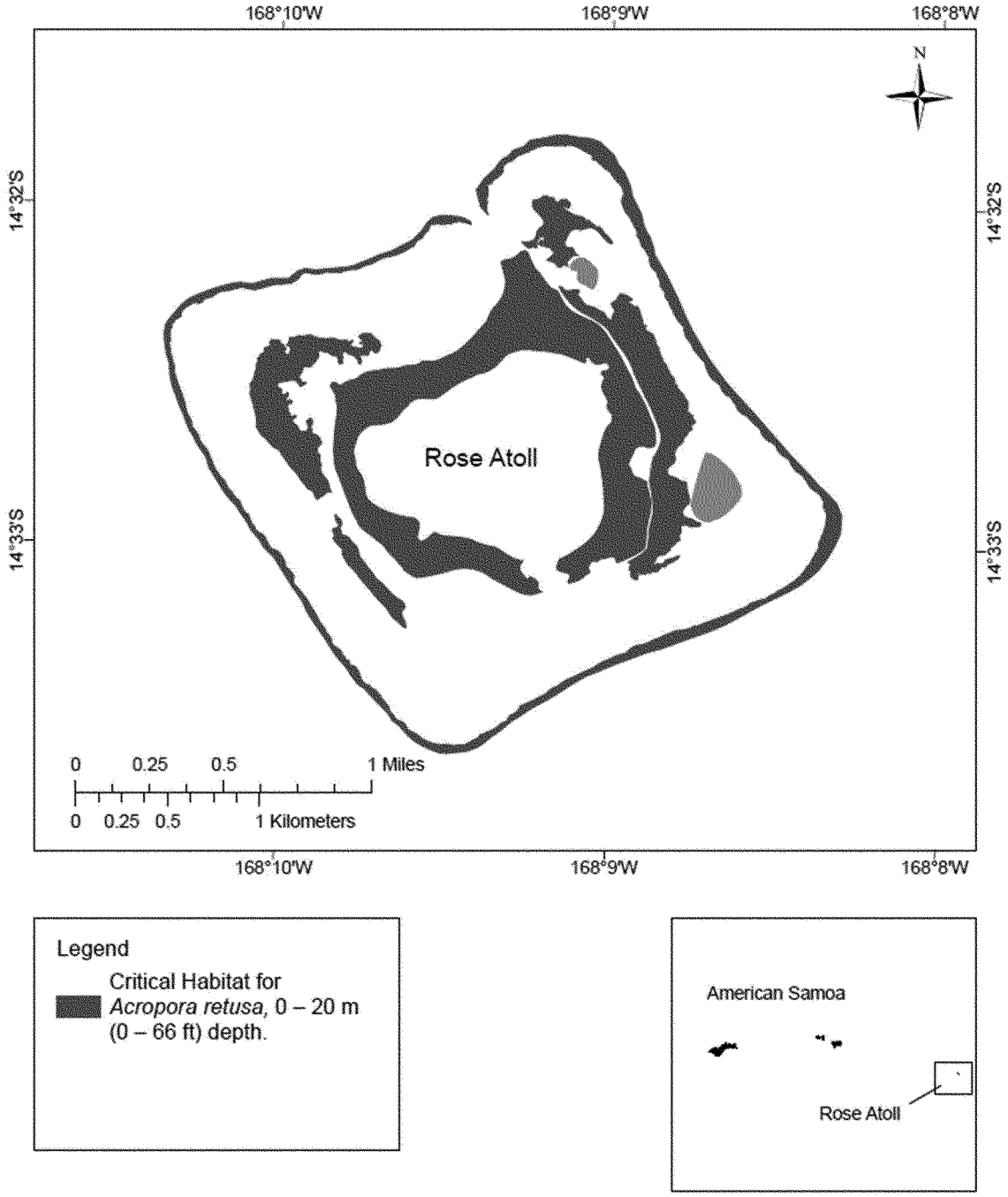


Figure 13 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Guam.

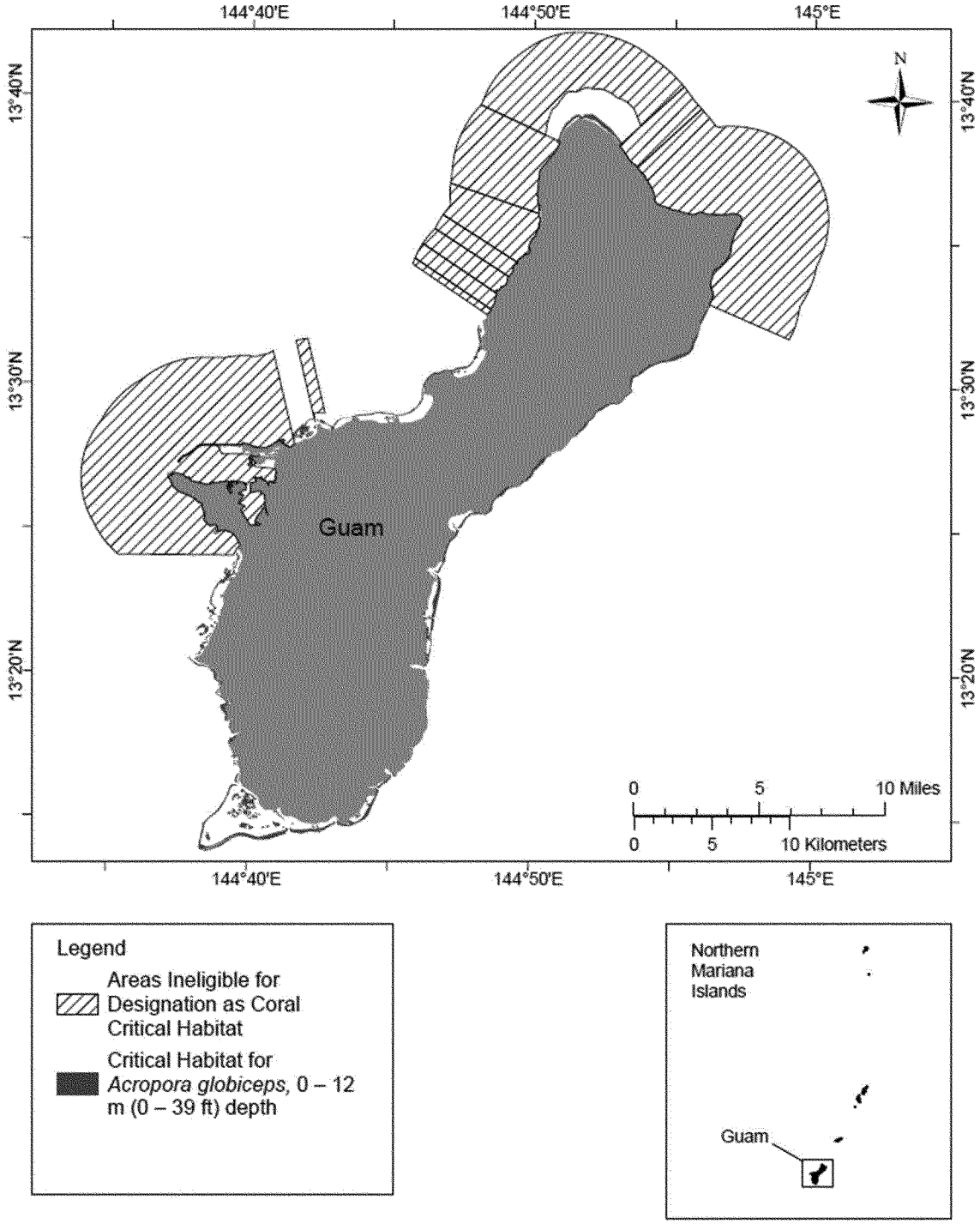


Figure 14 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Rota.

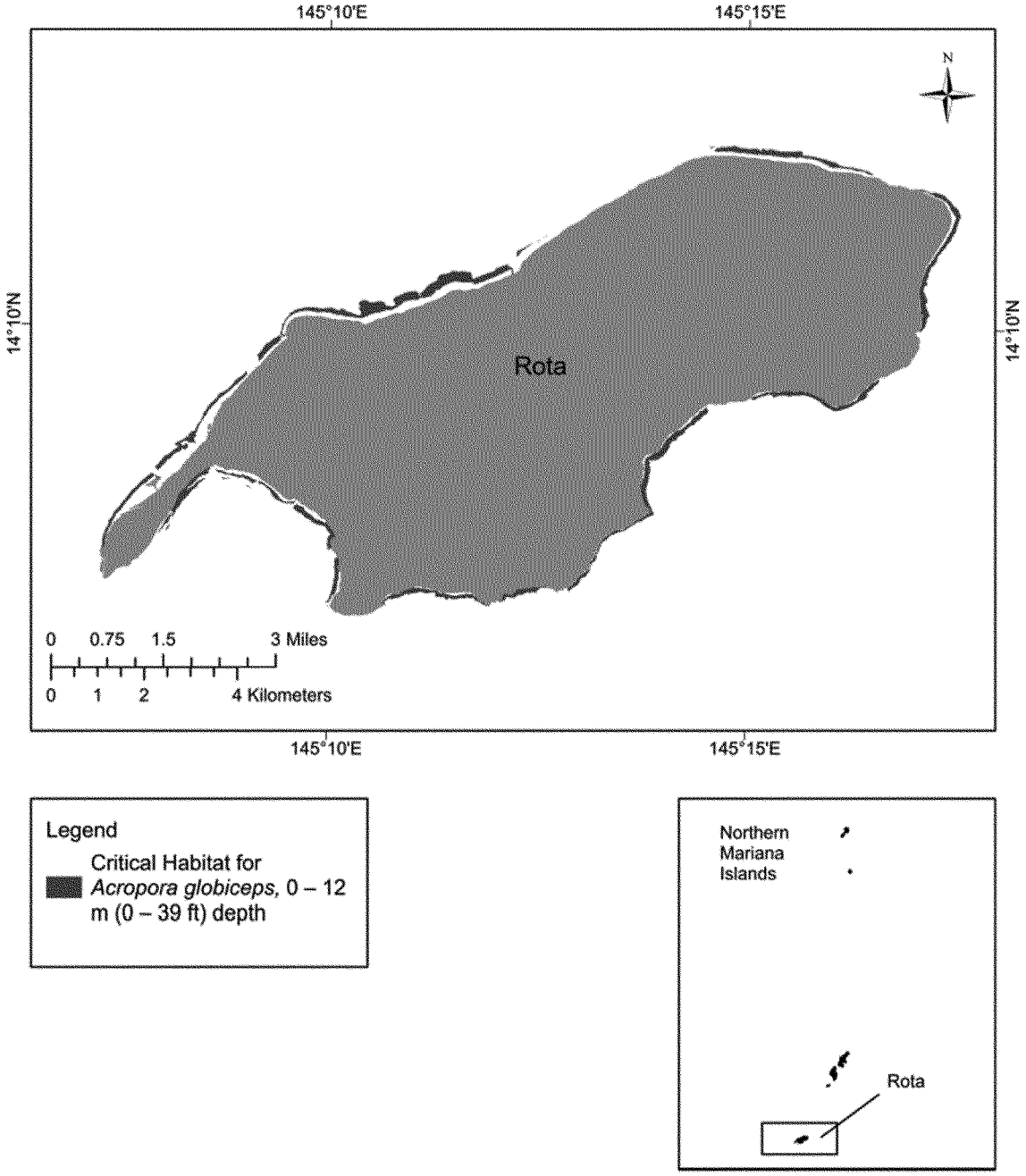


Figure 15 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Aguijan.

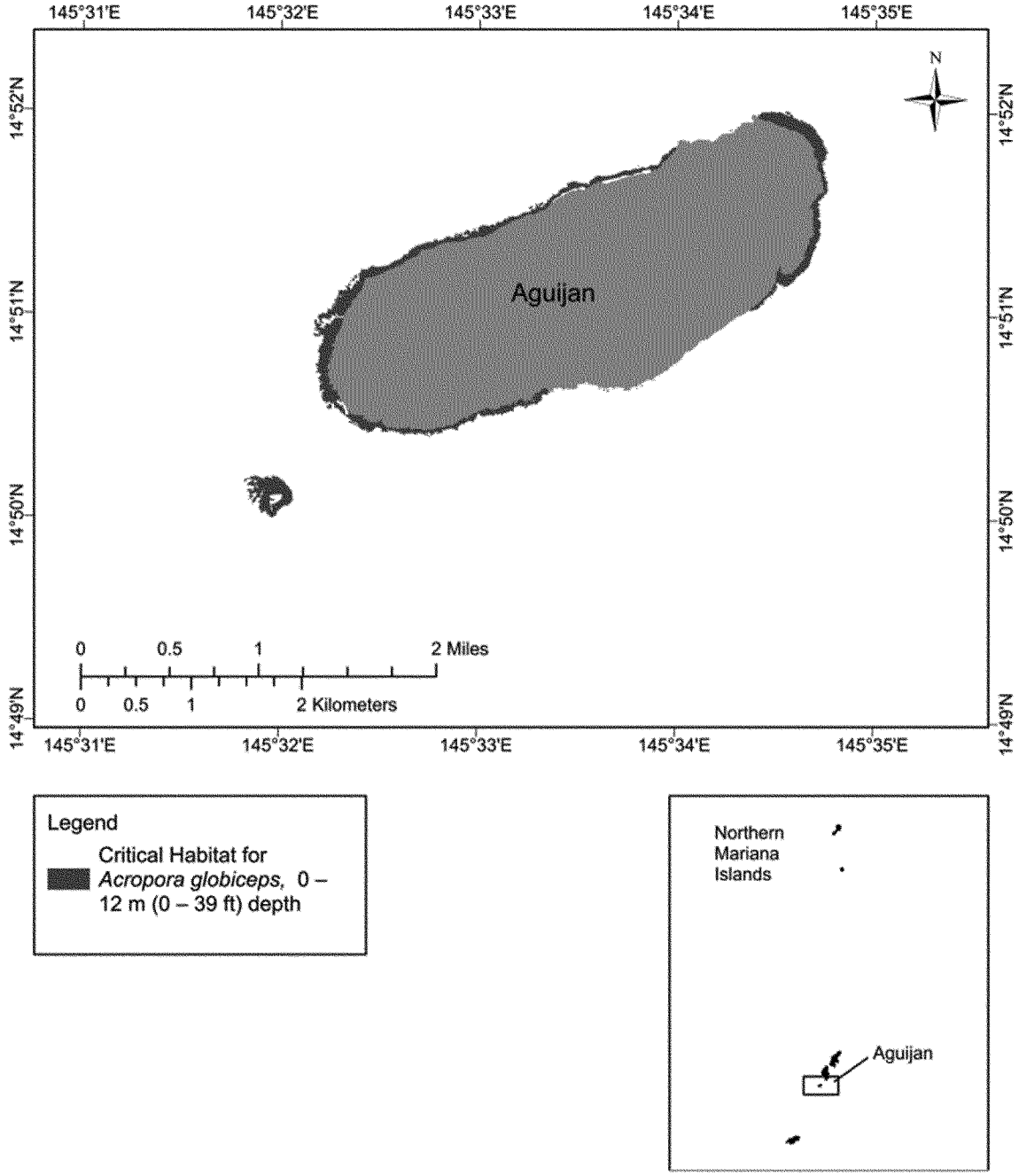


Figure 16 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Tinian.

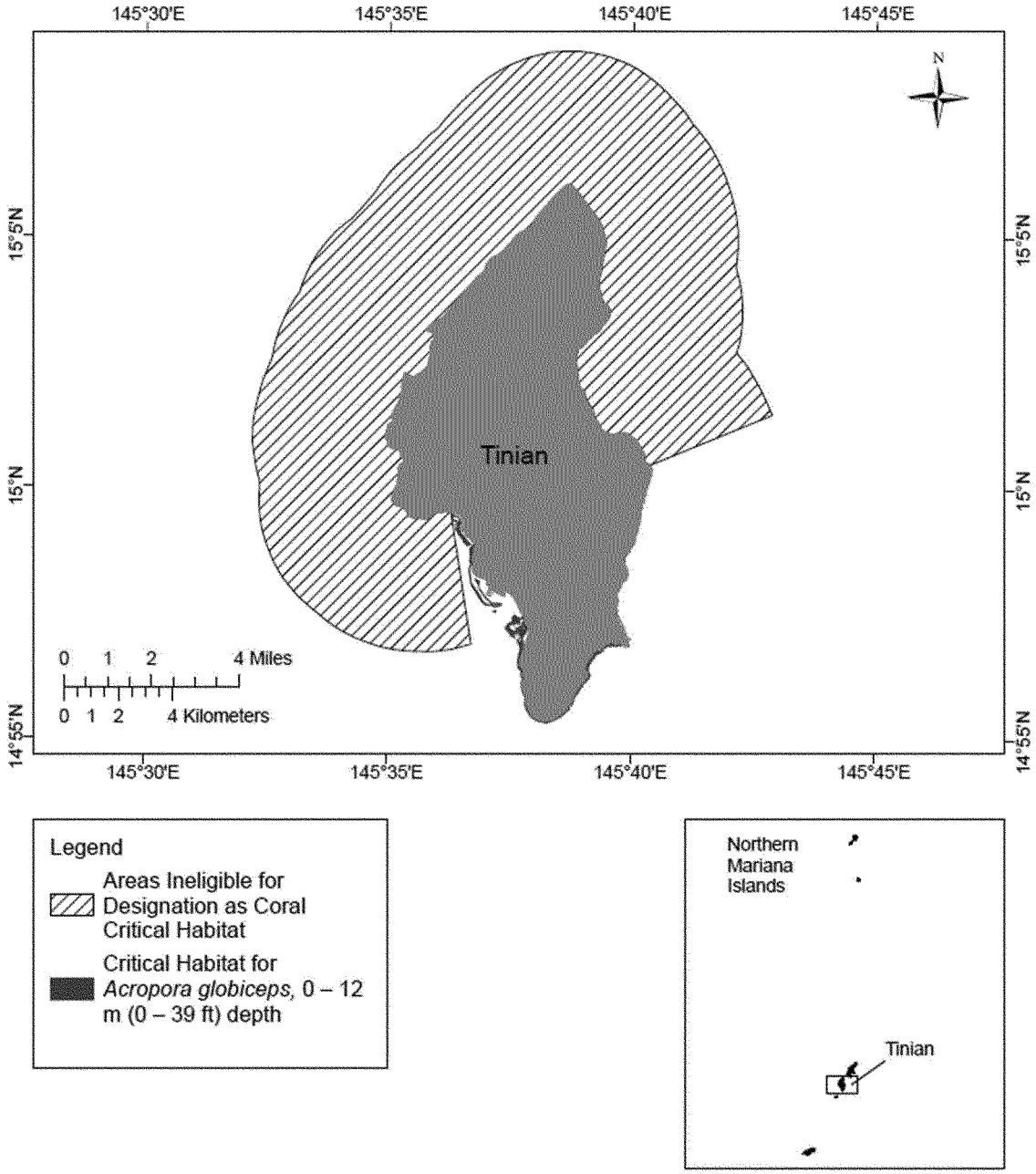


Figure 17 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Saipan.

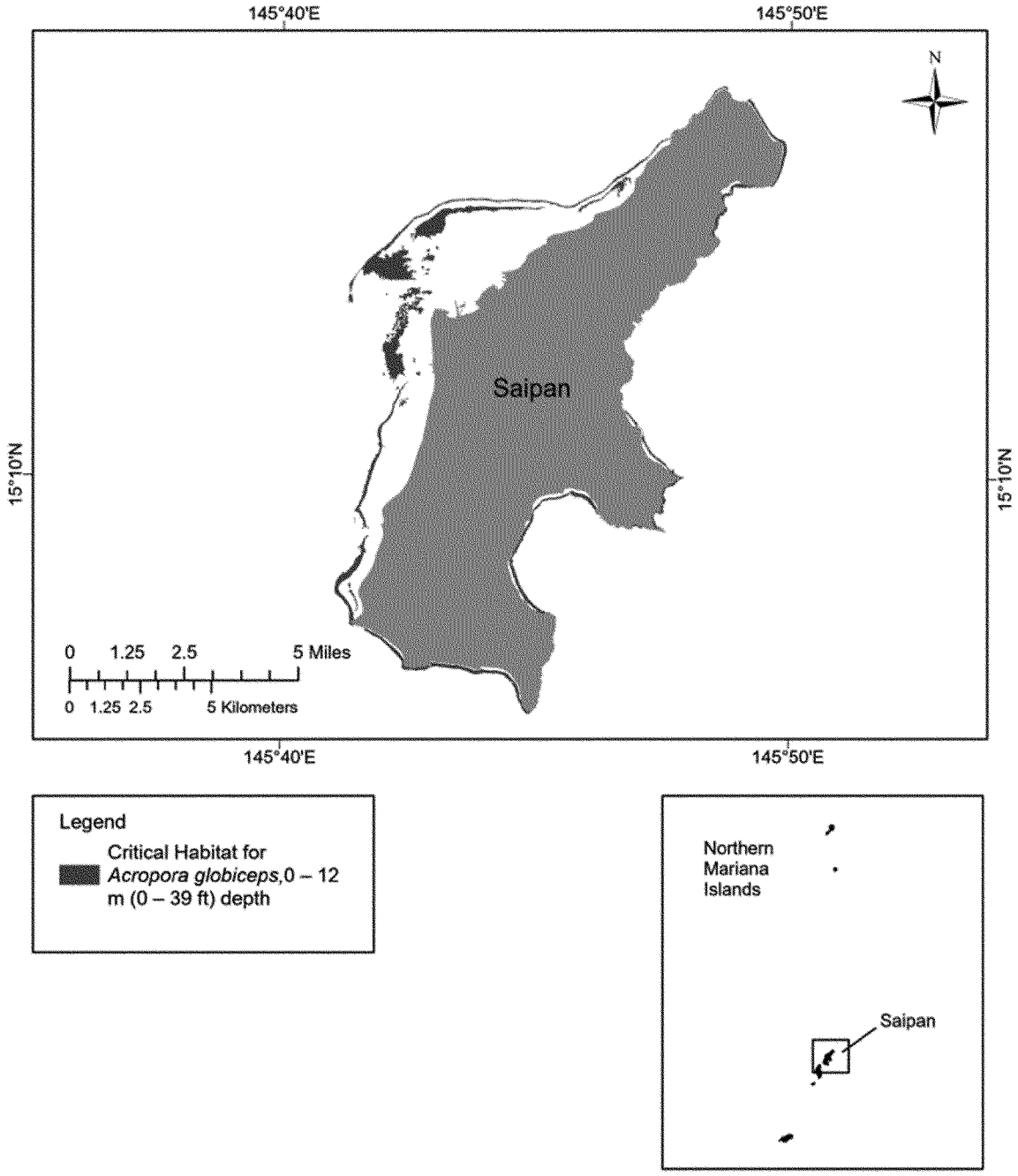


Figure 18 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Alamagan.

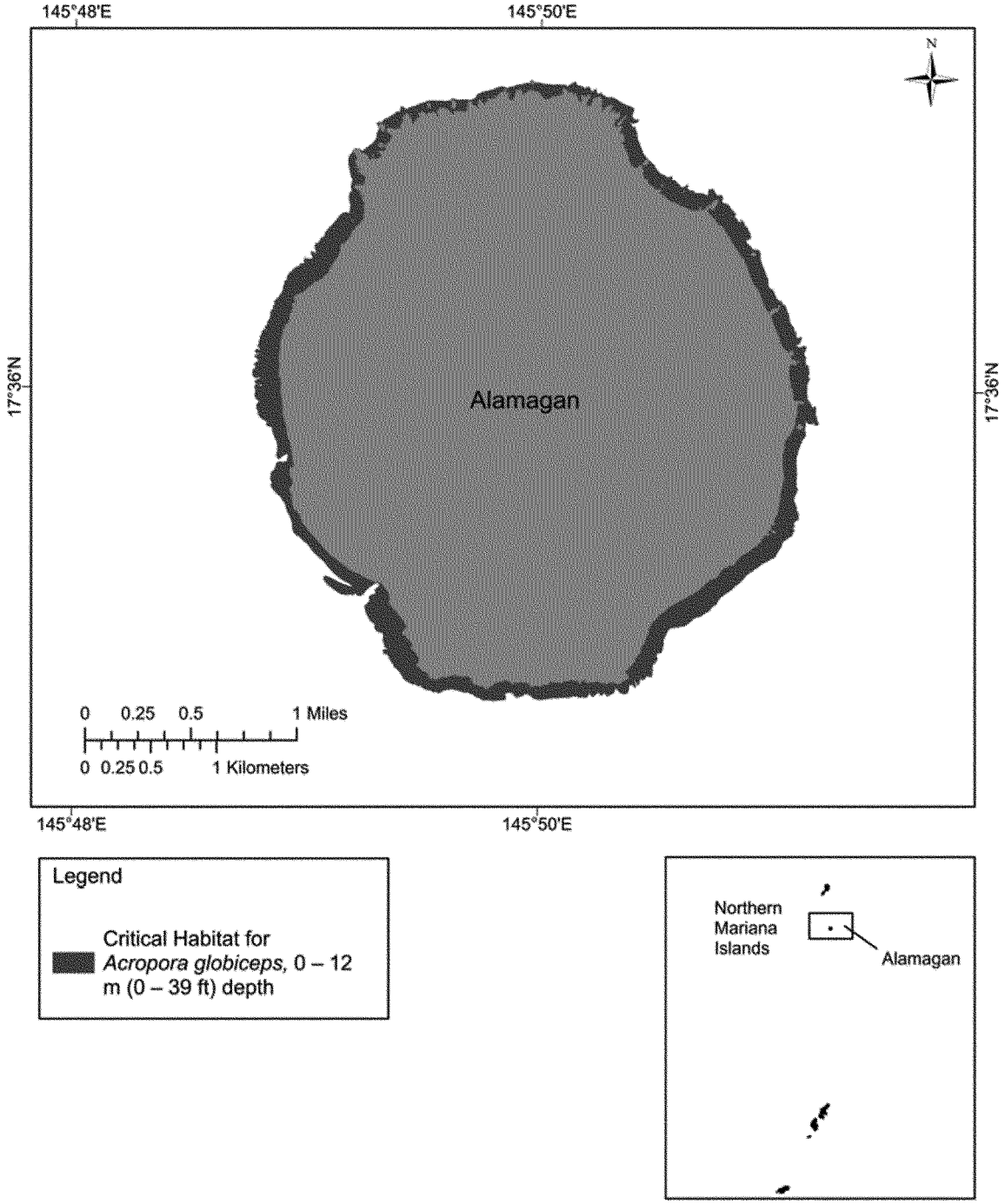


Figure 19 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Pagan.

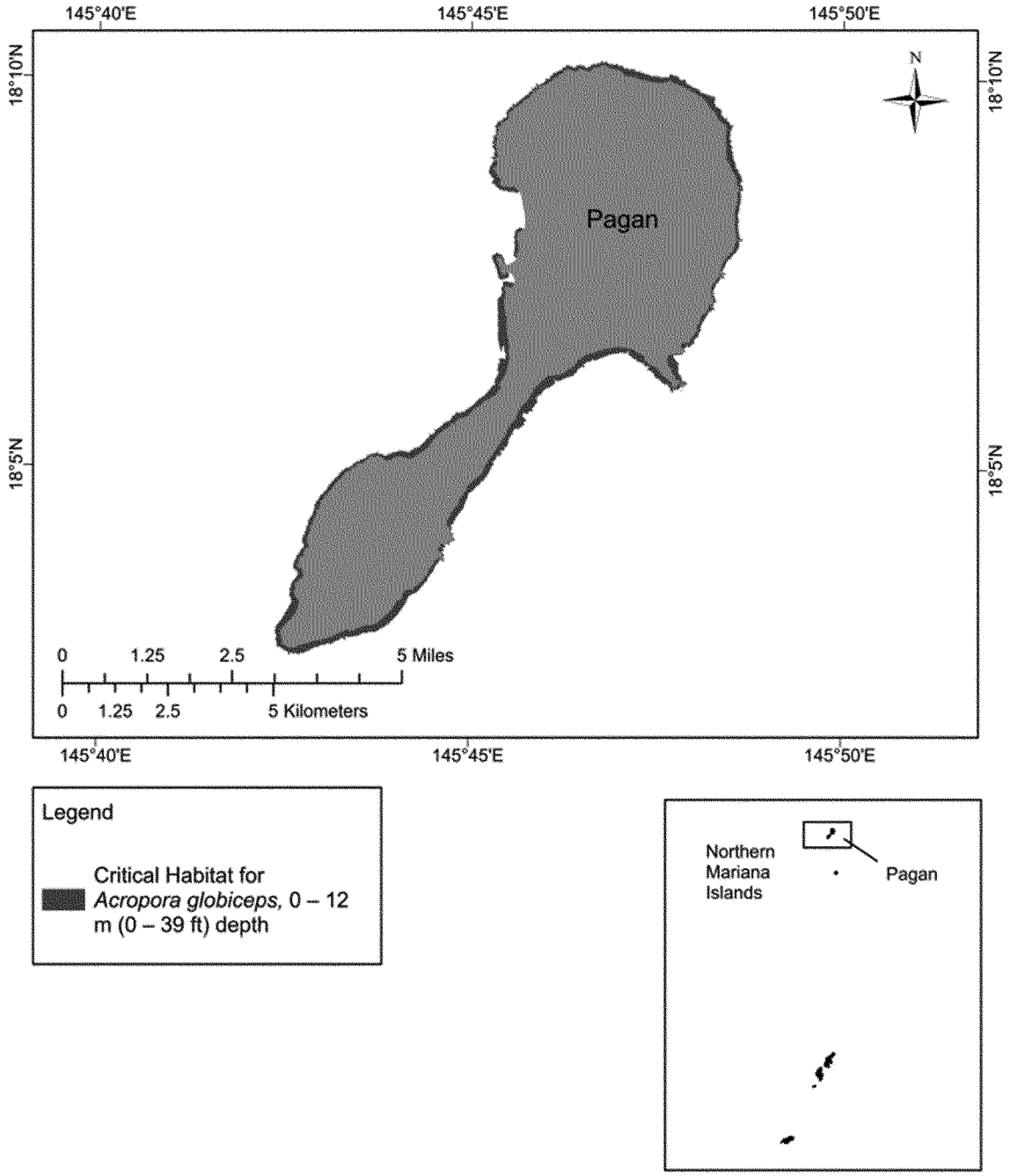


Figure 20 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Maug Islands.

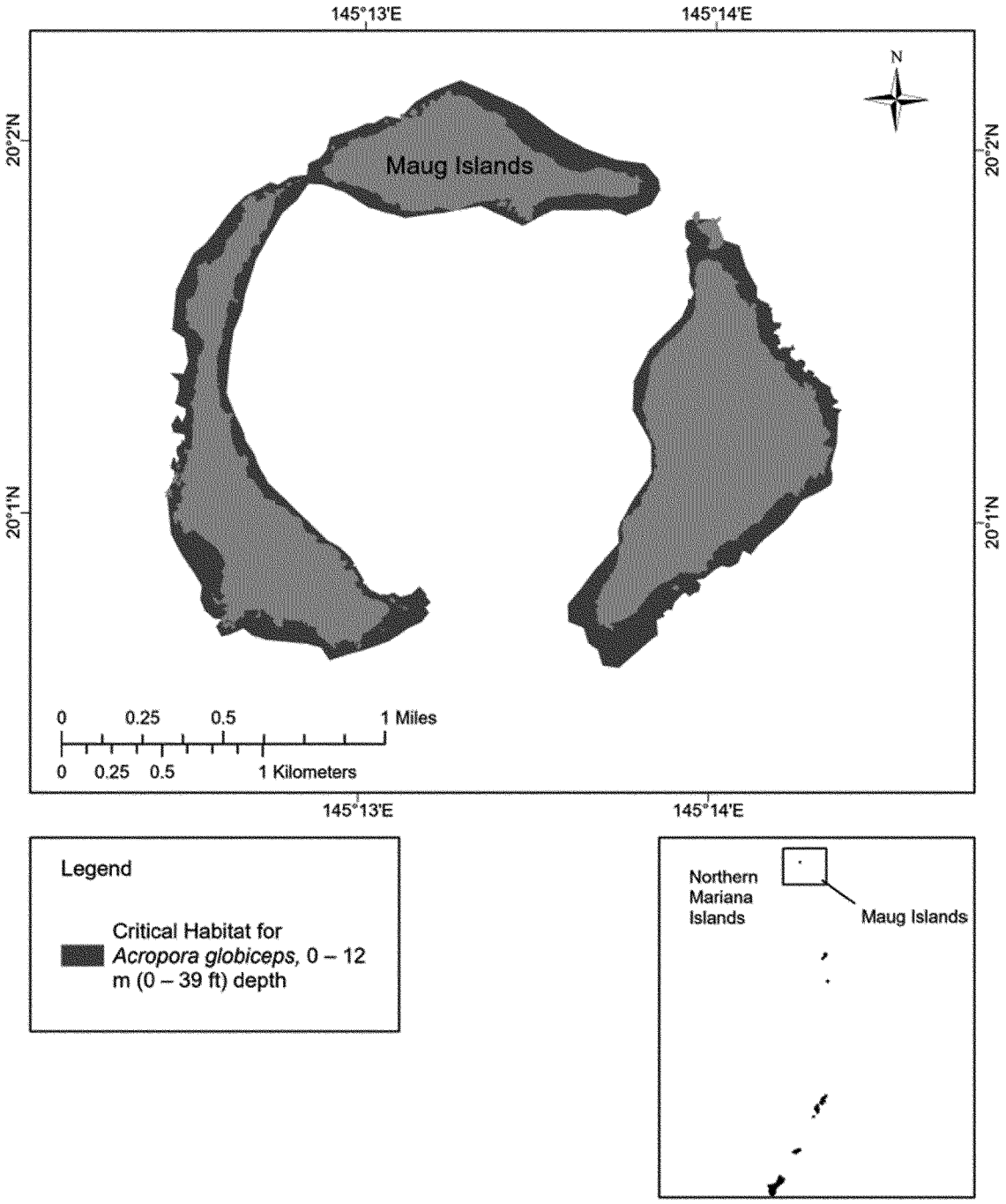


Figure 21 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Uracas.

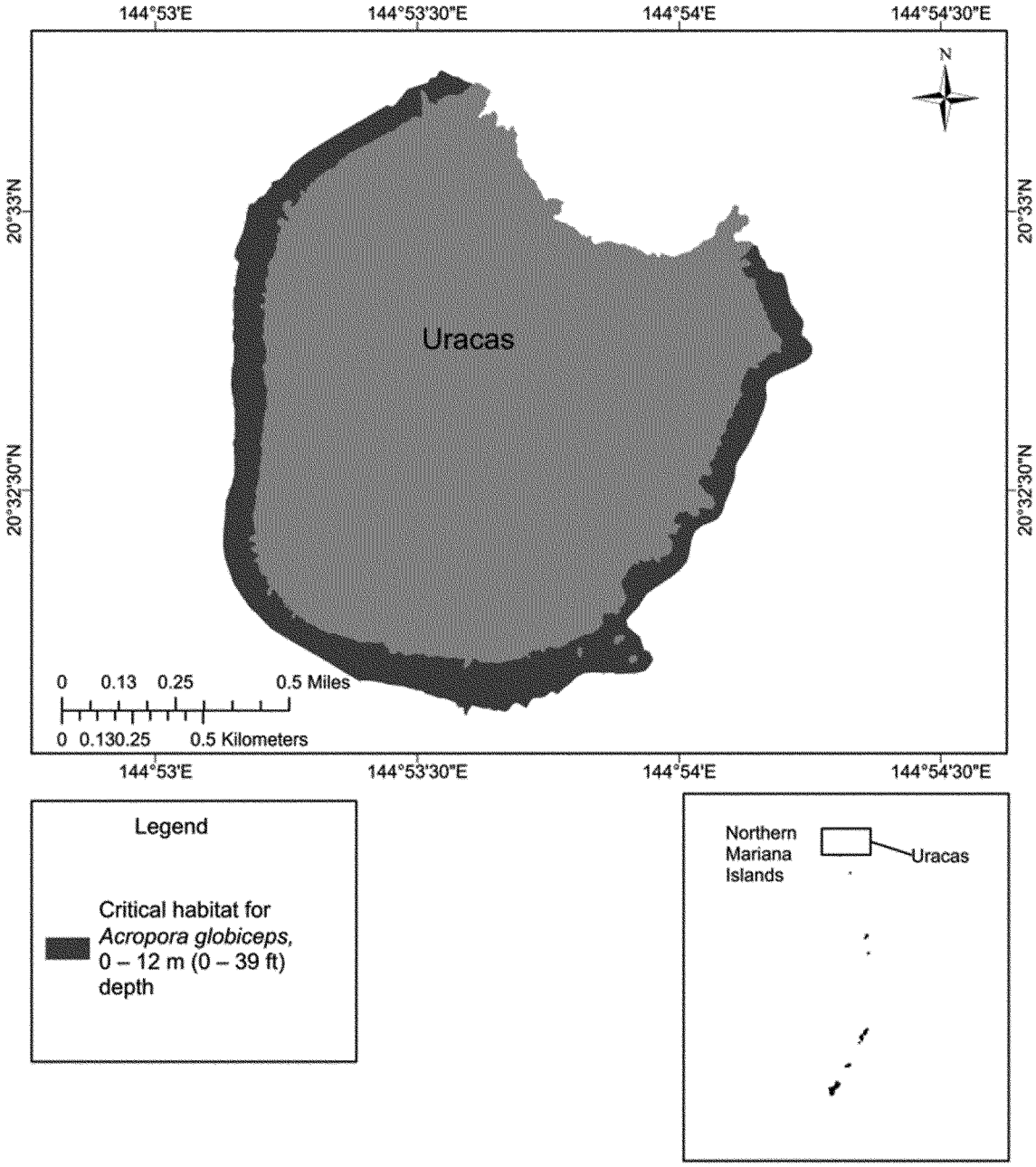


Figure 22 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, Palmyra Atoll.

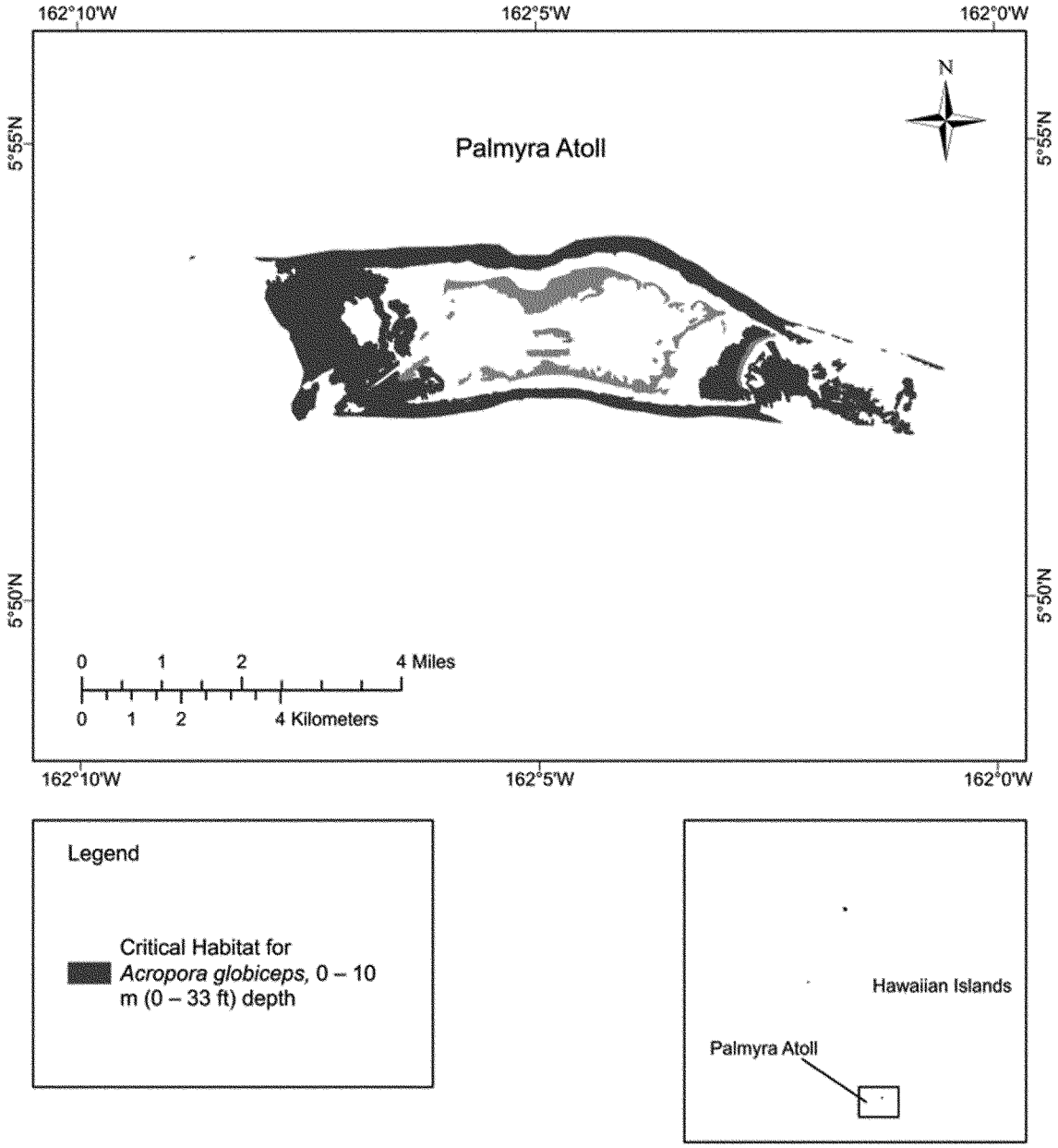


Figure 23 to paragraph (e).Proposed critical habitat for *Acropora globiceps*, Johnston Atoll.

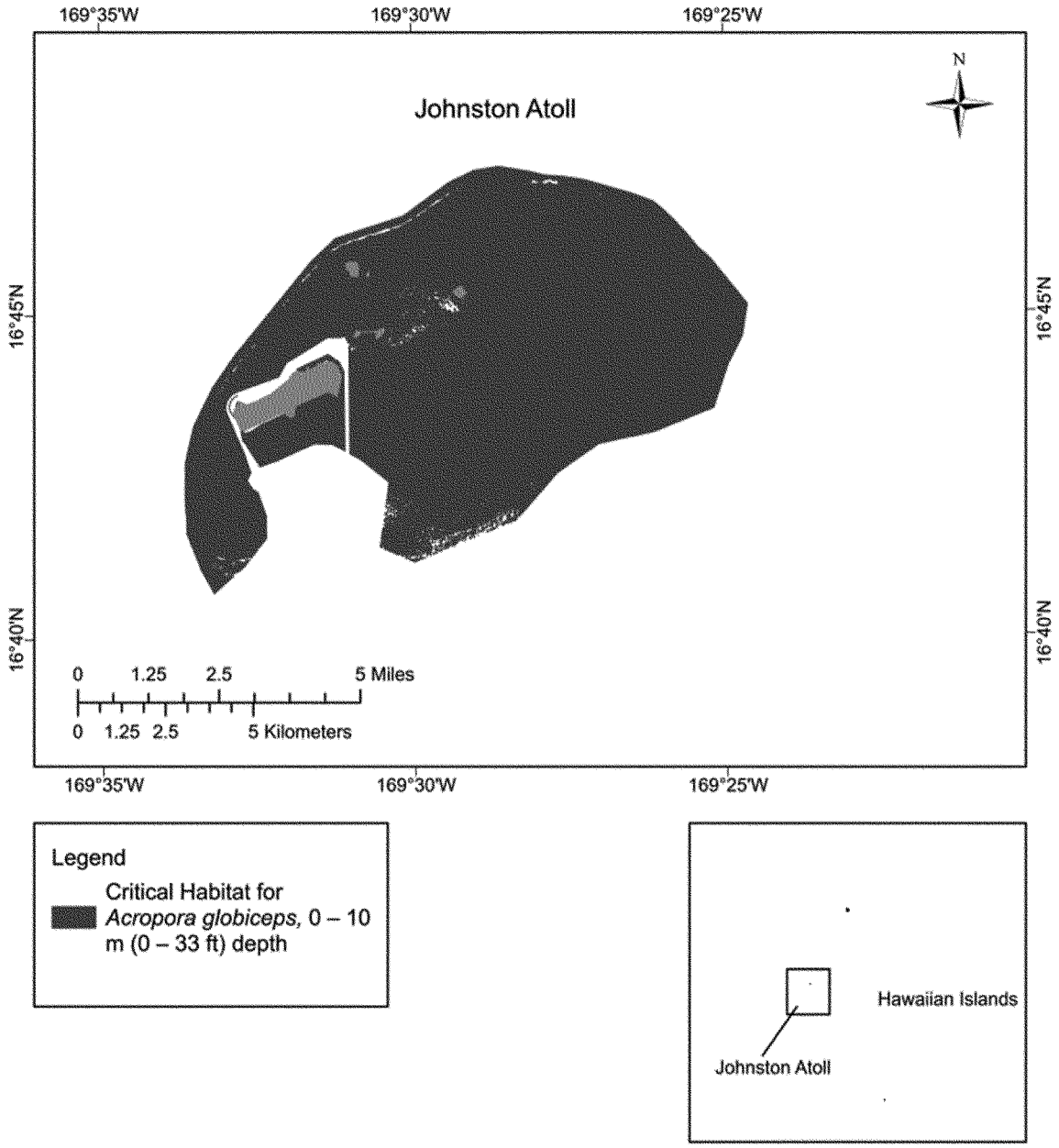
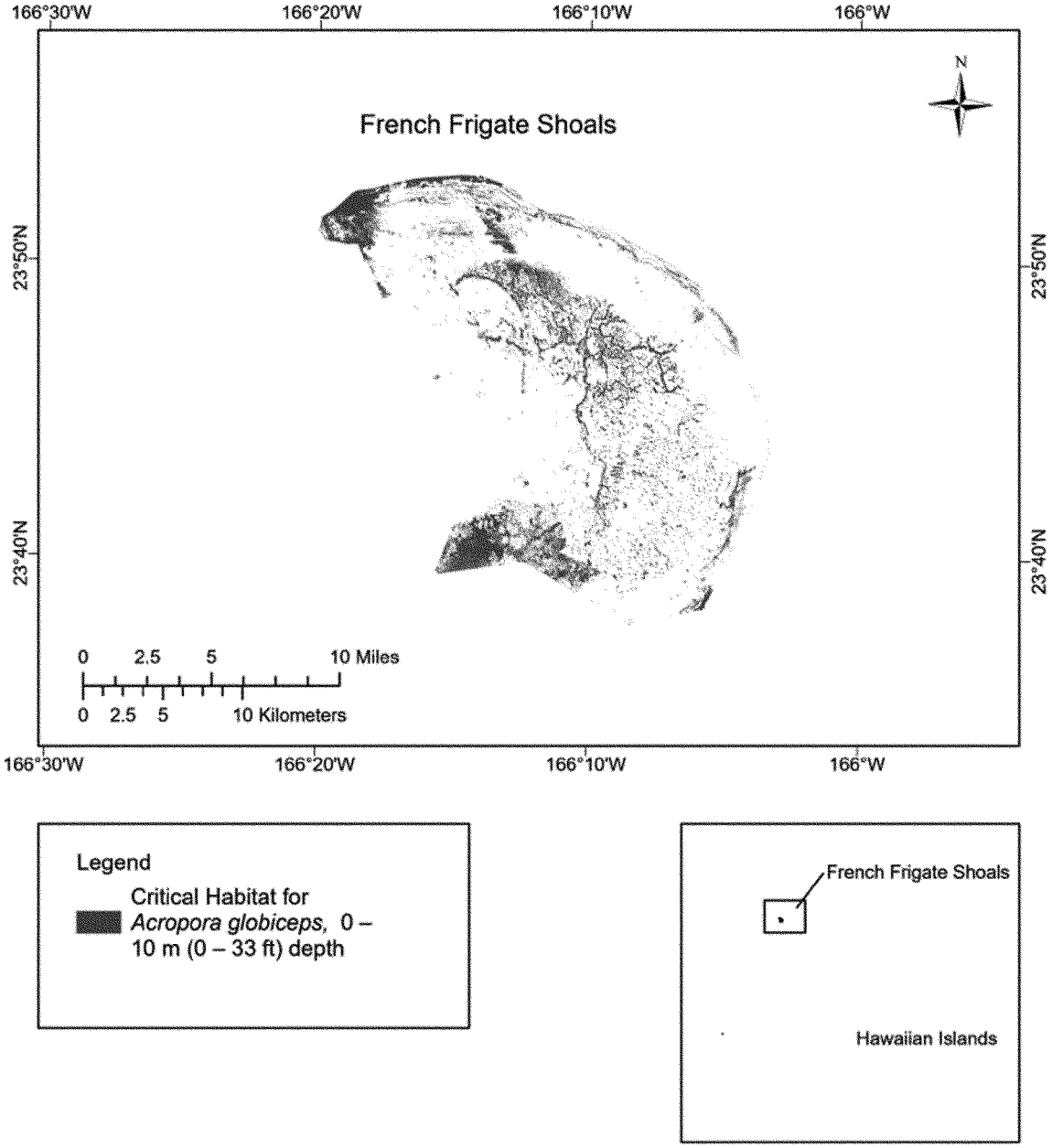


Figure 24 to paragraph (e). Proposed critical habitat for *Acropora globiceps*, French Frigate Shoals.



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Part III

Department of the Interior

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Documents Incorporated by Reference; Proposed Rule

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2022–0005 EEEE500000 245E1700D2 ET1SF0000.EAQ000]

RIN 1014–AA51

Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Documents Incorporated by Reference

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE), Interior.

ACTION: Proposed rule.

SUMMARY: BSEE proposes to incorporate documents by reference (Production Measurement Industry Standards and Safety Industry Standards, including one International Organization for Standardization/International Electrotechnical Commission standard) into the regulations governing oil, gas, and sulfur operations on the Outer Continental Shelf (OCS). Incorporation of these documents by reference would provide industry with up-to-date, minimum requirements for measuring oil and gas production volumes and enhancing safety. This would reduce uncertainty in the measurement of oil and gas production and update the minimum standards in the safety regulations.

DATES: Submit comments by February 28, 2024. BSEE is not obligated to consider or include in the Administrative Record for the final rule comments that we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed below (see **ADDRESSES**).

ADDRESSES: You may submit comments on the rulemaking by any of the following methods. Please use the Regulation Identifier Number 1014–AA51 as an identifier in your message. See also Public Availability of Comments under Procedural Matters.

- *Federal eRulemaking Portal: www.regulations.gov.* In the entry entitled, ''Enter Keyword or ID,'' enter BSEE–2022–0005 then click search. Follow the instructions to submit public comments and view supporting and related materials available for this rulemaking. BSEE may post all submitted comments.

Mail or hand-carry comments to BSEE: Attention: Regulations and Standards Branch, 45600 Woodland Road, VAE–ORP, Sterling, VA 20166. Please reference Regulation Identifier Number 1014–AA51, ''Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Documents Incorporated by Reference'' in your comments and include your name and return address.

- All API standards that are safety-related and that are incorporated into Federal regulations are available to the public for free viewing online in the Incorporation by Reference Reading Room or for purchase on API's website at: *https://publications.api.org* and *https://www.api.org/products-and-services/standards/purchase,* respectively.
- For the convenience of the viewing public who may not wish to purchase or view the incorporated documents online, the documents may be inspected at BSEE's offices at: 1919 Smith Street, Suite 14042, Houston, Texas 77002 (phone: 1–844–259–4779), or 45600 Woodland Road, Sterling, Virginia 20166 (email: *regs@bsee.gov*), by appointment only.
- Send comments on the information collection in this rule to: Interior Desk Officer 1014–0028, Office of Management and Budget; 202–395–5806 (fax); email: *oira_submission@omb.eop.gov.* Please send a copy to BSEE at *regs@bsee.gov.*

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. In order for BSEE to withhold from disclosure your personal identifying information, you must identify any information contained in your comment submittal that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequence(s) of the disclosure of information, such as embarrassment, injury, or other harm. While you may request that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: For technical or procedural questions contact Alton Payne at 713–220–9204, or David Izon at 703–787–1706, or by email: *standards@bsee.gov.*

SUPPLEMENTARY INFORMATION: BSEE uses standards, specifications, recommended practices (RPs), and other Standard Development Organizations (SDO) documents as a means of establishing requirements for activities on the OCS. This practice, known as incorporation by reference, allows BSEE to incorporate the requirements of technical documents into the regulations at 30 CFR 250.198 without increasing the volume of the Code of Federal Regulations (CFR). BSEE currently incorporates by reference the requirements found in 125 SDO documents into the offshore operating regulations.

The regulations found at 1 CFR part 51 govern how BSEE and other Federal agencies incorporate requirements found in various documents by reference. Agencies can only incorporate by reference through publication in the **Federal Register**. Agencies must also gain approval from the Director of the Federal Register for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the edition of the document or publication cited in the regulations. This means that newer editions, amendments, or revisions to documents already incorporated by reference in regulations are not part of BSEE regulations until they are specifically incorporated by reference.

BSEE reviews and analyzes potential standards for incorporation into the regulations. In some cases, BSEE may find that a specific standard has particular utility. As a result, BSEE may incorporate that particular standard or only that portion of a relevant standard. Standards that are considered for incorporation are subject to a side-by-side comparison of similar standards that are under consideration for proposed incorporation into BSEE's regulations. Once the BSEE review is complete, we make a final determination regarding whether incorporating a standard will properly address our regulatory concerns and either accept or reject the standard proposed for incorporation.

Availability of Incorporated Documents for Public Viewing

When a copyrighted technical industry standard is incorporated by reference into our regulations, BSEE must observe and protect that copyright. BSEE provides members of the public with website addresses where these standards may be accessed for viewing—sometimes for free and sometimes for a fee. Each SDO is the copyright owner and decides whether to charge a fee. The American Petroleum Institute (API) provides free read-only online public access to about 160 key industry standards. The free read-only online standards represent almost one-third of all API standards and include all that are safety-related or have been

incorporated into Federal regulations, including the standards in this proposed rule. The newly incorporated standards will be available for review online for free, and hardcopies and printable versions will continue to be available for purchase.

We are also proposing to incorporate standards from other SDOs, including the American Gas Association (AGA), GPA Midstream Association (GPA), and American Society of Mechanical Engineers (ASME). Descriptions of the proposed standards below are adopted or paraphrased from the SDO publications. To purchase the copyrighted documents, the website addresses and telephone numbers are: for API Documents, contact IHS Markit at 1–800–854–7179 or 303–397–7956 or their website *www.global.ihs.com* and; for AGA Documents, contact Techstreet at 1–800–699–9277 or their website *www.techstreet.com/contact.tmpl;* for ASME Documents, contact the organization at 1–800–843–2763 or their website *www.customercare@asme.org;* and for GPA Documents, contact the organization at 1–918–493–3872 or their website *www.Gpamidstream.org.*

For the convenience of the viewing public who may not wish to purchase or view these documents online, they may be inspected at the Bureau of Safety and Environmental Enforcement, 1919 Smith Street, Suite 14042, Houston, Texas 77002; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

These documents, if incorporated in a final rule, would continue to be made available to the public for viewing upon request. Specific information on where these documents could be inspected or purchased would be set forth at 30 CFR 250.198, Documents Incorporated by Reference.

BSEE is proposing to incorporate the requirements found in API Manual of Petroleum Measurement Standards (MPMS), AGA documents, and GPA standards. These documents reflect the latest measurement standards, and their incorporation would provide industry with up-to-date requirements for measurement technology. BSEE is also proposing to incorporate other documents dealing with a variety of safety topics as described below.

Ten standards proposed for incorporation by reference in this rulemaking (newly proposed standards) have not previously been incorporated by reference but have been used in practice by industry for at least a year and some for over a decade. The ten newly proposed standards are minimum safety standards. BSEE relies on standards as part of the bureau's review of development and operations plans required for permit applications. Further, BSEE has inspection programs that monitor compliance with regulations, which includes the incorporated industry standards.

The ten newly proposed standards comprise four integrity management standards, two offshore structure standards, two bolting/metallurgy standards, one crane related standard, and one well workover standard. The four integrity management standards pertain to recordkeeping and maintenance. The two structures standards are modifications of international standards that have been in use worldwide for decades. The two bolting/metallurgy standards are normative references in standards that are already incorporated by reference. The well workover standard is the second edition of a document that has already been in use by industry for approximately the past decade. The update to this standard was requested and reviewed by BSEE.

The National Technology Transfer and Advancement Act (NTTAA) requires that ''all Federal agencies . . . use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' 104 Public Law 113, 12(d)(1) (March 7, 1996). The relevant guidance in OMB Circular A–119 instructs federal agencies to use appropriate industry consensus standards when developing regulations because consensus standards are written and updated routinely by industry experts. This standard-specific rulemaking is part of the Department's effort to keep the standards in the regulations up to date. The American National Standards Institute (ANSI) generally requires that industry standards be updated at least every five years by the SDOs. The continual updating of standards results in standards that progressively evolve with the most recent safety criteria and industry norms, thereby evolving with new technology and addressing lessons learned.

Measurement documents were chosen for incorporation into the regulations based on the latest technological advances introduced in these standards and highlighted in the synopsis below. BSEE, in cooperation with independent reviewers from industry and academia, reviews and comments on the contents of these documents. Additionally, since this is a proposed rulemaking, BSEE will consider any public comments that we receive and may rely on them in developing the final rule.

BSEE continually participates in reviews, revisions, and updates of standards with SDOs and determines whether new editions should be incorporated into the Department's regulations. This may be necessary because of changes in technology, environmental concerns, individual incidents, or incident trends. Also, BSEE may request an SDO to develop a new standard based on incident analysis or due to the introduction of new technologies, such as deep-water operations and floating production systems.

BSEE has reviewed the requirements in the standards listed below and proposes to incorporate new standards into and revise some standards that have already been incorporated into the regulations at 30 CFR part 250 to ensure that industry uses the best available and most accurate measurement technologies. BSEE's review indicates that the decision to use these standards will not impose additional costs on the offshore oil and gas industry, because industry currently uses these standards.

Standards Proposed for Incorporation for the First Time or Proposed for Revisions and Summaries.

What requirements must I follow for cranes and other material-handling equipment? (§ 250.108)

BSEE proposes to add a reference to API Standard 2CCU (as incorporated by reference in § 250.198(e)(59)) to § 250.108 new paragraph (g).

Documents Incorporated by Reference. (§ 250.198)

The standards listed below are presented in the order in which they would appear with proposed additions and revisions in § 250.198:

Paragraph (b).

BSEE does not propose any changes to subparagraph (b)(1). BSEE proposes to retain the AGA Reports Numbers 7 and 10 as incorporated in existing § 250.198, add and update the other AGA Reports identified below in paragraph (b), and renumber the resulting subparagraphs as shown below and in the regulatory text:

American Gas Association (AGA) Report No. 8, Part 1, Thermodynamic Properties of Natural Gas and Related Gases Detail and Gross Equations of State, Third Edition, April 2017.

BSEE proposes to revise paragraph (b) of § 250.198 to incorporate by reference

for the first time AGA Report No. 8, Part 1, into its regulations (proposed regulatory text: § 250.198(b)(2)). Part 1 presents information for the computation of thermodynamic properties (*e.g.,* compressibility factor, density, and speed of sound) of natural gas and related gases with the DETAIL and GROSS equations of state. Uncertainty estimations for different compositions, pressures, and temperatures are given in Part 1. The computations described in Part 1 are valid for single-phase gaseous states only. BSEE proposes to add a reference to this standard in § 250.1203(b).

AGA Report No. 8, Part 2, Thermodynamic Properties of Natural Gas and Related Gases, GERG—2008 Equation of State, First Edition, April 2017.

BSEE proposes to incorporate by reference for the first time AGA Report No. 8, Part 2 (proposed regulatory text: § 250.198(b)(3)). Part 2 presents information for computation of thermodynamic properties, including compressibility factors, densities, and speeds of sound, of natural gas and related gases, for gaseous states, vapor-liquid equilibrium states, and liquid states, based on the GERG–2008 equation of state. It also improves upon the performance of the AGA 8 DETAIL equation for gas-phase properties, especially at high pressures and low temperatures. The ranges of temperature, pressure, and composition for which the GERG–2008 equation of state applies are much wider than the AGA 8 DETAIL equation. Uncertainty estimations for different compositions, pressures, and temperatures are given. With the availability of vapor-liquid equilibrium and liquid state calculations, Part 2 enables the calculation of dew points, bubble points, and the critical point. BSEE proposes to add a reference to this standard in § 250.1203(b)

AGA Report No. 9—Measurement of Gas by Multipath Ultrasonic Meters, Fourth Edition, 2022.

BSEE proposes to update the already incorporated reference of AGA Report No. 9 from the Second edition to the Fourth edition in its regulations (proposed regulatory text: § 250.198(b)(4)). This standard describes the optimum conditions and best practices for multipath ultrasonic transit-time flow meters used for the measurement of natural gas. Multipath ultrasonic meters have at least two independent pairs of measuring transducers (acoustic paths). Typical applications include measuring the flow of gas through production facilities, transmission pipelines, storage facilities, distribution systems, and large end-use customer meter sets. BSEE currently requires multipath ultrasonic meters used for gas royalty measurement to contain at least three independent pairs of measuring transducers. BSEE incorporated the Second edition of this standard on March 29, 2012 (77 FR 18916). BSEE proposes to update the reference from the Second to the Fourth edition of this standard in § 250.1203(b)(2). The latest edition of AGA Report 9 allows the calibration of ultrasonic meters with laboratory piping in lieu of shipping the entire metering package to the calibration lab.

AGA Report Number 10 will remain as previously incorporated by reference into the regulations, but will be renumbered to § 250.198(b)(5).

AGA Report No. 11—Measurement of Natural Gas by Coriolis Meter, Second Edition, February 2013.

BSEE proposes to incorporate by reference for the first time AGA Report No. 11, Second Edition, into its regulations (proposed regulatory text: § 250.198(b)(6)). AGA Report No. 11 was developed for the specification, calibration, installation, operation, maintenance, and verification of Coriolis flow meters and is limited to the measurement of single-phase natural gas, consisting primarily of hydrocarbon gases mixed with other associated gases usually known as ''diluents.'' Although Coriolis meters are used to measure a broad range of compressible fluids, non-natural gas applications are beyond the scope of this document. BSEE proposes to add a reference to this standard in § 250.1203(b) as well.

Paragraph (e)—American Petroleum Institute (API), API Recommended Practices, Specifications, Standards, Manual of Petroleum Measurement Standards (MPMS) chapters.

BSEE proposes to reorganize paragraph (e) of § 250.198 to make it more user-friendly and easier to locate the API standards that BSEE incorporates by reference. BSEE proposes to replace the numbered list of the API standards that BSEE incorporates by reference with a table organized by category and standard number. Except as otherwise expressly discussed below, these changes are purely organizational and do not alter the substance of the paragraph.

Separately, BSEE proposes to incorporate by reference additional API Standards in § 250.198 paragraph (e) and update others. BSEE also proposes to remove the references to API Bulletin 2INT–MET, *Interim Guidance on Hurricane Conditions in the Gulf of Mexico,* May 2007, located in the existing regulations at § 250.198(e)(5), and API RP 86, *Recommended Practice for Measurement of Multiphase Flow,* September 2005, located in the existing regulations at § 250.198(e)(76). API Bulletin 2INT–MET was an interim document that provided best practices as of 2007 and is replaced in this rule by API RP 2MET—Derivation of Metocean Design and Operating Conditions, Second Edition, January 2021. Similarly, API RP 86 was a document that provided best practices as of 2005 and is superseded by API MPMS, Chapter 20.3—Measurement of Multiphase Flow, First Edition January 2013; reaffirmed October 2018, and supplemented in this rule by AGA Report No. 9—Measurement of Gas by Multipath Ultrasonic Meters, Fourth Edition, 2022. For explanations of the more up to date replacement standards, see the relevant locations in the section-by-section discussions.

API MPMS Chapter 1—Vocabulary, Second Edition, July 1994 is incorporated by reference in the current § 250.198(e)(7) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(1).

API MPMS Chapter 2—Tank Calibration, Section 2A—Measurement and Calibration of Upright Cylindrical Tanks by the Manual Tank Strapping Method, First Edition, February 1995, reaffirmed August 2017 is incorporated by reference in the current § 250.198(e)(8) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(2). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (l) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 2—Tank Calibration, Section 2B—Calibration of Upright Cylindrical Tanks Using the Optical Reference Line Method, First Edition, March 1989; reaffirmed April 2019 (including Addendum 1, October 2019) is incorporated by reference in the current § 250.198(e)(9) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(3). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (l) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 2.2E, Petroleum and Liquid Petroleum Products—Calibration of Horizontal Cylindrical Tanks, Part 1: Manual Methods, First Edition, April 2004, Reaffirmed August 2014, Errata November 2009.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 2.2E, Part 1, into its regulations in § 250.198(e)(4). This standard is part of ISO 12917 and specifies manual methods for the calibration of nominally horizontal cylindrical tanks, installed at a fixed location. It is applicable to horizontal tanks up to 4 meters in diameter and 30 meters in length. The methods are applicable to insulated and non-insulated tanks, either when they are aboveground or underground. The methods are applicable to pressurized tanks, and to both knuckle-dish-end and flat-end cylindrical tanks, as well as elliptical and spherical head tanks. Information is also provided to address tanks that are larger than these dimensions. BSEE proposes to add a reference to this standard in § 250.1202(a) as well.

API MPMS Chapter 2.2F, Petroleum and Liquid Petroleum Products—Calibration of Horizontal Cylindrical Tanks, Part 2: Internal Electro-optical Distance-Ranging Method, First Edition, April 2004, reaffirmed September 2014.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 2.2F, Part 2, into its regulations in § 250.198(e)(5). This standard is part of ISO 12917–2 and specifies a method for the calibration of horizontal cylindrical tanks having diameters greater than 2 meters by means of internal measurements using an electro-optical distance-ranging instrument, and for the subsequent compilation of tank-capacity tables. This method is known as the internal electro-optical distance-ranging method. This part of ISO 12917–2 is also applicable to tanks inclined by up to 10 percent from the horizontal provided a correction is applied for the measured tilt. BSEE proposes to add a reference to this standard in § 250.1202 as well.

API MPMS Chapter 3.1A, Standard Practice for the Manual Gauging of Petroleum and Petroleum Products, Third Edition, August 2013, Errata 1, January 2021.

BSEE proposes to update the incorporation by reference of this standard in the current § 250.198(e)(10) from the Second to the Third Edition, and to relocate it to § 250.198(e)(6). The title also changed from API MPMS Chapter 3, Section 1A to API MPMS Chapter 3.1A. The Third Edition added sections on gauging procedures, reading and recording gauges, operational precautions, and system integrity. This document describes the following procedures and influences for manual gauging:

(1) The procedures for manually gauging the liquid level of petroleum and petroleum products in non-pressure fixed-roof, floating-roof tanks and marine tank vessels;

(2) Procedures for manually gauging the level of free water that may be found with the petroleum or petroleum products;

(3) Methods used to verify the length of gauge tapes under field conditions and the influence of bob weights and temperature on the gauge tape length; and

(4) Influences that may affect the position of gauging reference point (either the datum plate or the reference gauge point).

Throughout this standards document, the term petroleum is used to denote petroleum, petroleum products, or the liquids normally associated with the petroleum industry. This document is applicable for gauging quantities of liquids having Reid vapor pressures less than 103 kPa (15 psia). The Department incorporated the Second edition into its regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the incorporation of the Third edition of this standard into § 250.1202(a).

API MPMS Chapter 3—Tank Gauging, Section 1B—Standard Practice for Level Measurement of Liquid Hydrocarbons in Stationary Tanks by Automatic Tank Gauging, Second Edition, June 2001; reaffirmed February 2016 is incorporated by reference in the current § 250.198(e)(11) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(7). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (l) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 4—Proving Systems, Section 1—Introduction, Third Edition, February 2005; reaffirmed June 2014 is incorporated by reference in the current § 250.198(e)(12) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(8). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (d) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 4—Proving Systems, Section 2—Displacement Provers, Third Edition, September 2003, Addendum February 2015, Reaffirmed December 2022.

BSEE proposes to correct the reference to API MPMS Chapter 4, Section 2, in the current regulations at § 250.198(e)(13), to reflect the 2022 reaffirmation and the 2015 Addendum, and to relocate it to § 250.198(e)(9). This chapter outlines the essential elements of provers that do, and do not, accumulate a minimum of 10,000 whole meter pulses between detector switches, and provides design and installation details for the types of displacement provers that are currently in use. The provers discussed in this chapter are designed for proving measurement devices under dynamic operating conditions with single-phase liquid hydrocarbons. These provers consist of a pipe section through which a displacer travels and activates detection devices before stopping at the end of the run as the stream is diverted or bypassed. The Department incorporated the Third edition of this standard into its regulations on March 15, 2007 (72 FR 12088). The Department here proposes to update that incorporated edition to acknowledge the 2022 reaffirmation and 2015 Addendum. BSEE proposes to update the reference of this standard in § 250.1202 as well.

API MPMS Chapter 4—Proving Systems, Section 4—Tank Provers, Second Edition, May 1998, reaffirmed December 2020 is incorporated by reference in the current § 250.198(e)(14) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(10). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (f) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 4.5, Master Meter Provers, Fourth Edition, June 2016.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 4.5, currently located at § 250.198(e)(15), from the Second to the Fourth edition in its regulations, and to relocate it to § 250.198(e)(11). The title of this standard has changed from API MPMS Chapter 4, Section 5 to API MPMS Chapter 4.5. The Fourth Edition added sections on Master Meter Factors for combined uncertainty, random uncertainty, and related examples. This standard covers the use of displacement, turbine, Coriolis, and ultrasonic meters as master meters. The requirements in this standard are intended for single-

phase liquid hydrocarbons. Meter proving requirements for other fluids should be appropriate for the overall custody transfer accuracy and should be agreeable to the parties involved. This document does not cover master meters to be used for the calibration of provers. For information concerning master meter calibration of provers, see API MPMS Chapter 4.9.3. The Department incorporated the Second edition of this standard into the regulations on March 15, 2007 [72 FR 12088]. BSEE proposes to update the reference of this standard into § 250.1202 as well.

API MPMS Chapter 4—Proving Systems, Section 6—Pulse Interpolation, Second Edition, May 1999; Errata April 2007; reaffirmed October 2013 is incorporated by reference in the current § 250.198(e)(16) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(12). BSEE is proposing to add an express reference to this standard in § 250.1202 paragraphs (a) and (h) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 4—Proving Systems, Section 7—Field Standard Test Measures, Third Edition, April 2009, reaffirmed June 2014.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 4, Section 7, currently located at § 250.198(e)(17), from the Second to the Third Edition in its regulations, and to relocate it to § 250.198(e)(13). The Third Edition includes information on calibration frequency of test measurements and an example of a NIST report of calibration. This standard describes the essential elements of field standard test measures by providing descriptions, construction requirements, as well as inspection, handling, and calibration methods. Bottom-neck scale test measures and prover tanks are not addressed in this document. The scope of this standard is limited to the certification of ''delivered volumes'' of test measures. The Department incorporated the Second edition of this standard into its regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a) as well.

API MPMS Chapter 4.8—Operation of Proving Systems, Third Edition, July 2021.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 4.8, currently located at § 250.198(e)(18), from the First to the Third Edition in its regulations, and to relocate it to § 250.198(e)(14). The title of this standard also changed from API MPMS Chapter 4, Section 8 to API MPMS Chapter 4.8. The Third Edition added information on frequency of meter proving, proving locations, types of provers, calibration frequency, and proving concerns. This standard provides information for operating meter provers on single-phase liquid hydrocarbons. It is a reference manual for operating proving systems. The requirements of this chapter are based upon customary practices for single-phase liquids. The standard is purposely written for hydrocarbons, but much of the information contained may be applicable to other liquids. Specific requirements for other liquids should be agreeable to parties involved. BSEE incorporated the First edition of this standard into its regulations on March 29, 2012 (77 FR 18916). BSEE proposes to update the reference of this standard in § 250.1202.

API MPMS Chapter 4, Proving Systems, Section 9—Methods of Calibration for Displacement and Volumetric Tank Provers, Part 2—Determination of the Volume of Displacement and Tank Provers by the Water-draw Method of Calibration, First Edition, December 2005, reaffirmed July 2015.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 4, Proving Systems, Section 9, Part 2, into its regulations in § 250.198(e)(15). This standard covers all the procedures required to determine the field data necessary to calculate a base prover volume, of either displacement provers or volumetric tank provers, by the water-draw method of calibration. The document will enable the user to perform all the activities necessary to prepare the prover, conduct calibration runs, and record all the required data necessary to calculate the base volumes of displacement and tank provers. Evaluation of the results and troubleshooting of many calibration problems are also discussed. Detailed calculation procedures are not included in this standard. For complete details regarding the calculations applicable to this standard, refer to the latest edition of the API *Manual of Petroleum Measurement Standards,* Chapter 12, Section 2, Part 4, entitled, ''Calculation of Prover Volumes by the Water-draw Method.'' BSEE proposes to add a reference to this standard in § 250.1202.

API MPMS, Chapter 5—Metering, Section 1—General Considerations for Measurement by Meters, Fourth Edition, September 2005, Errata 1 June 2008, Errata 2 June 2011, reaffirmed December 2022.

BSEE proposes to update its incorporation of API MPMS Chapter 5, Metering, Section 1, currently located at § 250.198(e)(19), to include Errata 1, Errata 2, and the December 2022, and to relocate it to § 250.198(e)(16). The errata corrected printing errors of references at the end of a paragraph, *e.g.,* ''Paragraph 5.1.9.4.2, the reference at the end of the paragraph should read: (see 5.1.9.5).'' API MPMS Chapter 5 is a guide for the proper specification, installation, and operation of meter runs designed to dynamically measure liquid hydrocarbons so that acceptable accuracy, service life, safety, reliability, and quality control can be achieved. API MPMS Chapter 5 also includes information that will assist in troubleshooting and improving the performance of meters. The Department updated its incorporation of the Fourth edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 5—Metering, Section 2—Measurement of Liquid Hydrocarbons by Displacement Meters, Third Edition, September 2005; reaffirmed December 2020 is incorporated by reference in the current § 250.198(e)(20) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(17). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 5—Metering, Section 3—Measurement of Liquid Hydrocarbons by Turbine Meters, Fifth Edition, September 2005; reaffirmed August 2014 is incorporated by reference in the current § 250.198(e)(21) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(18). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 5—Metering, Section 4—Accessory Equipment for Liquid Meters, Fourth Edition, September 2005; reaffirmed August 2015 is incorporated by reference in the current § 250.198(e)(22) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(19).

BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 5—Metering, Section 5—Fidelity and Security of Flow Measurement Pulsed-Data Transmission Systems, Second Edition, August 2005; reaffirmed August 2015 is incorporated by reference in the current § 250.198(e)(23) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(20). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 5—Metering, Section 6—Measurement of Liquid Hydrocarbons by Coriolis Meters; First Edition, October 2002; reaffirmed November 2013 is incorporated by reference in the current § 250.198(e)(24) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(21).

API MPMS Chapter 5.8—Measurement of Liquid Hydrocarbons by Ultrasonic Flow Meters, Second Edition, November 2011, Errata February 2014, reaffirmed May 2017.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 5.8, currently located at § 250.198(e)(25), from the First edition to the Second edition, including Errata and Reaffirmation, in its regulations, and to relocate it to § 250.198(e)(22). The title of this standard changed from API MPMS Chapter 5, Section 8 to API MPMS Chapter 5.8. The Second Edition updated the normative references and the sections on meter performance, accuracy, and repeatability. This document defines the application criteria for Ultrasonic Flow Meters (UFMs) and addresses the appropriate considerations regarding the liquids to be measured. Also, this document addresses the installation, operation, and maintenance of UFMs in liquid hydrocarbon service. This document pertains only to spool type, two or more path ultrasonic flow meters with permanently affixed transducer assemblies. While this document was specifically written for custody transfer measurement, other acceptable applications may include allocation measurement, check meter measurement, and leak detection measurement. BSEE updated its incorporation of the First edition of this standard into the regulations on March 29, 2012 (77 FR 18916). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 6.1, Lease Automatic Custody Transfer (LACT) Systems, Second Edition, May 1991, Addendum 1 August 2020.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 6.1 in its regulations, currently located at § 250.198(e)(26), to include the 2020 Addendum in § 250.198(e)(23). The title of this standard changed from API MPMS Chapter 6, Section 1 to API MPMS Chapter 6.1. The Addendum added information on determining normal operating conditions. This publication describes the metering function of a LACT unit and is intended to complement API Specification 11N, Specification for Lease Automatic Custody Transfer (LACT) Equipment. LACT equipment includes a meter (either displacement or turbine), a proving system (either fixed or portable), devices for determining temperature and pressure and for sampling the liquid, and a means of determining non-merchantable oil. Many of the aspects of the metering function of a LACT unit are considered at length in other parts of this manual and are referenced in paragraph 6.1.4. API reaffirmed the standard without substantive change in May 2012, and BSEE updated its incorporation of the Second edition of this standard in the regulations on December 20, 2020 (85 FR 84230). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 6—Metering Assemblies, Section 6—Pipeline Metering Systems, Second Edition, May 1991; reaffirmed December 2017 is incorporated by reference in the current § 250.198(e)(27) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(24). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 6—Metering Assemblies, Section 7—Metering Viscous Hydrocarbons, Second Edition, May 1991; reaffirmed March 2018 is incorporated by reference in the current § 250.198(e)(28) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(25). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS, Chapter 7.1—Temperature Determination-Liquid-in-Glass Thermometers, Second Edition, August 2017.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 7.1 into its regulations in § 250.198(e)(26). API MPMS Chapter 7, Temperature Determination, First Edition, June 2001, which is currently incorporated by reference at § 250.198(e)(29), was withdrawn by API as outdated and superseded by API MPMS Chapters 7.1, 7.2, 7.3, and 7.4. This rule deletes outdated API MPMS Chapter 7 and adds API MPMS Chapters 7.1 and 7.3. API MPMS Chapter 7.1 is specific to liquid-in-glass thermometers. API MPMS Chapter 7.1 describes the methods, equipment, and procedures for manually determining the temperature of liquid petroleum and petroleum products under both static and dynamic conditions with liquid-in-glass thermometers. Further, Chapter 7.1 discusses temperature measurement requirements in general for custody transfer, inventory control, and marine measurements. The actual method and equipment selected for temperature determination are left to the agreement of the parties involved. The manual method covers non-pressurized tanks and non-pressurized marine vessels and gas-blanketed tanks and gas-blanketed marine vessels. It does not cover hydrocarbons under pressures in excess of 21 kPa (3 psi gauge) or cryogenic temperature measurement, unless equipped with a thermowell. BSEE proposes to add a reference to this standard in § 250.1202(a).

API MPMS, Chapter 7.3—Temperature Determination—Temperature Determination—Fixed Automatic Tank Temperature Systems, Second Edition, October 2011, reaffirmed September 2021.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 7.3, Second Edition as reaffirmed, into its regulations in § 250.198(e)(27). API MPMS Chapter 7, Temperature Determination, First Edition, June 2001, which is currently incorporated by reference at § 250.198(e)(29), was withdrawn by API as outdated and superseded by API MPMS Chapters 7.1, 7.2, 7.3, and 7.4. This rule deletes outdated API MPMS Chapter 7 and adds API MPMS Chapters 7.1 and 7.3. API MPMS Chapter 7.3 describes the methods, equipment, and procedures for determining the temperature of petroleum and

petroleum products under static conditions by the use of an automatic method. Automatic temperature measurement is discussed for custody transfer and inventory control for both onshore and marine measurement applications. Temperatures of hydrocarbon liquids under static conditions can be determined by measuring the temperature of the liquid at specific locations. Examples of where static temperature determination is required include storage tanks, ships, and barges. The application of this standard is restricted to automatic methods for the determination of temperature using fixed automatic tank thermometer (ATT) systems for hydrocarbons having a Reid Vapor Pressure at or below 101.325 kPa (14.696 psia). BSEE proposes to add a reference to this standard in § 250.1202(a).

API MPMS Chapter 8.1—Standard Practice for Manual Sampling of Petroleum and Petroleum Products, Sixth Edition, September 2022.

BSEE proposes to update the incorporation of API MPMS Chapter 8.1, currently located at § 250.198(e)(30), from the Third edition to the Sixth Edition in its regulations, and to relocate it to § 250.198(e)(28). The title of this section changed from API MPMS Chapter 8, Section 1 to API MPMS Chapter 8.1. The Sixth Edition added sections on health and safety precautions, sampling requirements, considerations, and procedures, as well as instructions for special products. This practice covers procedures and equipment for manually obtaining samples of liquid petroleum and petroleum products, crude oils, and intermediate products from the sample point into the primary container. Procedures are also included for the sampling of free water and other heavy components associated with petroleum and petroleum products. This practice also addresses the sampling of semi-liquid or solid-state petroleum products. This practice provides additional specific information about sample container selection, preparation, and sample handling. This practice does not cover sampling of electrical insulating oils and hydraulic fluids. If sampling is for the precise determination of volatility, use Practice D5842 (API MPMS Chapter 8.4) in conjunction with this practice. For sample mixing and handling, refer to Practice D5854 (API MPMS Chapter 8.3). The Department updated its incorporation of the Third edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS, Chapter 8.2—Standard Practice for Automatic Sampling of Liquid Petroleum and Petroleum Products, Sixth Edition, September 2022.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 8.2, currently located at § 250.198(e)(31), from the 1995 Second edition to the Sixth edition, September 2022 in its regulations, and to relocate it to § 250.198(e)(29). The title of this standard changed from API MPMS Chapter 8, Section 2 to API MPMS Chapter 8.2. The Sixth Edition added representative sampling components and performance criteria. This document describes general procedures and equipment for automatically obtaining samples of liquid petroleum and petroleum products, crude oils, and intermediate products from the sample point into the primary container. This practice also provides additional specific information about sample container selection, preparation, and sample handling. If sampling is for the precise determination of volatility, use Practice D5842 (API MPMS Chapter 8.4) in conjunction with this practice. For sample mixing and handling, refer to Practice D5854 (API MPMS Chapter 8.3). This practice does not cover sampling of electrical insulating oils and hydraulic fluids. Combining values from the two systems may result in non-conformance with the standard. This standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade Committee. The Department updated its incorporation of the Second edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 8.3—Standard Practice for Mixing and Handling of Liquid Samples of Petroleum and Petroleum Products, Second Edition, September 2019.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 8.3, into its regulations in § 250.198(e)(30). The Second Edition added text on labeling, transport, mixing, sample integrity, storage, preservation, and audit. This practice covers handling, mixing, and conditioning procedures that are required to ensure that a representative sample of the liquid petroleum or petroleum product is delivered from the primary sample container or other container or both into the analytical apparatus or into intermediate containers. Appendix X1 in this document details the background information on the development of Table 1 used in performance testing. Appendix X2 provides guidance in the acceptance testing for water in crude oil. Appendix X3 provides a guide for materials of sample containers. Appendix X4 provides a summary of recommended mixing procedures. Appendix X5 provides a flow chart for sample container/mixing system acceptance test. BSEE proposes to add a reference to this standard in § 250.1202(a).

API MPMS Chapter 9.1—Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method, Third Edition, December 2012, reaffirmed May 2017.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 9.1, currently located at § 250.198(e)(32), from the 2002 Second edition to the December 2012 Third edition, Reaffirmed in May 2017, in its regulations, and to relocate it to § 250.198(e)(31). The title of this standard changed from API MPMS Chapter 9, Section 1 to API MPMS Chapter 9.1. The Third Edition included information on procedures, reporting, and precision and bias. This test method covers the laboratory determination of the density, relative density, or API gravity of crude petroleum, petroleum products, or mixtures of petroleum and nonpetroleum products normally handled as liquids and having a Reid vapor pressure of 101.325 kPa (14.696 psi) or less. The relevant test method involves using a glass hydrometer in conjunction with a series of calculations. Values are determined at existing temperatures and corrected to 15 °C or 60 °F by means of a series of calculations and international standard tables. The Department updated its incorporation of the Second edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 9.2—Standard Test Method for Density or Relative Density of Light Hydrocarbons by Pressure Hydrometer, Fourth Edition, November 2022.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 9.2, currently located at § 250.198(e)(33), from the 2003 Second

edition to the November 2022 Fourth edition in its regulations, and to relocate it to § 250.198(e)(32). The title of this standard changed from API MPMS Chapter 9, Section 2 to API MPMS Chapter 9.2. The Fourth Edition included distinguishing mandatory information and amended the referenced documents section. This test method covers the determination of the density or relative density of light hydrocarbons including liquefied petroleum gases (LPG) having Reid vapor pressures exceeding 101.325 kPa (14.696 psi). The prescribed apparatus should not be used for materials having vapor pressures higher than 1.4 MPa (200 psi) at the test temperature. This pressure limit is dictated by the type of equipment. Higher pressures can apply to other equipment designs. The initial pressure hydrometer readings obtained are uncorrected hydrometer readings and not density measurements. Readings are measured on a hydrometer at either the reference temperature or at another convenient temperature, and readings are corrected for the meniscus effect, the thermal glass expansion effect, alternate calibration temperature effects, and to the reference temperature by means of calculations and Adjunct to D1250 Guide for Petroleum Measurement Tables (API MPMS Chapter 11.1) or API MPMS Chapter 11.2.4 (GPA TP–27), as applicable. The Department updated its incorporation of the Second edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 9.4—Continuous Density Measurement Under Dynamic (Flowing) Conditions, First Edition, January 2018.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 9.4, into its regulations in § 250.198(e)(33). This document covers the continuous on-line determination and application of flowing liquid densities for custody transfer. This document covers liquid and dense phase fluids, including natural gas liquids, refined products, chemicals, crude oil, and other liquid products commonly encountered in the petroleum industry. This document does not apply to the density measurement of natural gas, liquified natural gas, multiphase mixtures, semi-solid liquids such as asphalt, and solids such as coke and slurries. This standard also provides criteria and procedures for designing, installing, operating, and proving continuous on-line density measurement systems for custody transfer. This standard also discusses the different levels and requirements of accuracy for various applications. BSEE proposes to add a reference to this standard in § 250.1202(a).

API MPMS Chapter 10—Sediment and Water, Section 1—Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method, Third Edition, November 2007; reaffirmed October 2012 is incorporated by reference in the current § 250.198(e)(34) and will remain in the proposed reorganized table as previously incorporated by reference in § 250.198(e)(34). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 10.2—Standard Test Method for Water in Crude Oil by Distillation, Fifth Edition, December 2022.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 10.2, currently located at § 250.198(e)(35), from the 2007 Second edition to the December 2022 Fifth edition in its regulations in § 250.198(e)(35). The title of this standard changed from API MPMS Chapter 10, Section 2 to API MPMS Chapter 10.2. The Fifth Edition accumulated references to ASTM documents and API documents associated terms and terminology along with related text. This test method covers the determination of water in crude oil by distillation. The values stated in the International System of Units (SI units) are to be regarded as standard. No other units of measurement are included in this standard. The Department updated its incorporation of the Second edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard into § 250.1202(a).

API MPMS Chapter 10.3—Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure), Fifth Edition, December 2022.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 10.3, currently located at § 250.198(e)(36), from the 2008 Third edition to the December 2022 Fifth edition in § 250.198(e)(36). The title of this standard changed from API MPMS Chapter 10, Section 3 to API MPMS Chapter 10.3. The Fifth Edition provides additional references to ASTM documents and API documents, mandatory and nonmandatory documents, test methods and associated terms and terminology, and additional information on constraints. This test method describes the laboratory determination of water and sediment in crude oils by means of the centrifuge procedure. This centrifuge method for determining water and sediment in crude oils is not entirely satisfactory. The amount of water detected is almost always lower than the actual water content. When a highly accurate value is required, the revised procedures for water by distillation, Test Method D4006 (API MPMS Chapter 10.2) (Note 1), and sediment by extraction, Test Method D473 (API MPMS Chapter 10.1), shall be used. Test Method D4006 (API MPMS Chapter 10.2) has been determined to be the preferred and most accurate method for the determination of water. The values stated in SI units are to be regarded as standard. The Department updated its incorporation of the Third edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 10.4—Determination of Water and/or Sediment in Crude Oil by the Centrifuge Method (Field Procedure), Fifth Edition, August 2020.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 10.4, currently located at § 250.198(e)(37), from the 1999 Third edition to the 2020 Fifth edition in § 250.198(e)(37). The title of this standard changed from API MPMS Chapter 10, Section 4 to API MPMS Chapter 10.4. The Fifth Edition amended text concerning procedures, calculations, and reporting related to centrifuge tube spin calculations, test procedures, and test reading requirements. This section describes the field centrifuge method for determining both sediment and water or sediment only in crude oil. This method may not always produce the most accurate results, but it is considered the most practical method for field determination of sediment and water. This method may also be used for field determination of sediment. When a higher degree of accuracy is required, the laboratory procedure described in API MPMS Ch. 10.3, Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure) (ASTM D4007); API MPMS Chapter 10.2, Standard Test Method for Water in Crude Oil by Distillation (ASTM D4006); or API MPMS Chapter 10.9, Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration (ASTM D4928); and the procedure described in API MPMS Chapter 10.1, Standard Test Method for

Sediment in Crude Oils and Fuel Oils by the Extraction Method (ASTM D473) should be used. The Department updated its incorporation of the Third edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 10.9—Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration, Third Edition, May 2013, reaffirmed June 2018.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 10.9 at § 250.198(e)(38) from the 2002 Second edition to the 2013 Third edition, reaffirmed in 2018. The title of this standard changed from API MPMS Chapter 10, Section 9 to API MPMS Chapter 10.9. The Third Edition was updated with modern terminology to bring content into compliance with existing practices. This test method covers the determination of water in the range from 0.02 to 5.00 mass or volume % in crude oils. Mercaptan (RSH) and sulfide (S^- or H_2S) as sulfur are known to interfere with this test method, but at levels of less than 500 μg/g [ppm(m)], the interference from these compounds is insignificant. This test method can be used to determine water in the 0.005 to 0.02 mass % range, but the effects of the mercaptan and sulfide interference at these levels has not been determined. For the range 0.005 to 0.02 mass %, there is no precision or bias statement. This test method is intended for use with standard commercially available coulometric Karl Fischer reagent. The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard. The Department updated its incorporation of the Second edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a).

API MPMS Chapter 11—Physical Properties Data, Section 1—Temperature and Pressure Volume Correction Factors for Generalized Crude Oils, Refined Products, and Lubricating Oils, 2004 Edition, May 2004, Addendum 1 September 2007, Addendum 2 May 2019.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 11, Section 1, currently located at § 250.198(e)(41), in its regulations, and to relocate it to § 250.198(e)(39). The 2007 Addendum replaced the term ''Correction for Temperature and Pressure of a Liquid'' for the term ''Volume Correction Factor.'' Where there is no pressure correction, then the Correction for Temperature (CTL) will replace the Volume Correction Factor. The 2019 Addendum added 33 pages concerning compressibility, volume corrections, new terms, gauge pressure, and procedures. This standard provides the algorithm and implementation procedure for the correction of temperature and pressure effects on density and volume of liquid hydrocarbons which fall within the categories of crude oil, refined products, or lubricating oils. Natural gas liquids and liquid petroleum gases are excluded from consideration in this standard. The combination of density and volume correction factors for both temperature and pressure are collectively referred to in this standard as a Correction for Temperature and Pressure of a Liquid. The temperature portion of this correction is termed the Correction for the effect of Temperature on Liquid, also historically known as Volume Correction Factor. The pressure portion is termed the Correction for the effect of Pressure on Liquid. BSEE updated its incorporation of this standard into the regulations on March 29, 2012 (77 FR 18916). BSEE proposes to update the reference of this standard in § 250.1202(l).

API MPMS Chapter 11.1—Volume Correction Factors, Volume 1, Table 5A—Generalized Crude Oils and JP–4 Correction of Observed API Gravity to API Gravity at 60°F, and Table 6A—Generalized Crude Oils and JP–4 Correction of Volume to 60°F Against API Gravity at 60°F, API Standard 2540, First Edition, August 1980; reaffirmed March 1997 is incorporated by reference in the current § 250.198(e)(39) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(40).

API MPMS Chapter 11.2.2—Compressibility Factors for Hydrocarbons: 0.350–0.637 Relative Density (60°F/60°F) and −50°F to 140°F Metering Temperature, Second Edition, October 1986; reaffirmed: September 2017 is incorporated by reference in the current § 250.198(e)(40) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(41). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 11—Physical Properties Data, Addendum to Section 2, Part 2—Compressibility Factors for Hydrocarbons, Correlation of Vapor Pressure for Commercial Natural Gas Liquids, First Edition, December 1994; reaffirmed, December 2002 is incorporated by reference in the current § 250.198(e)(42) and will remain as previously incorporated by reference in the proposed reorganized table in § 250.198(e)(42). BSEE is proposing to add an express reference to this standard in § 250.1202(a) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 12.2, Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Second Edition, July 2021.

BSEE proposes to incorporate by reference API MPMS Chapter 12.2, Second Edition, July 2021 into its regulations in § 250.198(e)(43). API MPMS Chapter 12.2 supersedes three documents that have been withdrawn by API as outdated. Namely, API has withdrawn API MPMS Chapter 12.2.1, Second Edition 1995 (currently located at § 250.198(e)(43)), API MPMS Chapter 12.2.2, Third Edition 2003 (currently located at § 250.198(e)(44)), and API MPMS Chapter 12.2.3, First Edition 1998 (currently located at § 250.198(e)(45)), and BSEE therefore proposes to remove those standards from the regulations in this rule. API MPMS Chapter 12.2 (2021) provides standardized calculation methods for the quantification of liquids, regardless of the point of origin or destination or the units of measure required by governmental customs or statute. The criteria contained in this document allow different entities using various computer languages on different computer hardware (or manual calculations) to arrive at output results within a defined tolerance within this document, using the same input data. The document specifies the equations for computing correction factors, rules for rounding, calculation sequence, and discrimination levels to be employed in the calculations. The intent of this document is to serve as a rigorous standard. This document also covers multiple calculations as required by dynamic, online, integrated, continuous flow measurement. BSEE proposes to add a reference to this standard in § 250.1202(a).

API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 1—Introduction, Second Edition, May 1995; reaffirmed March 2014 is incorporated by reference in the current

§ 250.198(e)(43), and because it has been withdrawn as outdated by API, BSEE is removing it from the regulations. As discussed above, API MPMS Chapter 12.2 (2021) replaces API MPMS Chapter 12.2.1 (1995).

API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 2—Measurement Tickets, Third Edition, June 2003; reaffirmed February 2016 is incorporated by reference in the current § 250.198(e)(44), and because it has been withdrawn as outdated by API, BSEE is removing it from the regulations. As discussed above, API MPMS Chapter 12.2 (2021) replaces API MPMS Chapter 12.2.2 (2003).

API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 3—Proving Reports; First Edition, October 1998, reaffirmed March 2014 is incorporated by reference in the current § 250.198(e)(45), and because it has been withdrawn as outdated by API, BSEE is removing it from the regulations. As discussed above, API MPMS Chapter 12.2 (2021) replaces API MPMS Chapter 12.2.3 (1998).

API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 4—Calculation of Base Prover Volumes by the Waterdraw Method, First Edition, December 1997; reaffirmed January 2022 is incorporated by reference in the current § 250.198(e)(46) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(44).

API MPMS Chapter 14.1, Collecting and Handling of Natural Gas Samples for Analysis by Gas Chromatography, Eighth Edition, September 2022.

BSEE proposes to incorporate by reference API MPMS Chapter 14.1, Eighth edition (September 2022) into its regulations in § 250.198(e)(45). This standard provides comprehensive guideline and procedures for properly extracting, collecting, conditioning, and handling a sample from a flowing natural gas stream at or above its dew point temperature and that represents the composition of the vapor-phase portion of the source fluid. This standard considers spot, composite, continuous, online, and mobile sampling systems and does not include sampling of liquid or multiphase streams. BSEE proposes to add a reference to this standard into § 250.1203(b).

API MPMS Chapter 14.3.1, Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids—Concentric, Square-Edged Orifice Meters, Part 1: General Equations and Uncertainty Guidelines, Fourth Edition, September 2012, Errata July 2013, Reaffirmed September 2017.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 14.3.1, currently located at § 250.198(e)(47), from the 1990 Third edition to the 2012 Fourth edition, with Errata through 2013 and reaffirmation in 2017, in its regulations, and to relocate it to § 250.198(e)(46). The title of this standard changed from API MPMS Chapter 14, Section 3, Part 1 to API MPMS Chapter 14.3.1. The Fourth Edition made changes to equations to bring them into conformance with more recent practice. This standard provides a single reference for engineering equations, uncertainty, estimations, construction, and installation requirements, and standardized implementation recommendations for the calculation of flow rate through concentric, square-edged, flange-tapped orifice meters. Both U.S. customary and SI units are included. The standard is organized into four parts. Parts 1, 2, and 4 apply to the measurement of any Newtonian fluid in the petroleum and chemical industries. Part 3 focuses on the application of parts 1, 2, and 4 to the measurement of natural gas. This was previously titled Natural Gas Fluids Measurement, Section 3-Concentric, Square-Edged Orifice Meters, Part 1, now retitled as above to align with American Gas Association (AGA) Report No. 3, Part 1. The Department updated its incorporation of the Third edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1203(b).

API MPMS Chapter 14.3.2, Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids—Concentric, Square-Edged Orifice Meters, Part 2: Specification and Installation Requirements, Fifth Edition, March 2016, Errata 1, March 2017, Errata 2, January 2019, Reaffirmed January 2019.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 14.3.2, currently located § 250.198(e)(48), from the 2000 Fourth edition to the 2016 Fifth edition, including subsequent errata and reaffirmation, in its regulations, and to relocate it to § 250.198(e)(47). The title of this standard changed from API MPMS Chapter 14, Section 3, Part 2 to API MPMS Chapter 14.3.2. The Fifth Edition made changes concerning normative references, specifications, considerations, and installation requirements. This publication outlines the specification and installation requirements for the measurement of single-phase, homogenous Newtonian fluids using concentric, square-edged, flange-tapped orifice meters. It provides specifications for the construction and installation of orifice plates, meter tubes, and associated fittings when designing metering facilities using orifice meters. The Department updated its incorporation of the Fourth edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference to this standard in § 250.1203(b).

API MPMS Chapter 14.3.3, Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids—Concentric Square-Edged Orifice Meters, Part 3: Natural Gas Applications, Fourth Edition, November 2013, Reaffirmed June 2021.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 14.3.3, currently located at § 250.198(e)(49), from the Third to the Fourth edition in its regulations, and to relocate it to § 250.198(e)(48). The title of this standard changed from API MPMS Chapter 14, Section 3, Part 3 to API MPMS Chapter 14.3.3. The Fourth Edition made changes in the applicability of the use of standard conditions and added functionality to the flow equations. This standard was developed as an application guide for the calculation of natural gas flow through a flange-tapped, concentric orifice meter, using the U.S. customary inch-pound system of units. It also provides practical guidelines for applying MPMS 14.3.1 and MPMS 14.3.2 to the measurement of natural gas. The Department updated its incorporation of the Third edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1203(b).

API MPMS, Chapter 14.5/GPA Standard 2172–09; Calculation of Gross Heating Value, Relative Density, Compressibility and Theoretical Hydrocarbon Liquid Content for Natural Gas Mixtures for Custody Transfer; Third Edition, January 2009; reaffirmed November 2020 is incorporated by reference in the current § 250.198(e)(50) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(49). BSEE is proposing to add an express reference to this

standard in § 250.1203(b) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 14—Natural Gas Fluids Measurement, Section 6—Continuous Density Measurement, Second Edition April 1991, reaffirmed February 2006, has been withdrawn and is superseded by API MPMS Chapter 9.4—Continuous Density Measurement Under Dynamic (Flowing) Conditions, First Edition January 2018. Thus, BSEE is proposing to remove API MPMS Chapter 14, Section 6 from § 250.198(e)(51) and to incorporate API MPMS Chapter 9.4 into the regulations at § 250.198(e)(33), as discussed above.

API MPMS Chapter 14—Natural Gas Fluids Measurement, Section 8—Liquefied Petroleum Gas Measurement, Second Edition, July 1997; reaffirmed, March 2006 is incorporated by reference in the current § 250.198(e)(52) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(50). BSEE is proposing to add an express reference to this standard in § 250.1203(b) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 20—Allocation Measurement, Section 1—Allocation Measurement, First Edition, September 1993, reaffirmed October 2016, Addendum 1 January 2013, Addendum 2 November 2016, Addendum 3 December 2017, Errata 1 November 2022, excluding sections 1.16.1, 1.16.3, 1.16.3.1, 1.16.3.2, and 1.16.3.3 of the First Edition, September 1993.

BSEE proposes to update the incorporation by reference of API MPMS Chapter 20, Section 1, currently located at § 250.198(e)(53), to include the 2016 Reaffirmation and Addenda and Errata in its regulations, and to relocate it to § 250.198(e)(51), excluding sections 1.16.1, 1.16.3, 1.16.3.1, 1.16.3.2, and 1.16.3.3 of the First Edition, September 1993. The excluded sections of the First Edition are superseded by API MPMS Chapter 20.3, First Edition January 2013, Reaffirmed October 2018, as further discussed below. The Addenda and Errata addressed measurement, calibration, equipment, and testing. This standard provides design and operating guidelines for liquid and gas allocation measurement systems. It includes recommendations for metering, static measurement, sampling, proving, calibrating, and calculating procedures. The Department updated its incorporation of the First edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in § 250.1202(a) and § 250.1203(b).

API MPMS, Chapter 20.3—Measurement of Multiphase Flow, First Edition January 2013; reaffirmed October 2018.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 20.3, First Edition January 2013, Reaffirmed October 2018, into its regulations in § 250.198(e)(52). This document supersedes API Recommended Practice 86–2005, which is withdrawn. Further, this document supersedes API MPMS Chapter 20.1, First Edition 1993 sections 1.16.1, 1.16.3, 1.16.3.1, 1.16.3.2, and 1.16.3.3 and API Recommended Practice 85, First Edition 2003, portions of sections 4, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, and 6.7. This publication addresses multiphase flow measurement in the production environment, upstream of the custody transfer (single-phase) measurement point, where allocation measurement for onshore, offshore, or subsea is applied. For other multiphase flow measurement applications such as reservoir management, well tests, and flow assurance, the standard can be used as a reference or guide. However, the focus of this standard is on those applications where the accuracy of multiphase flow measurement for allocation systems is required. This document refers to existing standards and RPs to supplement the guidance it provides in this subject area. The document addresses principles used in multiphase flow measurement, multiphase metering types and classifications, assessment of expected performance, and selecting and operating multiphase measurement systems. It addresses operational requirements or constraints, including expectations for flow meter acceptance, calibration criteria, flow loop and in situ verifications, and other guidance specific to different multiphase flow metering applications. The document does not address specific meter configurations. BSEE proposes to add a reference to this standard in § 250.1203(b).

API MPMS, Chapter 20.5—Recommended Practice for Application of Production Well Testing in Measurement and Allocation, First Edition, December 2017; reaffirmed March 2023.

BSEE proposes to incorporate by reference for the first time API MPMS Chapter 20.5, First Edition, December 2017, into its regulations in § 250.198(e)(53). This document supersedes API MPMS Chapter 20.1, First Edition 1993, sections 1.7.2.2.2, 1.11.1, 1.16.3.2, 1.16.3.3, 1.16.3.5.1, and Appendix J. This publication establishes a framework to conduct and apply production well testing for well rate determination in measurement and allocation. Production well testing addressed in this document refers to measurement of gas, oil, and water quantities from a single well during a specified length of time under controlled operational conditions. The intent of this document is to provide operators with a consistent and transparent approach for conducting, applying, and managing production well testing within an upstream measurement and allocation system. It is not intended to prescribe a particular production well test method, or particular application of production well test data use in allocation. This document provides recommendations and guidelines for the application of production well testing in production measurement and allocation. The recommendations and guidelines apply to conducting a production well test, calculating production well test volumes and rates, and the application of production well test data for use in measurement and allocation. This includes production well testing preparation, initiation, measurement, validation, and volume and rate calculations for separator, multiphase flow meter, and tank production well test systems. Additionally, this document addresses the proration of production well test results for use in allocation, the application of production well tests for validation and update of well flow models and virtual flow metering, and the adjustment of gas well continuous measurement results with production well test data. This document also provides recommendations and guidelines for the application of well flow modeling and virtual flow metering in production measurement and allocation. BSEE proposes to add a reference to this standard in § 250.1203(b).

API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 1—Electronic Gas Measurement, First Edition, August 1993; reaffirmed, July 2005 is incorporated by reference in the current § 250.198(e)(54) and will remain as previously incorporated by reference into the regulations in the proposed reorganized table in § 250.198(e)(54). BSEE is proposing to add an express reference to this standard in § 250.1203(b) to clarify the longstanding use of this document already incorporated in the current regulations.

API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 2—Electronic Liquid

Volume Measurement Using Positive Displacement and Turbine Meters; First Edition, June 1998; reaffirmed October 2016 is incorporated by reference in the current § 250.198(e)(55) and will remain as previously incorporated by reference in the proposed reorganized table in § 250.198(e)(55).

API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Addendum to Section 2—Flow Measurement Using Electronic Metering Systems, Inferred Mass; First Edition August 2000; reaffirmed October 2016 is incorporated by reference in the current § 250.198(e)(56) and will remain as previously incorporated by reference in the proposed reorganized table in § 250.198(e)(56).

API RP 2A–WSD, Recommended Practice for Planning, Designing, and Constructing Fixed Offshore Platforms—Working Stress Design, Twenty-second Edition, November 2014, Reaffirmation, September 2020.

BSEE proposes to update the incorporation by reference of API Recommended Practice 2A–WSD, currently located at § 250.198(e)(57), from the 2000 Twenty-first edition to the 2014 Twenty-second edition in its regulations, and will remain as previously incorporated by reference in § 250.198(e)(57). This RP is based on global industry best practices and serves as a guide for those who are concerned with the design and construction of new fixed offshore platforms and for the relocation of existing platforms used for the drilling, development, production, and storage of hydrocarbons in offshore areas. Specific guidance for hurricane conditions in the Gulf of Mexico and other U.S. offshore areas, previously provided in API RP 2A–WSD, 21st Edition, Section 2, is now provided in API RP 2MET. Specific guidance for earthquake loading in U.S. offshore areas, previously provided in the API RP 2A–WSD, 21st Edition, Section 2, is now provided in API 2EQ. Specific guidance for soil and foundation considerations in offshore areas, previously provided in API RP 2A–WSD, 21st Edition, Section 6, is now provided in API RP 2GEO. Specific guidance for the evaluation of structural damage, above and below water structural inspection, fitness-for-purpose assessment, risk reduction and mitigation planning, plus the process of decommissioning has been removed and is now provided in API RP 2SIM. Specific guidance for fire and blast loading, previously provided in the API RP 2A–WSD, 21st Edition, Section 18, is now provided in API 2FB. The Department updated its incorporation of the Twenty-first edition of this standard into the regulations on March 15, 2007 (72 FR 12088). BSEE proposes to update the reference of this standard in the existing regulations at: §§ 250.901, 250.908, 250.919, and 250.920.

API Spec 2C, Specification for Offshore Pedestal Mounted Cranes, Eighth Edition, October 2020; API Monogram Program Effective Date: May 1, 2021.

BSEE proposes to update the incorporation by reference of API Specification 2C, currently located at § 250.198(e)(81), from the 2004 Sixth edition to the 2020 Eighth edition in its regulations, and to relocate it to § 250.198(e)(58). The Eighth Edition made changes concerning normative references, documentation, loads, structure, mechanical, and ratings. This standard provides requirements for design, construction, and testing of new offshore pedestal-mounted cranes. Offshore cranes are defined as pedestal-mounted elevating and rotating lift devices for transfer of materials and personnel to or from marine vessels, barges, and structures or for transfer of materials to or from the sea or the seabed. Typical applications can include: offshore oil exploration and production applications which are typically mounted on a fixed structure, floating structure, or vessel used in drilling and production operations, shipboard applications which are mounted on surface-type vessels and are used to move cargo, containers, and other materials while the crane is within a harbor or sheltered area, and crane vessel applications which are typically mounted on ship-shaped vessels, semi-submersibles, barge, or self-elevating type marine vessels specialized in lifting heavy and/or unique loads for construction, pipe lay, renewable energy, salvage, and subsea applications in both harbor and offshore waters. The Department updated its incorporation of the Sixth edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in the existing regulations at § 250.108.

API Standard 2CCU—Offshore Cargo Carrying Units; First Edition, August 2017.

BSEE proposes to incorporate by reference for the first time API Standard 2CCU, first Edition, August 2017, into its regulations in § 250.198(e)(59). API Standard 2CCU defines the design, material, manufacture, inspection, repair, maintenance, and marking requirements for offshore cargo carrying units (CCU) and lifting sets, to include dry-goods boxes, baskets, and other skids designed to move equipment and goods offshore with maximum gross weight up to 70,000 kg (154,323 lb.). Annex A outlines the assessment criteria and parameters for in-service CCU equipment for continued fit-for purpose applications by users of CCU equipment in conjunction with equipment built to this standard. BSEE proposes to add an incorporation by reference of this standard in § 250.108(g).

API RP 2D, Operation and Maintenance of Offshore Cranes, Seventh Edition, December 2014; Errata August 2015, Addendum 1, October 2020.

BSEE proposes to update the incorporation of API Recommended Practice 2D, currently located at § 250.198(e)(58), from the 2007 Sixth edition to the 2014 Seventh edition in its regulations, and to relocate it to § 250.198(e)(60). The Seventh Edition added refueling, fire extinguishers, load testing, pull testing, derating, planning, risk assessment, lift plans, design, and preventative maintenance. This standard establishes general principles for the safe operation and maintenance of offshore pedestal-mounted revolving cranes on fixed or floating offshore platforms, offshore support vessels, jackup drilling rigs, semi-submersible drilling rigs and other types of mobile offshore drilling units, as a companion to API Spec 2C and API 2D–2. This standard also provides requirements and recommendations for lift planning, pre-use inspection, and testing of temporary cranes that are erected offshore.

Typical applications can include:

(1) Offshore oil exploration and production applications: These cranes are typically mounted on a fixed (bottom-supported) structure, floating platform structure, or vessel used in drilling and production operations,

(2) Shipboard applications: These lifting devices are mounted on surface-type vessels and are used to move cargo, containers, and other materials while the crane is within a harbor or sheltered area, and

(3) Crane vessel applications.

These cranes are typically mounted on ship-shaped vessels, semisubmersibles, barges, or self-elevating-type marine vessels specialized in lifting heavy and/or unique loads for construction, pipe lay, renewable energy, salvage, and subsea applications in both harbor and offshore waters. Equipment (*e.g.,* davits, launch frames) used only for launching life-saving appliances (lifeboats or life rafts) are not included in the scope of this standard. Lifting devices not covered by this standard would be operated, inspected, and maintained in

accordance with the manufacturer's recommendations. The Department updated its incorporation of the Sixth edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in § 250.108.

API RP 2FPS, Recommended Practice for Planning, Designing, and Constructing Floating Production Systems, Second Edition, October 2011; Reaffirmed September 2020.

BSEE proposes to update the incorporation by reference of API Recommended Practice 2FPS, currently located at § 250.198(e)(59), from the 2001 First edition to the 2011 Second edition in its regulations, and to relocate it to § 250.198(e)(61). The Second Edition made changes to bring the document into conformance with more recent practice, namely adding as normative references five API documents (API RP 2A–WSD, API Bulletin 2INT–MET, API RP 2SK, API RP 14J, 75L) and four ISO documents (13702, 19900–2002, 19901–1, 19902–2007). This document provides requirements and guidance for the structural design and/or assessment of floating offshore platforms used by the petroleum and natural gas industries to support the following functions: production, storage and/or offloading, and drilling. The Department updated its incorporation of the First edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in the existing regulations at: § 250.901.

API RP 2FSIM—Floating Systems Integrity Management, First Edition, September 2019.

BSEE proposes to incorporate by reference for the first time API RP 2FSIM First Edition, September 2019 into its regulations in § 250.198(e)(62). This RP provides guidance for floating system integrity management of floating production systems, which include tension leg platforms, used by the petroleum and natural gas industries to support drilling, production, storage, and/or offloading operations. Floating production systems described in this document are governed by local regulatory requirements and recognized classification society (RCS) rules, if classed. No specific regulatory compliance or RCS requirements are restated in the document. The requirements of this document do not apply to mobile offshore drilling units or to mobile offshore units used in support of construction operations. This document does not address dynamic positioning, moorings, or risers. BSEE proposes to add a reference to this standard in § 250.901.

API RP 2GEO—Geotechnical and Foundation Design Considerations; First Edition, April 2011, Addendum 1, October 2014; Includes all amendments and changes through Reaffirmation Notice, January 2021.

BSEE proposes to incorporate by reference for the first time API RP 2GEO, First Edition October 2014, including all addenda and amendments through the January 2021 reaffirmation, into its regulations in § 250.198(e)(63). This document contains requirements and recommendations for those aspects of geoscience and foundation engineering that are applicable to a broad range of offshore structures, rather than to a particular structure type. Such aspects are site characterization, soil and rock characterization, design and installation of foundations supported by the seabed (shallow foundations), identification of hazards, design of pile foundations, and soil-structure interaction for risers, flowlines, and auxiliary subsea structures. Aspects of soil mechanics and foundation engineering are not addressed by the document. BSEE proposes to add a reference to this standard in § 250.901.

API RP 2I, In-Service Inspection of Mooring Hardware for Floating Structures; Third Edition, April 2008 is incorporated by reference in the current § 250.198(e)(60) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as§ 250.198(e)(64).

API RP 2MET—Derivation of Metocean Design and Operating Conditions; Second Edition, January 2021; ISO 19901–1:2015 (Modified) Part 1.

BSEE proposes to incorporate by reference for the first time API RP 2MET, Second Edition, January 2021 into its regulations in § 250.198(e)(65). This standard gives requirements for the determination and use of meteorological and oceanographic (metocean) conditions for the design, construction, and operation of offshore structures of all types used in the petroleum, natural gas, and renewable energy industries. The requirements are divided into two broad types: those that relate to the determination of environmental conditions in general, together with the metocean parameters that are required to adequately describe them; and those that relate to the characterization and use of metocean parameters for the design, the construction activities, or the operation of offshore structures. BSEE proposes to add a reference to this standard in § 250.901.

API RP 2MIM—Mooring Integrity Management; First Edition, September 2019.

BSEE proposes to incorporate by reference for the first time API RP 2MIM, First Edition, September 2019 into its regulations in § 250.198(e)(66). This RP provides guidance for the integrity management of mooring systems connected to a permanent floating production system used for the drilling, development, production, and/or storage of hydrocarbons in offshore areas. The scope of this RP extends from the anchor to the connection to the floating unit (*e.g.,* chain stopper) and includes components critical to the mooring system (*e.g.,* turret bearings, fairleads, chain stoppers, anchors, suction piles). BSEE proposes to add an incorporation by reference to this standard in § 250.901.

ANSI/API RP 2N, Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions, Third Edition, April 2015, ISO 19906:2010 (Modified) is incorporated by reference in the current § 250.198(e)(61) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(67).

API Standard 2RD, Dynamic Risers for Floating Production Systems, Second Edition, September 2013, Reaffirmed September 2020.

BSEE proposes to update the incorporation by reference of API Standard 2RD, currently located at § 250.198(e)(62), from the 1998 Recommended Practice First Edition to the 2013 Standard Second Edition in its regulations, and to relocate it to § 250.198(e)(68). The type and title of this document changed from API Recommended Practice 2RD to API Standard 2RD. The Standard Second Edition was updated to include high pressure high temperature considerations for hydrocarbon exploration and production in deep waters and made changes to testing to bring the document into conformance with more recent practice. This standard discusses riser systems that are part of a floating production system. Guidelines for design, construction, installation, operation, and maintenance of FPSs are in API RP 2FPS. A riser is a subsystem in a floating production system. The provisions of this standard do not apply to the riser systems of mobile offshore drilling units. There is significant interaction among the subsystems in a floating production system. Hull motions affect risers and mooring, and conversely, risers and mooring affect hull motions. Global behavior of the

system provides input to assessment of subsystems. Assessment of a subsystem provides feedback (loads) for assessment of the hull and other subsystems. Determination of the boundaries of a riser system and management of the interactions with other subsystems is the responsibility of the operator. A riser system is an assembly of components, including pipe and connectors. A riser system can include a riser tensioning system, buoyancy modules, etc. Pipe components can be steel, titanium, or unbonded flexible pipe. Design considerations for unbonded flexible pipe are included primarily by reference to API 17B and API Spec 17J. Design considerations for titanium alloy pipe are included primarily by reference to DNV–RP–F201. Steel and titanium pipe are referred to as rigid pipe and unbonded flexible pipe is referred to as flexible pipe. All or part of several existing codes, standards, specifications, and RPs are included by reference. Design loads and conditions are described in Section 4. Structural design criteria for rigid pipe are in Section 5. Structural capacity formulae for steel pipe are also in Section 5. Additional requirements for components, including pipe, are in Section 6. Material requirements are in Section 7. Fabrication and installation requirements are in Section 8. Integrity Management is addressed in Section 9. BSEE updated its incorporation of the First edition of this standard into the regulations on April 29, 2016 (81 FR 25888). BSEE proposes to update the reference of this standard in §§ 250.733, 250.800(c), 250.901, and 250.1002(b).

API RP 2RIM—Integrity Management of Risers from Floating Production Systems; First Edition, September 2019.

BSEE proposes to incorporate by reference for the first time API RP 2RIM, First Edition, September 2019 into its regulations in § 250.198(e)(69). This RP provides guidance for the integrity management of risers connected to a permanent floating production system used for the drilling, development, production, and storage of hydrocarbons in offshore areas. A riser is typically part of a larger subsea system extending from a wellhead, tree, manifold, template, or other structure on the seabed, to a boarding valve or pig trap on the host platform's topsides. This document addresses the integrity management of the dynamic portion of the riser system. For the purposes of this document, a riser has a top boundary that is somewhere at or above the point where it transfers load to the platform structure, and it has a lower boundary where it transfers load into a foundation, which could be a wellhead, pipeline, or subsea structure. For a top-tensioned riser, the top boundary would typically be the tensioner system hang-off point, and the bottom boundary would be the wellhead. For a steel catenary riser (SCR), the top boundary would typically be the stress joint or flexible joint. Unusual configurations, such as pull-tube steel catenary risers, merit special consideration. The top boundaries of a flexible or hybrid riser are typically a flanged connection to the riser end fitting at the top of an I-tube or J-tube, and a bend stiffener at the bottom of an I-tube or J-tube. The integrity management of the structural support for a riser on the host platform is in the scope of API RP 2FSIM, although some hybrid configurations, such as pull tubes, can require overlapping riser and structural integrity management. For risers structurally connected to the platform below the topsides, hull piping can be structurally clamped to the hull up to a boarding valve or pig launcher at the topsides. BSEE proposes to add an incorporation by reference to this standard in § 250.901.

API RP 2SIM—Structural Integrity Management of Fixed Offshore Structures, First Edition, November 2014; reaffirmed September 2020.

BSEE proposes to incorporate by reference for the first time API RP 2SIM, First Edition, November 2014, reaffirmed September 2020, into its regulations in § 250.198(e)(70). This RP provides guidance for the structural integrity management of existing fixed offshore structures used for the drilling, development, production, and storage of hydrocarbons in offshore areas. However, the general principles of SIM apply to any structure. Specific guidance is provided for the evaluation of structural damage, above- and below-water structural inspection, fitness-for-purpose assessment, risk reduction, mitigation planning, and the process of decommissioning. This RP incorporates and expands on the recommendations of Section 14, ''Surveys'' and Section 17, ''Assessment of Existing Platforms'' as previously provided in API RP 2A–WSD, 21st Edition. See Annex A for additional information and guidelines on the provisions stated in the numbered sections of this document. The structural integrity management process provided in this RP is applicable to existing platforms installed at any location worldwide. However, the RP provides specific met-ocean criteria, which are only applicable for use in fitness-for-purpose assessments of platforms located in the U.S. Gulf of Mexico and off the U.S. West Coast. For guidelines, RPs, and other requirements relating to planning, designing, and constructing new fixed offshore platforms, including reuse and change-in-use of existing platforms, reference should be made to the latest edition of API RP 2A–WSD. For guidelines, RPs, and other requirements relating to planning, designing, and constructing new offshore floating production systems, including reuse and change-in-use of existing floating production systems, reference should be made to the latest edition of API RP 2FPS. BSEE proposes to add an incorporation by reference of this standard in § 250.901(d).

API RP 2SK, Design and Analysis of Stationkeeping Systems for Floating Structures, Third Edition, October 2005, Addendum, May 2008, reaffirmed June 2015 is incorporated by reference in the current § 250.198(e)(63) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(71).

API RP 2SM, Recommended Practice for Design, Manufacture, Installation, and Maintenance of Synthetic Fiber Ropes for Offshore Mooring, Second Edition, July 2014; Reaffirmation, September 2020.

BSEE proposes to update the incorporation of API Recommended Practice 2SM, currently located at § 250.198(e)(64), from the 2001 First edition to the 2014 Second edition in its regulations, and to relocate it to § 250.198(e)(72). The Second Edition made changes to include applications to floating production, storage, and offloading units, floating storage units, mobile offshore drilling units, spar platforms, catenary anchor leg mooring buoys, and mobile offshore units. Further, the Second Edition added provisions for rope design, specification, and testing. This document applies to synthetic fiber ropes used in the form of taut leg or catenary moorings for both permanent and temporary offshore installations. This document covers the following aspects of synthetic fiber ropes: design and analysis considerations of mooring system, design criteria for mooring components, rope design, rope specification and testing, rope manufacture and quality assurance, rope handling and installation, and in-service inspection and maintenance. Application of this document to other offshore mooring applications is at the discretion of the designer and operator. This document is not intended to cover other marine applications of synthetic fiber ropes such as tanker mooring at piers and harbors, towing hawsers, mooring hawsers at single-point

moorings, and tension leg platform tethers. Additionally, very little test data are available for large synthetic fiber ropes permanently deployed around fairleads and thus this document is limited to fiber ropes which span freely between end terminations. The Department updated its incorporation of the First edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in the existing regulations at: §§ 250.800(c) and 250.901.

API RP 2T, Recommended Practice for Planning, Designing, and Constructing Tension Leg Platforms, Third Edition, July 2010, reaffirmed June 2015.

BSEE proposes to update the incorporation by reference of API Recommended Practice 2T, currently located at § 250.198(e)(65), from the 1997 Second edition to the 2010 Third edition in its regulations, and to relocate it to § 250.198(e)(73). The Third Edition made changes to include normative references, seafloor characteristics, materials-welding-corrosion protection, design criteria, safety categories, design load cases, vortex-induced vibrations, system and frequency domain modeling, material considerations, and design loads. This RP is a guide to the designer in organizing an efficient approach to the design of a tension leg platform. Emphasis is placed on participation of all engineering disciplines during each stage of planning, development, design, construction, installation, and inspection. The Department updated its incorporation of the Second edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in the existing regulations at § 250.901.

API Specification 6A, Specification for Wellhead and Christmas Tree Equipment, Twenty-First Edition, November 2018, API Monogram Program Effective Date: November 2019, Errata 1 April 2019, Errata 2 June 2020, Errata 3 September 2020, Errata 4 September 2021, Addendum 1 July 2020 (API Monogram Program Effective Date: January 2021), Addendum 2, June 2021 (API Monogram Program Effective Date: December 2021), Addendum 3, August 2022 (API Monogram Program Effective Date: February 2023).

BSEE proposes to update the incorporation by reference of API Specification 6A, currently located at § 250.198(e)(82), from the 2010 Twentieth edition to the 2018 Twenty-first edition, including Errata through 2021 and Addenda through 2022, in its regulations, and to relocate it to § 250.198(e)(74). The title of this standard changed from ANSI/API Spec. 6A to API Specification 6A. The Twenty-First Edition made changes concerning normative references, performance, design, materials, welding, bolting, pressure boundaries, and quality control. This specification provides requirements and gives recommendations for the performance, dimensional and functional interchangeability, design, materials, testing, inspection, welding, marking, handling, storing, shipment, and purchasing of wellhead and tree equipment for use in the petroleum and natural gas industries. This specification establishes requirements for four product specification levels (PSLs), namely, PSL 1, PSL 2, PSL 3, and PSL 4 as well as a supplemental designation of PSL 3G that define different levels of technical quality requirements. The subject matter of Annexes B, C, D, E, F, G, H, I, J, K, L, and M has been arranged in a way that minimizes the impact of changes on users of this document. BSEE updated its incorporation of the Twentieth edition of this standard into the regulations on September 28, 2018 (83 FR 49216). BSEE proposes to update the reference of this standard in existing regulations at: §§ 250.730, 250.802(a), 250.803(a), 250.833, 250.873(b), 250.874(g), and 250.1002(b).

API Standard 6AV1, Validation of Safety and Shutdown Valves for Sandy Service, Third Edition, July 1, 2018

BSEE proposes to update the incorporation by reference of API Standard 6AV1, currently located at § 250.198(e)(83), from the 2013 Specification Second Edition to the 2018 Standard Third Edition in its regulations, and to relocate it to § 250.198(e)(75). The Third Edition modified the Second Edition sufficient to change the document designation from Specification to Standard. Changes between editions included the terms and conditions, equipment specifications, validation requirements, seal tests, and procedural requirements. Further, the Standard establishes sandy service design validation for valves to meet Class II and Class III, but not for Class I safety valves or actuators. There are three service classes, Class I, Class II, and Class III, for API Specification 6A surface safety valve, underwater safety valve, or boarding shutdown valve. Class II is intended to validate the valve bore sealing mechanism if substances such as sand can be expected to cause safety or shutdown valve failure. Class III adds requirements and validation of the bonnet assembly inclusive of stem seals. BSEE updated its incorporation of the Second edition of this document into the regulations on September 28, 2018 (83 FR 49216). BSEE proposes to update the reference of this standard in BSEE's existing regulations at: §§ 250.802(a), 250.833, 250.873(b), and 250.874(g).

API STD 6AV2, Installation, Maintenance, and Repair of Surface Safety Valves and Underwater Safety Valves Offshore; First Edition, March 2014; Errata 1, August 2014 is incorporated by reference in the current § 250.198(e)(84) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(76).

API Specification 6D, Specification For Pipeline Valves, Twenty-fifth Edition November 2021, API Monogram Program Effective Date: November 2022, Errata 1 December 2021, Errata 2 April 2022, Addendum 1 April 2023.

BSEE proposes to update the incorporation by reference of API Specification 6D, currently located at § 250.198(e)(85), from the 2008 Twenty-third edition to the 2021 Twenty-fifth edition, with all amendments and errata through April 2022, in its regulations, and to relocate it to § 250.198(e)(77). The Twenty-fifth Edition made changes concerning configuration, performance, pressure and temperature ratings, design, impact tests, welding, and inspections. This specification defines the requirements for the design, manufacturing, assembly, testing, and documentation of ball, check, gate, and plug valves for application in pipeline and piping systems for the petroleum and natural gas industries. If product is supplied bearing the API Monogram and manufactured at a facility licensed by API, the requirements of Annex A apply. Annexes B, C, D, E, F, G, H, I, J, K, L, M, N, and O are annexes that are used in the order listed. This specification is not applicable to subsea pipeline valves, which are covered by a separate specification, API 6DSS. This specification is not applicable to valves for pressure ratings exceeding Class 2500. The Department updated its incorporation of the Twenty-third edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in BSEE's existing regulations at § 250.1002(b).

API Spec 11D1, Packers and Bridge Plugs, Second Edition, July 2009 is incorporated by reference in the current § 250.198(e)(86) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(78).

ANSI/API Spec 14A, Specification for Subsurface Safety Valve Equipment,

Eleventh Edition, October 2005, reaffirmed, June 2012 is incorporated by reference in the current § 250.198(e)(87) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(79).

API RP 14B, Design, Installation, Operation, Test, and Redress of Subsurface Safety Valve Systems, Sixth Edition, September 2015 is incorporated by reference in the current § 250.198(e)(66) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(80).

API RP 14C, Recommended Practice for Analysis, Design, Installation, and Testing of Basic Surface Safety Systems for Offshore Production Platforms, Seventh Edition, March 2001, reaffirmed: March 2007 is incorporated by reference in the current § 250.198(e)(67) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(81).

API RP 14E, Recommended Practice for Design and Installation of Offshore Production Platform Piping Systems, Fifth Edition, October 1991; reaffirmed, January 2013 is incorporated by reference in the current § 250.198(e)(68) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(82).

API RP 14F, Recommended Practice for Design, Installation, and Maintenance of Electrical Systems for Fixed and Floating Offshore Petroleum Facilities for Unclassified and Class 1, Division 1 and Division 2 Locations, Upstream Segment, Fifth Edition, July 2008, reaffirmed: April 2013 is incorporated by reference in the current § 250.198(e)(69) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(83).

API RP 14FZ, Recommended Practice for Design, Installation, and Maintenance of Electrical Systems for Fixed and Floating Offshore Petroleum Facilities for Unclassified and Class I, Zone 0, Zone 1 and Zone 2 Locations, Second Edition, May 2013 is incorporated by reference in the current § 250.198(e)(70) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(84).

API RP 14G, Recommended Practice for Fire Prevention and Control on Fixed Open-type Offshore Production Platforms, Fourth Edition, April 2007; Reaffirmed, January 2013 is incorporated by reference in the current § 250.198(e)(71) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(85).

API RP 14J, Recommended Practice for Design and Hazards Analysis for Offshore Production Facilities, Second Edition, May 2001; reaffirmed: January 2013 is incorporated by reference in the current § 250.198(e)(72) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(86).

API Spec 16A, Specification for Drill-through Equipment, Third Edition, June 2004, reaffirmed August 2010 is incorporated by reference in the current § 250.198(e)(88) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(87).

API Spec 16C, Specification for Choke and Kill Systems, First Edition, January 1993, reaffirmed July 2010 is incorporated by reference in the current § 250.198(e)(89) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(88).

API Spec 16D, Specification for Control Systems for Drilling Well Control Equipment and Control Systems for Diverter Equipment, Second Edition, July 2004, reaffirmed August 2013 is incorporated by reference in the current § 250.198(e)(90) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(89).

API RP 16ST, Coiled Tubing Well Control Equipment Systems, Second Edition, February 2021, Addendum 1, February 2022.

BSEE proposes to add an incorporation by reference of API Recommended Practice 16ST in its regulations in § 250.198(e)(90). This RP addresses coiled tubing well control equipment assembly and operation as it relates to well control practices. This document covers well control equipment assembly and operations used in coiled tubing intervention and coiled tubing drilling/milling applications performed through: tree equipment constructed in accordance with API Specification 6A or API 11IW or both, a surface flow head or surface test tree constructed in accordance with API Specification 6A, a fracture stimulation wellhead assembly (with at least two gate valves installed for isolation), drill pipe or workstrings with connections manufactured in accordance with API 5CT, API 5DP or API 7–1, or a combination thereof. Industry practices for performing well control operations using fluids for hydrostatic pressure balance are not addressed in this document. BSEE proposes to add a reference to this standard in § 250.750(c).

API Specification 17D, Specification for Subsea Wellhead and Tree Equipment, Third Edition, October 2021, API Monogram Program Effective Date: October 2022, Errata 1, December 2021, Addendum 1, December 2022.

BSEE proposes to update the incorporation by reference of API Specification 17D, currently located at § 250.198(e)(91), from the 2011 Second edition to the 2021 Third edition, with subsequent errata and addendum, in its regulations, and this standard will remain previously incorporated by reference in § 250.198(e)(91). The title of this standard is corrected from ANSI/API Specification 17D to API Specification 17D. The Third Edition made changes concerning configuration, performance, and several design equations. This document provides specifications for subsea wellheads, mudline wellheads, drill-through mudline wellheads, and both vertical and horizontal subsea trees. It specifies the associated tooling necessary to handle, test, and install the equipment. It also specifies the areas of design, material, welding, quality control, including factory acceptance testing, marking, storing, and shipping for individual equipment, subassemblies, and subsea tree assemblies. BSEE updated its incorporation of the Second edition of this standard into the regulations on April 29, 2016 (81 FR 25888). BSEE proposes to update the reference of this standard in § 250.730.

API RP 17H, Remotely Operated Tools and Interfaces on Subsea Production Systems, Second Edition, June 2013; Errata, January 2014 is incorporated by reference in the current § 250.198(e)(73) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(92).

API Spec 17J, Specification for Unbonded Flexible Pipe, Fourth Edition, May 2014, Effective Date: November 2014, Errata 1 September 2016, Errata 2 May 2017, Addendum 1 October 2017, reaffirmed March 2021.

BSEE proposes to update the incorporation by reference of API Spec 17J, currently located at § 250.198(e)(92), from the 2008 Third edition to the 2014 Fourth edition, including all changes through the 2021 Reaffirmation, in its regulations, and to relocate it to § 250.198(e)(93). The Fourth Edition made changes concerning normative references, design parameters, quality assurance requirements, and testing. The document defines the technical requirements for safe, dimensionally, and functionally interchangeable flexible pipes that are designed and manufactured to uniform standards and criteria. Minimum requirements are specified for the design, material selection, manufacture, testing, marking, and packaging of flexible pipes, with reference to existing codes and standards where applicable. API Spec 17J applies to unbonded flexible pipe assemblies, consisting of segments of flexible pipe body with end fittings attached to both ends. The applications addressed by API Spec 17J are sweet and sour service production, including export and injection applications. Production products include oil, gas, water, and injection chemicals. API Spec 17J applies to both static and dynamic flexible pipes used as flowlines, risers, and jumpers. The Department updated its incorporation of the Third edition of this standard into the regulations on April 28, 2010 (75 FR 22219). BSEE proposes to update the reference of this standard in the existing regulations at: §§ 250.852(e), 250.1002(b), and 250.1007(a).

API Spec 20E—Alloy and Carbon Steel Bolting for Use in the Petroleum and Natural Gas Industries, Second Edition, February 2017, Effective Date: August 2017, Addendum 1 September 2018, Addendum 2 March 2019, Errata 1 November 2021, Errata 2 May 2022.

BSEE proposes to incorporate by reference for the first time API Spec 20E, Second Edition, February 2017, including all addenda and errata through May 2022, into its regulations in § 250.198(e)(94). This document specifies requirements for the qualification, production, and documentation of alloy and carbon steel bolting used in the petroleum and natural gas industries. This document applies when referenced by an applicable API equipment standard or otherwise specified as a requirement for compliance. An annex for supplemental requirements that may be invoked by the purchaser is included. This document establishes requirements for three bolting specification levels (BSL). These three BSL designations define different levels of technical, quality, and qualification requirements, BSL–1, BSL–2, and BSL–3. The BSLs are numbered in increasing levels of severity in order to reflect increasing technical, quality, and qualification criteria. This document covers the following finished product forms, processes, and sizes: machined studs, machined bolts, screws and nuts, cold formed bolts, screws, and nuts (BSL–1 only), hot formed bolts and screws <1.5 in. (38.1 mm) nominal diameter, hot formed bolts and screws > or = 1.5 in. (38.1 mm) nominal diameter, roll threaded studs, bolts, and screws <1.5 in. (38.1 mm) diameter, roll threaded studs, bolts, and screws > or = 1.5 in. (38.1 mm) diameter, hot formed nuts <1.5 in. (38.1 mm) nominal diameter, and hot formed nuts > or = 1.5 in. (38.1 mm) nominal diameter. BSEE proposes to add an incorporation by reference to this standard in § 250.730(a).

API Spec 20F—Corrosion-resistant Bolting for Use in the Petroleum and Natural Gas Industries, Second Edition, May 2018, API Monogram Program Effective Date: November 1, 2018, Errata 1 October 2020, Addendum 1 November 2021 (API Monogram Program Effective Date: May 1, 2022).

BSEE proposes to incorporate by reference for the first time API Spec 20F, Second Edition, including all addenda and errata through November 2021, into its regulations in § 250.198(e)(95). This document specifies requirements for the qualification, production, and documentation of corrosion-resistant bolting used in the petroleum and natural gas industries. This document applies when referenced by an applicable API equipment standard or otherwise specified as a requirement for compliance. This document establishes requirements for two bolting specification levels (BSL). These two BSL designations define different levels of technical, quality, and qualification requirements: BSL–2 and BSL–3. The BSLs are numbered in increasing levels of requirements in order to reflect increasing technical, quality, and qualification criteria. BSL–2 and BSL–3 are intended to be comparable to BSL–2 and BSL–3 as found in API Spec 20E. BSL–1 is omitted from this standard. This document covers the following product forms, processes, and sizes: machined studs, machined bolts, screws, and nuts, cold-formed bolts, screws, and nuts with cut or cold-formed threads, hot-formed bolts and screws <1.5 in. (38.1 mm) nominal diameter, hot-formed bolts and screws ≥1.5 in. (38.1 mm) nominal diameter, roll threaded studs, bolts, and screws <1.5 in. (38.1 mm) diameter, roll threaded studs, bolts, and screws ≥1.5 in. (38.1 mm) diameter, hot-formed nuts <1.5 in. (38.1 mm) nominal diameter, and hot-formed nuts ≥1.5 in. (38.1 mm) nominal diameter. BSEE proposes to add an incorporation by reference of this standard in § 250.730(a).

API Standard 53, Blowout Prevention Equipment Systems for Drilling Wells, Fifth Edition, December 2018.

BSEE proposes to update the incorporation by reference of API Standard 53, currently located at § 250.198(e)(94), from the 2012 Fourth edition to the 2018 Fifth edition in its regulations, and to relocate it to § 250.198(e)(96). The Fifth Edition made changes concerning sealing components, pressure measurement, control systems, testing, and examples. This document provides the requirements for the installation and testing of blowout prevention equipment systems on land and marine drilling rigs (barge, platform, bottom-supported, and floating). Well control equipment systems are designed with components that provide wellbore pressure control in support of well operations. The primary functions of these systems are to confine well fluids to the wellbore, provide means to add fluid to the wellbore, and allow controlled volumes to be removed from the wellbore. BSEE updated its incorporation of the Fourth edition of this standard into the regulations on April 29, 2016 (81 FR 25888). BSEE proposes to update the reference of this standard in the existing regulations at: §§ 250.730, 250.734, 250.735, 250.736, 250.737, and 250.739.

API RP 65, Recommended Practice for Cementing Shallow Water Flow Zones in Deepwater Wells, First Edition, September 2002 is incorporated by reference in the current § 250.198(e)(74) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(97).

API Standard 65—Part 2, Isolating Potential Flow Zones During Well Construction; Second Edition, December 2010 is incorporated by reference in the current § 250.198(e)(95) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(98).

API RP 75, Recommended Practice for Development of a Safety and Environmental Management Program for Offshore Operations and Facilities, Third Edition, May 2004, reaffirmed May 2008 is incorporated by reference in the current § 250.198(e)(75) and will

remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(99).

API RP 90, Annular Casing Pressure Management for Offshore Wells, First Edition, August 2006 is incorporated by reference in the current § 250.198(e)(77) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(100).

API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities Classified as Class I, Division 1 and Division 2, Third Edition, December 2012; Errata January 2014 is incorporated by reference in the current § 250.198(e)(78) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(101).

API RP 505, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities Classified as Class I, Zone 0, Zone 1, and Zone 2, First Edition, November 1997; reaffirmed, August 2013 is incorporated by reference in the current § 250.198(e)(79) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(102).

API 510, Pressure Vessel Inspection Code: In-Service Inspection, Rating, Repair, and Alteration, Tenth Edition, May 2014; Addendum 1, May 2017 is incorporated by reference in the current § 250.198(e)(1) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(103).

API 570, Piping Inspection Code: In-service Inspection, Rating, Repair, and Alteration of Piping Systems, Fourth Edition, February 2016; Addendum 1, May 2017 is incorporated by reference in the current § 250.198(e)(2) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(104).

API Standard 2552, USA Standard Method for Measurement and Calibration of Spheres and Spheroids, First Edition, 1966; reaffirmed, October 2007 is incorporated by reference in the current § 250.198(e)(96). BSEE proposes to remove the reference to API Standard 2552, USA Standard Method for Measurement and Calibration of Spheres and Spheroids, First Edition, 1966; reaffirmed, October 2007 because the document provided best practices as of 1965 which is now outdated and not applicable with the measurement and calibration requirements presently used.

API Standard 2555, Method for Liquid Calibration of Tanks, First Edition, September 1966; reaffirmed May 2014.

BSEE proposes to update the incorporation by reference of API Standard 2555, currently located at § 250.198(e)(97), to include reference to a newer 2014 Reaffirmation in its regulations, and to relocate it to § 250.198(e)(105). This standard describes the procedure for calibrating tanks, or portions of tanks, larger than a barrel or drum by introducing or withdrawing measured quantities of liquid. The Department updated its incorporation of the First edition of this standard into the regulations on April 28, 2010 (75 FR 22219). This update reflects a more recent reaffirmation of the standard without substantive change. BSEE proposes to update the reference of this standard in § 250.1202.

API RP 2556, Recommended Practice for Correcting Gauge Tables for Incrustation, Second Edition, August 1993; reaffirmed November 2013.

BSEE proposes to update the incorporation by reference of API Recommended Practice 2556, currently located at § 250.198(e)(80), to include a newer 2013 Reaffirmation in its regulations, and to relocate it to § 250.198(e)(106). Incrustation is defined for the purpose of this RP as any material that adheres to the internal vertical sidewall surfaces of a tank when the tank is otherwise empty. Incrustation has the same effect on tank capacity as deadwood (anything that displaces liquid inside a tank) and should be treated as such as long as it remains in the tank. The problem of deducting the volume of liquid displaced by incrustation is complicated by two of incrustation's basic and typical characteristics. First, incrustation is difficult to measure, and second, its thickness is usually variable. Some oils present no incrustation problem, but many others do, usually on a field-wide basis. The error in measurement from any one tank may be slight, but the accumulated error from an entire field or from any one tank over a period of time could be substantial. The error always has the effect of indicating too large a tank capacity; therefore, a receiving carrier cannot be expected to continually absorb the effect of these errors. The method selected to correct the error should depend upon the desired approach to accuracy of measurement.

The tables given in this RP (see Section 4) show the percent of error of measurement caused by varying thicknesses of uniform incrustation in tanks of various sizes. These tables may be used as a guide by the tank owner and the carrier to negotiate an allowance for incrustation. If it is established that incrustation is causing a substantial loss to a carrier or to any other receiver using affected tank gauges as the basis for custody transfer measurement, it is the responsibility of the tank owner to provide a tank that will permit an accurate measurement or to agree to a reasonable adjustment. The Department updated its incorporation of the Second edition of this standard into the regulations on April 28, 2010 (75 FR 22219). This update reflects a more recent reaffirmation of the standard without substantive change. BSEE proposes to update the reference of this standard in § 250.1202.

API Spec Q1, Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry, Ninth Edition, June 2013; Errata, February 2014; Errata 2, March 2014; Addendum 1, June 2016 is incorporated by reference in the current § 250.198(e)(93) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(107).

API Bulletin 2INT–DG, Interim Guidance for Design of Offshore Structures for Hurricane Conditions, May 2007 is incorporated by reference in the current § 250.198(e)(3) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(108).

API Bulletin 2INT–EX, Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions, May 2007 is incorporated by reference in the current § 250.198(e)(4) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(109).

API Bulletin 92L, Drilling Ahead Safely with Lost Circulation in the Gulf of Mexico, First Edition, August 2015 is incorporated by reference in the current § 250.198(e)(6) and will remain as previously incorporated by reference into the regulations, but will be renumbered in the proposed reorganized table as § 250.198(e)(110).

Paragraph (f)—American Society of Mechanical Engineers (ASME) Standards.

ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels; Division 1, 2021 Edition, July 1, 2021.

BSEE proposes to update the incorporation by reference of ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, at § 250.198(f)(3) from the 2017 edition to the 2021 edition in its regulations. The 2021 Edition made changes to bring the document into conformance with more recent practice, namely overpressure protections, permitted pressure relief devices and methods, design criteria, low temperature operation, and materials considerations. This code gives detailed requirements for the design, fabrication, testing, inspection, and certification of both fired and unfired pressure vessels. It specifically refers to those pressure vessels that operate at pressures, either internal or external, that exceed 15 psig. Section VIII is divided into 3 sections, each of which covers different vessel specifications. Division 1 addresses the requirements for design, fabrication, inspection, testing, and certification. Division 1 contains appendices, some mandatory and some non-mandatory, that detail supplementary design criteria, nondestructive examination techniques, and inspection acceptance standards for pressure vessels. Division 1 also contains rules that apply to the use of the single ASME certification mark with the U, UM, and UV designators. BSEE updated the incorporation of the 2017 edition of this standard into its regulations on September 28, 2018 (83 FR 49216). BSEE proposes to update the reference of this standard in existing regulations at: §§ 250.851(a) and 250.1629(b).

Paragraph (j)—International Organization for Standardization Standards.

BSEE is only proposing changes to subparagraph (1) in paragraph (j) of § 250.198.

ISO/IEC (International Electrotechnical Commission) 17011, Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second Edition 2017–11.

BSEE proposes to update the incorporation by reference of ISO/IEC 17011 at § 250.198(j)(1) from the 2004 First edition to the 2017 Second edition in its regulations. The Second Edition made changes to bring the document into conformance with more recent practice. This document specifies requirements for the competence, consistent operation, and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies. In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation, and verification. BSEE incorporated the First Edition of this standard into its regulations on April 5, 2013 (78 FR 20440). The second edition was revised and reorganized and an Annex A on knowledge and skills for performing accreditation activities was added. BSEE proposes to update the reference of this standard in existing regulations at: §§ 250.1900, 250.1903, 250.1904, and 250.1922.

Proposed paragraph (l)—Gas Processors Association (GPA) Standards.

BSEE proposes to add a new paragraph (l) to § 250.198 that would include three GPA Standards.

GPA Standard 2198–16—Selection, Preparation, Validation, Care and Storage of Natural Gas and Natural Gas Liquids Reference Standard Blends; Adopted as a Standard 1998; Revised August 2016; Reaffirmed 2017. (proposed § 250.198(l)(1)).

BSEE proposes to incorporate by reference for the first time GPA 2198–16, as revised in 2016 and reaffirmed in 2017, into its regulations (proposed regulatory text: § 250.198(l)(1)). This standard covers the recommended procedures for selecting the proper Natural Gas and Natural Gas Liquids Reference Standards, preparing the standards for use, verifying the accuracy of composition as reported by the manufacturer, and the proper care and storage of those standards to ensure their integrity and longevity during use. BSEE proposes to add a reference to this standard in § 250.1203(b).

GPA Standard 2261–20—Analysis for Natural Gas and Similar Gaseous Mixtures by Gas Chromatography; Adopted as a standard 1964; Revised 2020 (proposed § 250.198(l)(2)).

BSEE proposes to incorporate by reference for the first time GPA 2261–20, as revised in 2020, into its regulations (proposed regulatory text: § 250.198(l)(2)). This standard provides the gas processing industry with a method for determining the chemical composition of natural gas and similar gaseous mixtures using a Gas Chromatograph. The precision statements contained in this standard are based on the statistical analysis of round-robin laboratory data obtained by GPA Section B. This standard was developed by the cooperative efforts of many individuals from industry under the sponsorship of GPA Section B, Analysis and Test Methods. BSEE proposes to add a reference to this standard in § 250.1203(b).

GPA Standard 2286–14—Method for the Extended Analysis of Natural Gas and Similar Gaseous Mixtures by Temperature Program Gas Chromatography; Adopted as a standard 1995; Revised 2014 (proposed § 250.198(l)(3)).

BSEE proposes to incorporate by reference for the first time GPA 2286–14, as revised in 2014, into its regulations (proposed regulatory text: § 250.198(l)(3)). This standard covers the determination of the chemical composition of natural gas streams where precise physical property data of the hexanes and heavier fraction is required. This procedure is applicable for gaseous hydrocarbon mixes, which may contain nitrogen and carbon dioxide and/or hydrocarbon complexes C1 through C14 that fall within the ranges specified therein. This standard had previously seen only minor revisions since its adoption as a technical standard in 1986. The GPA revised portions of the standard that had become obsolete and that did not reflect current industry practices. In addition, the example calculations that use GPA 2145 to reflect the 2009 revision of GPA 2145 and all calculations related to those presented in GPA 2172 were removed and referenced to GPA 2172. The most significant changes to the standard involve updates to the method to maintain consistency with current technologies. BSEE proposes to add a reference to this standard in § 250.1203(b).

What additional information must I submit with my APD for Arctic OCS exploratory drilling operations? (§ 250.470)

BSEE proposes to update paragraph (g) of § 250.470 in order to update the reference from API RP 2N to ANSI/API RP 2N, to align with the title of the document as incorporated in § 250.198 paragraph (e).

What are the general requirements for BOP systems and system components? (§ 250.730)

BSEE proposes to update § 250.730(a)(2) by changing the references from ANSI/API Spec. 6A to API Specification 6A and ANSI/API Spec 17D to API Specification 17D and adding references to API Spec 20E and API Spec 20F, as described in the discussion of § 250.198 paragraph (e).

What are the requirements for a surface BOP stack? (§ 250.733)

BSEE proposes to update paragraph (b) of § 250.733 in order to update the reference from API RP 2RD to API

Standard 2RD, as described in the discussion of § 250.198 paragraph (e).

What are the coiled tubing requirements? (§ 250.750)

BSEE proposes to add paragraph (c) to § 250.750 in order to require adherence to API RP 16ST, as described in the discussion of § 250.198 paragraph (e).

General. (§ 250.800)

BSEE proposes to update paragraph (c) of § 250.800 in order to update the reference from API RP 2RD to API Standard 2RD, as described in the discussion of § 250.198 paragraph (e).

Requirements for SPPE. (§ 250.802)

BSEE proposes to update paragraphs (a) and (c) of § 250.802 in order to update the references from ANSI/API Spec. 6A to API Specification 6A and from API Spec 6AV1 to API Standard 6AV1, as described in the discussion of § 250.198 paragraph (e).

What SPPE failure reporting procedures must I follow? (§ 250.803)

BSEE proposes to update paragraph (a) of § 250.803 in order to update the reference from ANSI/API Spec 6A to API Specification 6A, as described in the discussion of § 250.198 paragraph (e).

Specification for Underwater Safety Valves (USVs). (§ 250.833)

BSEE proposes to update the introductory paragraph of § 250.833 in order to update the references from ANSI/API Spec 6A to API Specification 6A and from API Spec 6AV1 to API Standard 6AV1, as described in the discussion of § 250.198 paragraph (e).

Pressure Vessels (Including Heat Exchangers) and Fired Vessels. (§ 250.851)

Subsea Gas Lift Requirements. (§ 250.873)

Subsea Water Injection Systems. (§ 250.874)

BSEE proposes to update § 250.851, § 250.873, and § 250.874 by updating the references from ANSI/ASME Boiler and Pressure Vessel Code to ASME Boiler and Pressure Vessel Code; ANSI/API Spec 6A to API Specification 6A; and API Spec 6AV1 to API Standard 6AV1, as described in the discussion of § 250.198 paragraph (e).

What industry standards must your platform meet? (§ 250.901)

BSEE proposes to revise the references in paragraphs (a) and (d) from API RP 2RD to API Standard 2RD, as described in the discussion of § 250.198 paragraph (e). BSEE also proposes to add Standards API RP 2FSIM, API RP 2GEO, API RP 2MET, API RP 2MIM, and API RP 2RIM to paragraph (a), as described in the discussion of § 250.198 paragraph (e). BSEE also proposes to add Standards API RP 2FSIM, API RP 2GEO, API RP 2MET, API RP 2SIM, API RP 2MIM, and API RP 2RIM to paragraph (d) of § 250.901, as described in the discussion of § 250.198 paragraph (e).

Design Requirements for DOI Pipelines. (§ 250.1002)

BSEE proposes to update the references from ANSI/API Spec. 6A to API Specification 6A and from API RP 2RD to API Standard 2RD in paragraph (b) of § 250.1002, as described in the discussion of § 250.198 paragraph (e).

Liquid Hydrocarbon Measurement. (§ 250.1202)

BSEE proposes to update the references to the following standards in § 250.1202(a)(2) to reflect the incorporated updates described in the discussion of § 250.198:

API MPMS, Chapter 4, Section 8 to API MPMS Chapter 4.8;

API MPMS Chapter 5, Section 8 to API MPMS Chapter 5.8; and

API MPMS Chapter 11, Section 1 to API MPMS Chapter 11.1.

BSEE proposes to add references in paragraph (a)(2) to the incorporation by reference of the following standards, as described in the discussion of § 250.198:

API MPMS Chapter 4, Section 9, Part 2;
API MPMS Chapter 5, Section 1;
API MPMS Chapter 6.1;
API MPMS Chapter 7.1;
API MPMS Chapter 7.3;
API MPMS Chapter 8.1;
API MPMS Chapter 8.2;
API MPMS Chapter 8.3;
API MPMS Chapter 9.1;
API MPMS Chapter 9.2;
API MPMS Chapter 9.4;
API MPMS Chapter 10.2;
API MPMS Chapter 10.3;
API MPMS Chapter 10.4;
API MPMS Chapter 10.9;
API MPMS Chapter 12.2;
API MPMS Chapter 20, Section 1;
API Standard 2555;
API RP 2556;
API MPMS Chapter 2.2E, Part 1;
API MPMS Chapter 2.2F, Part 2;
API MPMS Chapter 3.1A;
API MPMS Chapter 4, Section 2;
API MPMS Chapter 4.5; and
API MPMS Chapter 4, Section 7.

Because API RP 86 has been superseded by more recent standards, the existing reference to API RP 86 in paragraph (a)(2) would be removed and replaced, as described in the discussion of § 250.198.

The resulting subparagraphs of paragraph (a)(2) would be reordered and renumbered to reflect these updates.

BSEE proposes to revise the references to the following standards in paragraph (a)(3), as described in the discussion of § 250.198: API MPMS, Chapter 4, Section 8 to API MPMS, Chapter 4.8; and

API MPMS Chapter 5, Section 8 to API MPMS Chapter 5.8.

BSEE is proposing to remove references to API RP 86 (which has been superseded by more current standards) from paragraph (a)(3).

The resulting subparagraphs of paragraph (a)(3) would be reordered and renumbered to reflect these updates.

Gas Measurement. (§ 250.1203)

BSEE proposes to revise the introductory language of § 250.1203(b)(2) to clarify the requirements for adherence to the identified standards. BSEE proposes to remove the reference to API RP 86 from § 250.1203(b)(2), as that standard has been superseded.

BSEE proposes to add references to the incorporation of the following standards into § 250.1203(b)(2), as described in the discussion of § 250.198:

AGA Report No. 8, Part 1;
AGA Report No. 8, Part 2;
AGA Report No. 11;
GPA Standard 2198–16;
GPA Standard 2261–20;
GPA Standard 2286–14;
API MPMS Chapter 14.1;
API MPMS Chapter 14.3.1;
API MPMS Chapter 14.3.2;
API MPMS Chapter 14.3.3;
API MPMS Chapter 20.1;
API MPMS Chapter 20.3; and
API MPMS Chapter 20.5.

The resulting subparagraphs of paragraph (b)(2) would be reordered and renumbered to reflect these updates.

Additional Production and Fuel Gas System Requirements. (§ 250.1629)

BSEE proposes to amend § 250.1629 to change all of the references from ANSI/ASME Boiler and Pressure Vessel Code to ASME Boiler and Pressure Vessel Code throughout.

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866, 13563, and 13771)

Executive Order (E.O.) 12866, as amended by E.O. 14094, provides that the OMB Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 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. E.O. 13563 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. E.O. 13563 further emphasizes 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.

BSEE is incorporating by reference consensus standards developed by industry. Industry construes the consensus standards to be minimum requirements for safe operations. BSEE proposes to incorporate by reference 67 consensus standards in its regulations. The consensus standards are widely practiced by industry operating on the OCS. The consensus standards proposed for incorporation by reference include ten standards that have not been previously incorporated in the BSEE regulations (30 CFR part 250) and the remainder that are updates of standards that have been previously incorporated. All the consensus standards proposed for incorporation by reference have been and continue to be widely used and practiced by the offshore industry. Thus, this rule aligns the BSEE regulations with the existing industry practice. Therefore, this rule maintains the burden that industry has set for itself. BSEE has developed this rule pursuant to the requirements of E.O. 13563 to use industry standards to promote predictability, reduce uncertainty, and maintain the status quo with respect to burden.

Regulatory Flexibility Act

The Department of the Interior certifies that 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 proposed rule would affect lessees and operators of oil and gas leases on the OCS. This includes approximately 130 active Federal oil and gas lessees. Lessees that conduct business under this rule are coded under the Small Business Administration's North American Industry Classification System (NAICS) codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111, Drilling Oil and Gas Wells. For these NAICS code classifications, a small company is defined as one with fewer than 500 employees. BSEE estimates that approximately 70 percent of the 130 lessees and operators that explore for and produce oil and gas on the OCS meet the definition of a small company. This rule proposes to incorporate consensus standards developed by accredited standard development organizations (SDOs) as minimum acceptable requirements. The accredited SDOs are required to develop standards with a process that is open, has balanced participation, provides due process, and has a specific appeal procedure—*i.e.,* a multi-stakeholder process. The accredited SDOs require that all aspects of a consensus standard are fully negotiated including scope, definitions, and content. Any interested party can comment during the development process, and the comments must be fairly considered by the SDO and the commentor advised of the outcome and why—*i.e.,* a consensus-based approach where comments from all stakeholders are considered. All the standards in this rule were developed by SDOs using this multi-stakeholder, fully negotiated, fairly considered, consensus-based approach.

BSEE understands that such a consensus-based approach leads to high voluntary conformance rates by industry participants because all parties are encouraged and allowed to participate. Consensus-building is a fundamental requirement encompassed by each standard in this rule. Industry parties are required by SDO rules to resolve substantial objections early in the standards development stage. Thus, the regulated industry has had an opportunity to adopt and adhere to each consensus, industry standard prior to the publication of the standard and since. Furthermore, many of the industry standards being incorporated in this proposed rule are either updates to existing industry standards already incorporated by reference or have been adopted, adhered to, and published for numerous years. This consensus-based process has given industry participants sufficient time to integrate the standard into their operations.

Since 2019, BSEE has made a concerted effort to work with industry and the public to understand and analyze the utility of consensus standards used by BSEE in its regulatory program. Over the past five years, three offshore standards workshops have been conducted by industry with BSEE participation, namely on January 29, 2020, March 30, 2021, and May 11, 2023. Each workshop included an analysis of the standards that BSEE uses or industry proposed BSEE use in its regulatory program. BSEE's engagement with SDOs and industry stakeholders during the SDO workshops confirmed that industry's voluntary conformance with consensus standards is high. The costs of incorporating such standards are, therefore, minimal since the high conformance rates mean the costs of adhering to the industry standard will be incurred regardless of this proposed rule and are appropriately considered to be part of the baseline. Although a few of the standards being incorporated by reference were adopted by SDOs within the last 2 years (*e.g.,* API Specification 6A, Specification for Wellhead and Christmas Tree Equipment and API Specification 6D, Specification for Pipeline Valves, both updated in 2023), voluntary conformance with these standards was already high at the time of adoption and is believed to have been increasing based on discussions during the SDO workshops. Therefore, most of the costs of adhering to these standards are also considered to be part of the baseline, as industry will incur them regardless of this proposed rule. Thus, incorporating the standards in this rule would not have a significant economic effect on a substantial number of small companies because any costs or burdens on any lessees or operators are a product of existing consensus minimum industry performance standards promulgated with broad stakeholder engagement and broadly adopted by industry regardless of incorporation into the regulations.

Although the standards are available as read-only documents at BSEE offices and on the SDO websites, if any business wanted to own a copy, then the primary economic effect of this rule on small business would be the nominal cost associated with the purchase of the standards.

Small Business Regulatory Enforcement Fairness Act

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of BSEE, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

Congressional Review Act

The proposed rule is not a major rule under the Congressional Review Act. This proposed rule:

1. Would not have an annual effect on the economy of $100 million or more. The main purpose of this rule would be to add and update industry standards in the regulations to provide industry with up-to-date requirements in the use of new measurement and safety technology, consistent with existing industry practice.

2. Would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The cost to comply with the rule would be consistent with the status quo, as it would only require compliance with industry standards to which affected entities already generally adhere.

3. Would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or ability of U.S.-based enterprises to compete with foreign-based enterprises. The requirements would apply to all entities operating on the OCS and reflect existing industry standards.

Unfunded Mandates Reform Act of 1995

This proposed rule would 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 would 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. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this proposed rule does not have significant takings implications. The proposed rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this proposed rule does not have federalism implications. This proposed rule would not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this proposed rule would not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

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

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)

BSEE strives to strengthen its government-to-government relationships with American Indian and Alaska Native Tribes through a commitment to consultation with the Tribes and recognition of their right to self-governance and Tribal sovereignty. We are also respectful of our responsibilities for consultation with Alaska Native Claims Settlement Act Corporations. We have evaluated this proposed rule under the Department's consultation policy, under Departmental Manual part 512 chapters 4 and 5, and under the criteria in E.O. 13175 and determined that it would have no substantial direct effects on federally recognized Indian Tribes.

Paperwork Reduction Act

The proposed revisions do not contain any information collection and do not require a submission to the Office of Management and Budget for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

National Environmental Policy Act of 1969 (NEPA)

This 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 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 falls within the Departmental categorical exclusion covering ''regulations . . . 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.'' 43 CFR 46.210(i); see also 516 Departmental Manual 15.4(C)(1) (covering ''[i]ssuance and modification of regulations''). 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 the National Environmental Policy Act.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C § 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

Clarity of This Regulation

We are required by E.O. 12866, E.O. 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 the **ADDRESSES** section. 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 you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

List of Subjects in 30 CFR Part 250

Administrative practice and procedure; Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Oil and gas exploration, Outer Continental Shelf—mineral resources, Outer Continental Shelf—rights-of-way, Penalties, Pipelines, Reporting and recordkeeping requirements, Sulfur.

Steven H. Feldgus,

Deputy Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Bureau of Safety and Environmental Enforcement (BSEE) is proposing to amend 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULFUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 30 U.S.C. 1751, 31 U.S.C. 9701, 33 U.S.C. 1321(j)(1)(C), 43 U.S.C. 1334.

■ 2. Amend § 250.108 by adding paragraph (g) to read as follows:

§ 250.108 What requirements must I follow for cranes and other material-handling equipment?

* * * * *

(g) You must operate and maintain offshore cargo carrying units in accordance with API Standard 2CCU (as incorporated by reference in § 250.198).

■ 3. Amend § 250.198 by:

■ a. Revising paragraphs (b)(1) through (3);

■ b. Adding paragraphs (b)(4) through (6);

■ c. Revising paragraphs (e), (f)(3), and (j)(1); and

■ d. Adding paragraph (l).

The revisions and additions read as follows:

§ 250.198 Documents incorporated by reference.

* * * * *

(b) * * *

(1) AGA Report No. 7—Measurement of Natural Gas by Turbine Meters, Revised February 2006; incorporated by reference at § 250.1203(b);

(2) AGA Report No. 8, Part 1, Thermodynamic Properties of Natural Gas and Related Gases Detail and Gross Equations of State, Third Edition, April 2017; incorporated by reference at § 250.1203(b).

(3) AGA Report No. 8, Part 2, Thermodynamic Properties of Natural Gas and Related Gases, GERG—2008 Equation of State, First Edition, April 2017; incorporated by reference at § 250.1203(b).

(4) AGA Report No. 9—Measurement of Gas by Multipath Ultrasonic Meters, Fourth Edition, 2022; incorporated by reference at § 250.1203(b);

(5) AGA Report No. 10—Speed of Sound in Natural Gas and Other Related Hydrocarbon Gases, Copyright 2003; incorporated by reference at § 250.1203(b);

(6) AGA Report No. 11—Measurement of Natural Gas by Coriolis Meter, Second Edition, February 2013; incorporated by reference at § 250.1203(b).

* * * * *

(e) American Petroleum Institute (API), API Recommended Practices (RP), Specs, Standards, Manual of Petroleum Measurement Standards (MPMS) chapters, 1220 L Street NW, Washington, DC 20005–4070; *www.api.org;* phone: 202–682–8000:

API standard title	Incorporated by reference at:
Manual of Petroleum Measurement Standards (MPMS)	
Chapter 1	
(1) *API MPMS Chapter 1—Vocabulary,* Second Edition, July 1994	§ 250.1201.
Chapter 2	
(2) *API MPMS Chapter 2—Tank Calibration, Section 2A—Measurement and Calibration of Upright Cylindrical Tanks by the Manual Tank Strapping Method,* First Edition, February 1995; reaffirmed August 2017.	§§ 250.1202(a)(2) and (l).
(3) *API MPMS Chapter 2—Tank Calibration, Section 2B—Calibration of Upright Cylindrical Tanks Using the Optical Reference Line Method,* First Edition, March 1989; reaffirmed April 2019 (including Addendum 1, October 2019).	§§ 250.1202(a)(2) and (l).
(4) *API MPMS Chapter 2.2E, Petroleum and Liquid Petroleum Products—Calibration of Horizontal Cylindrical Tanks, Part 1: Manual Methods,* First Edition, April 2004, Reaffirmed August 2014, Errata November 2009.	§ 250.1202(a).
(5) *API MPMS Chapter 2.2F, Petroleum and Liquid Petroleum Products—Calibration of Horizontal Cylindrical Tanks, Part 2: Internal Electro-optical Distance-Ranging Method,* First Edition, April 2004, reaffirmed September 2014.	§ 250.1202(a).
Chapter 3	
(6) *API MPMS Chapter 3.1A, Standard Practice for the Manual Gauging of Petroleum and Petroleum Products,* Third Edition, August 2013, Errata 1, January 2021.	§ 250.1202(a).
(7) *API MPMS Chapter 3—Tank Gauging, Section 1B—Standard Practice for Level Measurement of Liquid Hydrocarbons in Stationary Tanks by Automatic Tank Gauging,* Second Edition, June 2001; reaffirmed February 2016.	§§ 250.1202(a)(2) and (l).
Chapter 4	
(8) *API MPMS Chapter 4—Proving Systems, Section 1—Introduction,* Third Edition, February 2005; reaffirmed June 2014.	§§ 250.1202(a)(2) and (d).
(9) *API MPMS Chapter 4—Proving Systems, Section 2—Displacement Provers,* Third Edition, September 2003; Addendum February 2015, Reaffirmed December 2022.	§ 250.1202(a).
(10) *API MPMS Chapter 4—Proving Systems, Section 4—Tank Provers,* Second Edition, May 1998, reaffirmed December 2020.	§§ 250.1202(a)(2) and (f).
(11) *API MPMS Chapter 4.5—Master Meter Provers,* Fourth Edition, June 2016	§ 250.1202(a).
(12) *API MPMS Chapter 4—Proving Systems, Section 6—Pulse Interpolation,* Second Edition, May 1999; Errata April 2007; reaffirmed October 2013.	§§ 250.1202(a)(2) and (h).
(13) *API MPMS Chapter 4—Proving Systems, Section 7—Field Standard Test Measures,* Third Edition, April 2009, reaffirmed June 2014.	§ 250.1202(a).
(14) *API MPMS Chapter 4.8—Operation of Proving Systems,* Third Edition, July 2021	§ 250.1202.

API standard title	Incorporated by reference at:
(15) *API MPMS Chapter 4, Proving Systems, Section 9—Methods of Calibration for Displacement and Volumetric Tank Provers, Part 2—Determination of the Volume of Displacement and Tank Provers by the Water-draw Method of Calibration,* First Edition, December 2005; reaffirmed July 2015.	§ 250.1202(a).
Chapter 5	
(16) *API MPMS Chapter 5—Metering, Section 1—General Considerations for Measurement by Meters,* Fourth Edition, September 2005, Errata 1 June 2008, Errata 2 June 2011, reaffirmed December 2022.	§ 250.1202(a).
(17) *API MPMS Chapter 5—Metering, Section 2—Measurement of Liquid Hydrocarbons by Displacement Meters,* Third Edition, September 2005; reaffirmed December 2020.	§ 250.1202(a)(2).
(18) *API MPMS Chapter 5—Metering, Section 3—Measurement of Liquid Hydrocarbons by Turbine Meters,* Fifth Edition, September 2005; reaffirmed August 2014.	§ 250.1202(a)(2).
(19) *API MPMS Chapter 5—Metering, Section 4—Accessory Equipment for Liquid Meters,* Fourth Edition, September 2005; reaffirmed August 2015.	§ 250.1202(a)(2).
(20) *API MPMS Chapter 5—Metering, Section 5—Fidelity and Security of Flow Measurement Pulsed-Data Transmission Systems,* Second Edition, August 2005; reaffirmed August 2015.	§ 250.1202(a)(2).
(21) *API MPMS Chapter 5—Metering, Section 6—Measurement of Liquid Hydrocarbons by Coriolis Meters;* First Edition, October 2002; reaffirmed November 2013.	§ 250.1202.
(22) *API MPMS Chapter 5.8—Measurement of Liquid Hydrocarbons by Ultrasonic Flow Meters,* Second Edition, November 2011, Errata February 2014, reaffirmed May 2017.	§ 250.1202(a).
Chapter 6	
(23) *API MPMS Chapter 6.1, Lease Automatic Custody Transfer (LACT) Systems,* Second Edition, May 1991; Addendum 1 August 2020.	§ 250.1202(a).
(24) *API MPMS Chapter 6—Metering Assemblies, Section 6—Pipeline Metering Systems,* Second Edition, May 1991; reaffirmed December 2017.	§ 250.1202(a)(2).
(25) *API MPMS Chapter 6—Metering Assemblies, Section 7—Metering Viscous Hydrocarbons,* Second Edition, May 1991; reaffirmed March 2018.	§ 250.1202(a)(2).
Chapter 7	
(26) *API MPMS Chapter 7.1—Temperature Determination-Liquid-in-Glass Thermometers,* Second Edition, August 2017.	§ 250.1202(a).
(27) *API MPMS, Chapter 7.3—Temperature Determination—Temperature Determination-Fixed Automatic Tank Temperature Systems,* Second Edition, October 2011; reaffirmed September 2021.	§ 250.1202(a).
Chapter 8	
(28) *API MPMS, Chapter 8.1—Standard Practice for Manual Sampling of Petroleum and Petroleum Products,* Sixth Edition, September 2022.	§ 250.1202(a).
(29) *API MPMS, Chapter 8.2—Standard Practice for Automatic Sampling of Liquid Petroleum and Petroleum Products,* Sixth Edition, September 2022.	§ 250.1202(a).
(30) *API MPMS Chapter 8.3—Standard Practice for Mixing and Handling of Liquid Samples of Petroleum and Petroleum Products,* Second Edition, September 2019.	§ 250.1202(a).
Chapter 9	
(31) *API MPMS Chapter 9.1—Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method,* Third Edition, December 2012, reaffirmed May 2017.	§ 250.1202(a).
(32) *API MPMS Chapter 9.2—Standard Test Method for Density or Relative Density of Light Hydrocarbons by Pressure Hydrometer,* Fourth Edition, November 2022.	§ 250.1202(a).
(33) *API MPMS Chapter 9.4—Continuous Density Measurement Under Dynamic (Flowing) Conditions,* First Edition, January 2018.	§ 250.1202(a).
Chapter 10	
(34) *API MPMS Chapter 10—Sediment and Water, Section 1—Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method,* Third Edition, November 2007; reaffirmed October 2012.	§ 250.1202(a)(2).
(35) *API MPMS Chapter 10.2—Standard Test Method for Water in Crude Oil by Distillation,* Fifth Edition, December 2022.	§ 250.1202(a).
(36) *API MPMS Chapter 10.3—Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure),* Fifth Edition, December 2022.	§ 250.1202(a).
(37) *API MPMS Chapter 10.4—Determination of Water and/or Sediment in Crude Oil by the Centrifuge Method (Field Procedure),* Fifth Edition, August 2020.	§ 250.1202(a).
(38) *API MPMS Chapter 10.9—Standard Test Method for Water in Crude Oils by Coulometric Karl Fisher Titration,* Third Edition, May 2013, reaffirmed June 2018.	§ 250.1202(a).
Chapter 11	
(39) *API MPMS Chapter 11—Physical Properties Data, Section 1—Temperature and Pressure Volume Correction Factors for Generalized Crude Oils, Refined Products, and Lubricating Oils,* 2004 Edition, May 2004, Addendum 1, September 2007, Addendum 2, May 2019.	§ 250.1202.

API standard title	Incorporated by reference at:
(40) *API MPMS Chapter 11.1—Volume Correction Factors, Volume 1, Table 5A—Generalized Crude Oils and JP–4 Correction of Observed API Gravity to API Gravity at 60 °F, and Table 6A—Generalized Crude Oils and JP–4 Correction of Volume to 60 °F Against API Gravity at 60 °F, API Standard 2540,* First Edition, August 1980; reaffirmed March 1997.	§ 250.1202.
(41) *API MPMS Chapter 11.2.2—Compressibility Factors for Hydrocarbons: 0.350–0.637 Relative Density (60 °F/60 °F) and − 50 °F to 140 °F Metering Temperature,* Second Edition, October 1986; reaffirmed: September 2017.	§ 250.1202(a)(3).
(42) *API MPMS Chapter 11—Physical Properties Data, Addendum to Section 2, Part 2—Compressibility Factors for Hydrocarbons, Correlation of Vapor Pressure for Commercial Natural Gas Liquids,* First Edition, December 1994; reaffirmed, December 2002.	§ 250.1202(a)(3).
Chapter 12	
(43) *API MPMS Chapter 12.2, Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors,* Second Edition, July 2021.	§ 250.1202(a).
(44) *API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 4—Calculation of Base Prover Volumes by the Waterdraw Method,* First Edition, December 1997; reaffirmed January 2022.	§ 250.1202.
Chapter 14	
(45) *API MPMS Chapter 14.1—Collecting and Handling of Natural Gas Samples for Analysis by Gas Chromatography,* Eighth Edition, September 2022.	§ 250.1203(b).
(46) *API MPMS Chapter 14.3.1—Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids, Concentric Square-Edged Orifice Meters, Part 1: General Equations and Uncertainty Guidelines,* Fourth Edition, September 2012, Errata July 2013, Reaffirmed September 2017.	§ 250.1203(b).
(47) *API MPMS Chapter 14.3.2, Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids—Concentric, Square-Edged Orifice Meters, Part 2: Specification and Installation Requirements,* Fifth Edition, March 2016, Errata 1, March 2017, Errata 2, January 2019, Reaffirmed January 2019.	§ 250.1203(b).
(48) *API MPMS 14.3.3, Orifice Metering of Natural Gas and Other Related Hydrocarbon Fluids—Concentric Square-Edged Orifice Meters, Part 3: Natural Gas Applications,* Fourth Edition, November 2013, Reaffirmed June 2021.	§ 250.1203(b).
(49) *API MPMS, Chapter 14.5/GPA Standard 2172–09; Calculation of Gross Heating Value, Relative Density, Compressibility and Theoretical Hydrocarbon Liquid Content for Natural Gas Mixtures for Custody Transfer;* Third Edition, January 2009; reaffirmed November 2020.	§ 250.1203(b)(2).
(50) *API MPMS Chapter 14—Natural Gas Fluids Measurement, Section 8—Liquefied Petroleum Gas Measurement,* Second Edition, July 1997; reaffirmed, March 2006.	§ 250.1203(b)(2).
Chapter 20	
(51) *API MPMS Chapter 20—Allocation Measurement, Section 1—Allocation Measurement,* First Edition, September 1993; reaffirmed October 2016, Addendum 1 January 2013, Addendum 2 November 2016, Addendum 3 December 2017, Errata 1 November 2022.	§ 250.1202(a) and § 250.1203(b).
(52) *API MPMS, Chapter 20.3—Measurement of Multiphase Flow,* First Edition, January 2013; reaffirmed, October 2018.	§ 250.1203(b).
(53) *API MPMS, Chapter 20.5—Recommended Practice for Application of Production Well Testing in Measurement and Allocation,* First Edition, December 2017; reaffirmed, March 2023.	§ 250.1203(b).
Chapter 21	
(54) *API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 1—Electronic Gas Measurement,* First Edition, August 1993; reaffirmed, July 2005.	§ 250.1203(b)(2).
(55) *API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 2—Electronic Liquid Volume Measurement Using Positive Displacement and Turbine Meters;* First Edition, June 1998; reaffirmed October 2016.	§ 250.1202(a).
(56) *API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Addendum to Section 2—Flow Measurement Using Electronic Metering Systems, Inferred Mass;* First Edition August 2000; reaffirmed October 2016.	§ 250.1202(a).
2	
(57) *API RP 2A–WSD, Recommended Practice for Planning, Designing and Constructing Fixed Offshore Platforms—Working Stress Design,* Twenty-second Edition, November 2014; Reaffirmation, September 2020.	§§ 250.901, 250.908, 250.919, and 250.920.
(58) *API Spec 2C, Specification for Offshore Pedestal Mounted Cranes,* Eighth Edition, October 2020; API Monogram Program Effective Date: May 1, 2021.	§ 250.108.
(59) *API Standard 2CCU—Offshore Cargo Carrying Units;* First Edition, August 2017	§ 250.108(g).
(60) *API RP 2D, Operation and Maintenance of Offshore Cranes,* Seventh Edition, December 2014; Errata August 2015, Addendum 1, October 2020.	§ 250.108.
(61) *API RP 2FPS, Recommended Practice for Planning, Designing, and Constructing Floating Production Systems,* Second Edition, October 2011; Reaffirmed September 2020.	§ 250.901.
(62) *API RP 2FSIM—Floating Systems Integrity Management;* First Edition, September 2019	§ 250.901.

API standard title	Incorporated by reference at:
(63) *API RP 2GEO—Geotechnical and Foundation Design Considerations;* First Edition, April 2011, Addendum 1, October 2014; Includes all amendments and changes through Reaffirmation Notice, January 2021.	§ 250.901.
(64) *API RP 2I, In-Service Inspection of Mooring Hardware for Floating Structures;* Third Edition, April 2008	§§ 250.901(a) and (d).
(65) *API RP 2MET—Derivation of Metocean Design and Operating Conditions;* Second Edition, January 2021; ISO 19901–1:2015 (Modified) Part 1.	§ 250.901.
(66) *API RP 2MIM—Mooring Integrity Management;* First Edition, September 2019	§ 250.901.
(67) *ANSI/API RP 2N, Third Edition,* "*Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions*", Third Edition, April 2015.	§ 250.470(g).
(68) *API Standard 2RD, Dynamic Risers for Floating Production Systems,* Second Edition, September 2013, Reaffirmed September 2020.	§§ 250.733, 250.800(c), 250.901, and 250.1002(b).
(69) *API RP 2RIM—Integrity Management of Risers from Floating Production Systems;* First Edition, September 2019.	§ 250.901.
(70) *API RP 2SIM—Structural Integrity Management of Fixed Offshore Structures,* First Edition, November 2014; reaffirmed September 2020.	§ 250.901(d).
(71) *API RP 2SK, Design and Analysis of Stationkeeping Systems for Floating Structures,* Third Edition, October 2005, Addendum, May 2008, reaffirmed June 2015.	§§ 250.800(c) and 250.901(a) and (d).
(72) *API RP 2SM, Recommended Practice for Design, Manufacture, Installation, and Maintenance of Synthetic Fiber Ropes for Offshore Mooring,* Second Edition, July 2014; Reaffirmation, September 2020.	§§ 250.800(c) and 250.901.
(73) *API RP 2T, Recommended Practice for Planning, Designing, and Constructing Tension Leg Platforms,* Third Edition, July 2010, reaffirmed June 2015.	§ 250.901.
6	
(74) *API Specification 6A, Specification for Wellhead and Christmas Tree Equipment,* Twenty-First Edition, November 2018, API Monogram Program Effective Date: November 2019, Errata 1 April 2019, Errata 2 June 2020, Errata 3 September 2020, Errata 4 September 2021, Addendum 1 July 2020 (API Monogram Program Effective Date: January 2021), Addendum 2, June 2021 (API Monogram Program Effective Date: December 2021), Addendum 3, August 2022 (API Monogram Program Effective Date: February 2023).	§§ 250.730, 250.802(a), 250.803(a), 250.833, 250.873(b), 250.874(g) and 250.1002(b).
(75) *API Standard 6AV1, Validation of Safety and Shutdown Valves for Sandy Service,* Third Edition, July 1, 2018.	§§ 250.802(a), 250.833, 250.873(b), and 250.874(g).
(76) *API STD 6AV2, Installation, Maintenance, and Repair of Surface Safety Valves and Underwater Safety Valves Offshore;* First Edition, March 2014; Errata 1, August 2014.	§§ 250.820, 250.834, 250.836, and 250.880(c).
(77) API Specification 6D, Specification for Pipeline Valves, Twenty-fifth Edition November 2021, API Monogram Program Effective Date: November 2022, Errata 1 December 2021, Errata 2 April 2022, Addendum 1 April 2023.	§ 250.1002(b).
11	
(78) *API Spec 11D1, Packers and Bridge Plugs,* Second Edition, July 2009	§§ 250.518, 250.619, and 250.1703.
14	
(79) *ANSI/API Spec 14A, Specification for Subsurface Safety Valve Equipment,* Eleventh Edition, October 2005, reaffirmed, June 2012.	§§ 250.802 and 250.803(a).
(80) *API RP 14B, Design, Installation, Operation, Test, and Redress of Subsurface Safety Valve Systems,* Sixth Edition, September 2015.	§§ 250.802(b), 250.803(a), 250.814(d), 250.828(c), and 250.880(c).
(81) *API RP 14C, Recommended Practice for Analysis, Design, Installation, and Testing of Basic Surface Safety Systems for Offshore Production Platforms,* Seventh Edition, March 2001, reaffirmed: March 2007.	§§ 250.125(a), 250.292(j), 250.841(a), 250.842(a), 250.850, 250.852(a), 250.855, 250.856(a), 250.858(a), 250.862(e), 250.865(a), 250.867(a), 250.869(a) through (c), 250.872(a), 250.873(a), 250.874(a), 250.880(b) and (c), 250.1002(d), 250.1004(b), 250.1628(c) and (d), 250.1629(b), and 250.1630(a).
(82) *API RP 14E, Recommended Practice for Design and Installation of Offshore Production Platform Piping Systems,* Fifth Edition, October 1991; reaffirmed, January 2013.	§§ 250.841(b), 250.842(a), and 250.1628(b) and (d).
(83) *API RP 14F, Recommended Practice for Design, Installation, and Maintenance of Electrical Systems for Fixed and Floating Offshore Petroleum Facilities for Unclassified and Class 1, Division 1 and Division 2 Locations, Upstream Segment,* Fifth Edition, July 2008, reaffirmed: April 2013.	§§ 250.114(c), 250.842(c), 250.862(e), and 250.1629(b).
(84) *API RP 14FZ, Recommended Practice for Design, Installation, and Maintenance of Electrical Systems for Fixed and Floating Offshore Petroleum Facilities for Unclassified and Class I, Zone 0, Zone 1 and Zone 2 Locations,* Second Edition, May 2013.	§§ 250.114(c), 250.842(c), 250.862(e), and 250.1629(b).
(85) *API RP 14G, Recommended Practice for Fire Prevention and Control on Fixed Open-type Offshore Production Platforms,* Fourth Edition, April 2007; Reaffirmed, January 2013.	§§ 250.859(a), 250.862(e), 250.880(c), and 250.1629(b).
(86) *API RP 14J, Recommended Practice for Design and Hazards Analysis for Offshore Production Facilities,* Second Edition, May 2001; reaffirmed: January 2013.	§§ 250.800(b) and (c), 250.842(c), and 250.901(a) and (d).

API standard title	Incorporated by reference at:
16	
(87) *API Spec 16A, Specification for Drill-through Equipment,* Third Edition, June 2004, reaffirmed August 2010.	§ 250.730.
(88) *API Spec 16C, Specification for Choke and Kill Systems,* First Edition, January 1993, reaffirmed July 2010.	§ 250.730.
(89) *API Spec 16D, Specification for Control Systems for Drilling Well Control Equipment and Control Systems for Diverter Equipment,* Second Edition, July 2004, reaffirmed August 2013.	§ 250.730.
(90) *API RP 16ST, Coiled Tubing Well Control Equipment Systems,* Second Edition, February 2021, Addendum 1, February 2022.	§ 250.750(c).
17	
(91) *API Specification 17D, Specification for Subsea Wellhead and Tree Equipment,* Third Edition, October 2021, API Monogram Program Effective Date: October 2022, Errata 1, December 2021, Addendum 1, December 2022.	§ 250.730.
(92) *API RP 17H, Remotely Operated Tools and Interfaces on Subsea Production Systems,* Second Edition, June 2013; Errata, January 2014.	§ 250.734(a).
(93) *API Spec 17J, Spec. for Unbonded Flexible Pipe,* Fourth Edition, May 2014, Effective Date: November 2014, Errata 1 September 2016, Errata 2 May 2017, Addendum 1 October 2017, reaffirmed March 2021.	§§ 250.852(e), 250.1002(b), and 250.1007(a).
20	
(94) *API Spec 20E—Alloy and Carbon Steel Bolting for Use in the Petroleum and Natural Gas Industries,* Second Edition, February 2017, Effective Date: August 2017, Addendum 1 September 2018, Addendum 2 March 2019, Errata 1 November 2021, Errata 2 May 2022.	§ 250.730(a).
(95) *API Spec 20F—Corrosion-resistant Bolting for Use in the Petroleum and Natural Gas Industries;* Second Edition, May 2018, API Monogram Program Effective Date: November 1, 2018, Errata 1 October 2020, Addendum 1 November 2021 (API Monogram Program Effective Date: May 1, 2022).	§ 250.730(a).
53	
(96) *API Standard 53, Blowout Prevention Equipment Systems for Drilling Wells,* Fifth Edition, December 2018.	§§ 250.730, 250.734, 250.735, 250.736, 250.737, and 250.739.
65	
(97) *API RP 65, Recommended Practice for Cementing Shallow Water Flow Zones in Deepwater Wells,* First Edition, September 2002.	§ 250.415.
(98) *API Standard 65—Part 2, Isolating Potential Flow Zones During Well Construction;* Second Edition, December 2010.	§§ 250.415(f) and 250.420(a).
75	
(99) *API RP 75, Recommended Practice for Development of a Safety and Environmental Management Program for Offshore Operations and Facilities,* Third Edition, May 2004, reaffirmed May 2008.	§§ 250.1900, 250.1902, 250.1903, 250.1909, 250.1920.
90	
(100) *API RP 90, Annular Casing Pressure Management for Offshore Wells,* First Edition, August 2006	§ 250.519.
500s	
(101) *API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities Classified as Class I, Division 1 and Division 2,* Third Edition, December 2012; Errata January 2014.	§§ 250.114(a), 250.459, 250.842(a), 250.862(a) and (e), 250.872(a), 250.1628(b) and (d), and 250.1629(b).
(102) *API RP 505, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities Classified as Class I, Zone 0, Zone 1, and Zone 2,* First Edition, November 1997; reaffirmed, August 2013.	§§ 250.114(a), 250.459, 250.842(a), 250.862(a) and (e), 250.872(a), 250.1628(b) and (d), and 250.1629(b).
(103) *API 510, Pressure Vessel Inspection Code: In-Service Inspection, Rating, Repair, and Alteration,* Tenth Edition, May 2014; Addendum 1, May 2017.	§§ 250.851(a) and 250.1629(b).
(104) *API 570, Piping Inspection Code: In-service Inspection, Rating, Repair, and Alteration of Piping Systems,* Fourth Edition, February 2016; Addendum 1, May 2017.	§ 250.841(b).
2000s	
(105) *API Standard 2555, Method for Liquid Calibration of Tanks,* First Edition, September 1966; reaffirmed May 2014.	§ 250.1202(a).
(106) *API RP 2556, Recommended Practice for Correcting Gauge Tables for Incrustation,* Second Edition, August 1993; reaffirmed November 2013.	§ 250.1202.

API standard title	Incorporated by reference at:
Q	
(107) *API Spec Q1, Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry,* Ninth Edition, June 2013; Errata, February 2014; Errata 2, March 2014; Addendum 1, June 2016.	§§ 250.730 and 250.801(b) and (c).
API Bulletins	
(108) *API Bulletin 2INT–DG, Interim Guidance for Design of Offshore Structures for Hurricane Conditions,* May 2007.	§ 250.901.
(109) *API Bulletin 2INT–EX, Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions,* May 2007.	§ 250.901.
(110) *API Bulletin 92L, Drilling Ahead Safely with Lost Circulation in the Gulf of Mexico,* First Edition, August 2015.	§ 250.427(b).

(f) * * *

(3) ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels; Division 1, 2021 Edition, July 1, 2021, incorporated by reference at §§ 250.851(a) and 250.1629(b).

* * * * *

(j) * * *

(1) ISO/IEC (International Electrotechnical Commission) 17011, Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second Edition 2017–11; incorporated by reference at §§ 250.1900, 250.1903, 250.1904, and 250.1922.

* * * * *

(l) Gas Processors Association (GPA), 6526 East 60th Street, Tulsa, Oklahoma 74145. Tel: (918) 493–3872. Fax: (918) 493–3875. Email *gpa@gasprocessors.com.*

(1) GPA Standard 2198–16—Selection, Preparation, Validation, Care and Storage of Natural Gas and Natural Gas Liquids Reference Standard Blends; Adopted as a Standard 1998; Revised August 2016; Reaffirmed 2017; incorporated by reference at § 250.1203(b).

(2) GPA Standard 2261–20—Analysis for Natural Gas and Similar Gaseous Mixtures by Gas Chromatography; Adopted as a standard 1964; Revised 2020; incorporated by reference at § 250.1203(b).

(3) GPA Standard 2286–14—Method for the Extended Analysis of Natural Gas and Similar Gaseous Mixtures by Temperature Program Gas Chromatography; Adopted as a standard 1995; Revised 2014; incorporated by reference at § 250.1203(b).

■ 4. Amend § 250.470 by revising the introductory text of paragraph (g) to read as follows:

§ 250.470 What additional information must I submit with my APD for Arctic OCS exploratory drilling operations?

* * * * *

(g) Where it does not conflict with other requirements of this subpart, and except as provided in paragraphs (g)(1) through (11) of this section, you must comply with the requirements of ANSI/API RP 2N, Third Edition ''Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions'' (incorporated by reference as specified in § 250.198), and provide a detailed description of how you will utilize the best practices included in ANSI/API RP 2N during your exploratory drilling operations. You are not required to incorporate the following sections of ANSI/API RP 2N into your drilling operations:

* * * * *

■ 5. Amend § 250.730 by revising paragraph (a)(2) to read as follows:

§ 250.730 What are the general requirements for BOP systems and system components?

(a) * * *

(2) The provisions of the following industry standards (all incorporated by reference in § 250.198) that apply to BOP systems:

(i) API Specification 6A;
(ii) API Spec 16A;
(iii) API Spec 16C;
(iv) API Spec 16D;
(v) API Specification 17D;
(vi) API Spec 20E; and
(vii) API Spec 20F.

* * * * *

■ 6. Amend § 250.733 by revising the introductory text of paragraph (b)(2) to read as follows:

§ 250.733 What are the requirements for a surface BOP stack?

* * * * *

(b) * * *

(2) For risers installed after July 28, 2016, use a dual bore riser configuration before drilling or operating in any hole section or interval where hydrocarbons are, or may be, exposed to the well. The dual bore riser must meet the design requirements of API Standard 2RD (as incorporated by reference in § 250.198), including appropriate design for the maximum anticipated operating and environmental conditions.

* * * * *

■ 7. Amend § 250.750 by adding paragraph (c) to read as follows:

§ 250.750 What are the coiled tubing requirements?

* * * * *

(c) You must follow API RP 16ST (as incorporated by reference in § 250.198).

■ 8. Amend § 250.800 by revising paragraph (c)(2) to read as follows:

§ 250.800 General.

* * * * *

(c) * * *

(2) Meet the production riser standards of API Standard 2RD (incorporated by reference as specified in § 250.198), provided that you may not install single bore production risers from floating production facilities;

* * * * *

■ 9. Amend § 250.802 by revising paragraphs (a) and (c)(1)(i) to read as follows:

§ 250.802 Requirements for SPPE.

(a) All SSVs, BSDVs, USVs, and GLSDVs and their actuators must meet all of the specifications contained in API Specification 6A and API Standard 6AV1 (both incorporated by reference in § 250.198).

* * * * *

(c) * * *

(1) * * *

(i) The device design must be tested by an independent test agency according to the test requirements in the appropriate standard for that device (API Standard 6AV1 or ANSI/API Spec 14A), as identified in paragraphs (a) and (b) of this section.

* * * * *

■ 10. Amend § 250.803 by revising paragraph (a) to read as follows:

§ 250.803 What SPPE failure reporting procedures must I follow?

(a) You must follow the failure reporting requirements contained in section 10.20.7.4 of API Specification 6A for SSVs, BSDVs, GLSDVs and USVs. You must follow the failure reporting requirements contained in section 7.10 of ANSI/API Spec 14A and Annex F of API RP 14B for SSSVs (all incorporated by reference in § 250.198). Within 30 days after the discovery and identification of the failure, you must provide a written notice of equipment failure to the manufacturer of such equipment and to BSEE through the Chief, Office of Offshore Regulatory Programs, unless BSEE has designated a third party as provided in paragraph (d) of this section. A failure is any condition that prevents the equipment from meeting the functional specification or purpose.

* * * * *

■ 11. Amend § 250.833 by revising the introductory paragraph to read as follows:

§ 250.833 Specification for underwater safety valves (USVs).

All USVs, including those designated as primary or secondary, and any alternate isolation valve (AIV) that acts as a USV, if applicable, and their actuators, must conform to the requirements specified in §§ 250.801 through 250.803. A production master or wing valve may qualify as a USV under API Specification 6A and API Standard 6AV1 (both incorporated by reference in § 250.198).

* * * * *

§§ 250.851, 250.873 and 250.874 [Amended]

■ 12. In the table below, removing the text indicated in the left column wherever it appears in the sections, and adding the text indicated in the right column:

Remove	Add
ANSI/ASME Boiler and Pressure Vessel Code.	ASME Boiler and Pressure Vessel Code.
ANSI/API Spec. 6A ...	API Specification 6A.
API Spec. 6AV1	API Standard 6AV1.

■ 13. Amend § 250.901 by:

■ a. Revising paragraph (a)(10);

■ b. Adding paragraphs (a)(25) through (29);

■ c. Revising paragraph (d)(19); and

■ d. Adding paragraphs (d)(24) through (29).

The revisions and additions read as follows:

§ 250.901 What industry standards must your platform meet?

(a) * * *

(10) API Standard 2RD, Design of Risers for Floating Production Systems (FPSs) and Tension-Leg Platforms (TLPs) (as incorporated by reference in § 250.198);

* * * * *

(25) API RP 2FSIM (as incorporated by reference in § 250.198);

(26) API RP 2GEO (as incorporated by reference in § 250.198);

(27) API RP 2MET (as incorporated by reference in § 250.198);

(28) API RP 2MIM (as incorporated by reference in § 250.198); and

(29) API RP 2RIM (as incorporated by reference in § 250.198).

* * * * *

(d) * * *

Industry standard	Applicable to . . .
* * * * * * *	
(19) API Standard 2RD, Design of Risers for Floating Production Systems (FPSs) and Tension-Leg Platforms (TLPs);	
* * * * * * *	
(24) API RP 2FSIM, Floating Systems Integrity Management.	
(25) API RP 2GEO, Geotechnical and Foundation Design Considerations.	
(26) API RP 2MET, Derivation of Metocean Design and Operating Conditions.	
(27) API RP 2SIM, Structural Integrity Management of Fixed Offshore Structures.	
(28) API RP 2MIM, Mooring Integrity Management.	
(29) API RP 2RIM, Integrity Management of Risers from Floating Production Systems.	

■ 14. Amend § 250.1002 by revising paragraph (b)(1), (2), and (5) to read as follows:

§ 250.1002 Design requirements for DOI pipelines.

* * * * *

(b)(1) Pipeline valves shall meet the minimum design requirements of API Specification 6A (as incorporated by reference in § 250.198), API Specification 6D (as incorporated by reference in § 250.198), or the equivalent. A valve may not be used under operating conditions that exceed the applicable pressure-temperature ratings contained in those standards.

(2) Pipeline flanges and flange accessories shall meet the minimum design requirements of ANSI/ASME B16.5, API Specification 6A, or the equivalent (as incorporated by reference in § 250.198). Each flange assembly must be able to withstand the maximum pressure at which the pipeline is to be operated and to maintain its physical and chemical properties at any temperature to which it is anticipated that it might be subjected in service.

* * * * *

(5) You must design pipeline risers for tension leg platforms and other floating platforms according to the design standards of API Standard 2RD (as incorporated by reference in § 250.198).

* * * * *

■ 15. Amend § 250.1202 by:

■ a. Revising paragraphs (a)(2) and (3), (d)(5), (f)(1) and (2);

■ b. Adding paragraph (h)(5); and

■ c. Revising paragraph (l)(4).

The revisions and additions read as follows:

§ 250.1202 Liquid hydrocarbon measurement.

(a) * * *

(2) Use measurement equipment and procedures that will accurately measure the liquid hydrocarbons produced from a lease or unit to comply with the following additional API MPMS industry standards, API RP, and GPA standard:

(i) API MPMS, Chapter 2, Section 2A (incorporated by reference as specified in § 250.198);

(ii) API MPMS, Chapter 2, Section 2B (incorporated by reference as specified in § 250.198);

(iii) API MPMS, Chapter 3, Section 1B (incorporated by reference as specified in § 250.198);

(iv) API MPMS, Chapter 4, Section 1 (incorporated by reference as specified in § 250.198);

(v) API MPMS, Chapter 4, Section 4 (incorporated by reference as specified in § 250.198);

(vi) API MPMS, Chapter 4, Section 6 (incorporated by reference as specified in § 250.198);

(vii) API MPMS, Chapter 4.8 (incorporated by reference as specified in § 250.198);

(viii) API MPMS, Chapter 4, Section 9, Part 2 (incorporated by reference as specified in § 250.198);

(ix) API MPMS, Chapter 5, Section 1 (incorporated by reference as specified in § 250.198);

(x) API MPMS, Chapter 5, Section 2 (incorporated by reference as specified in § 250.198);

(xi) API MPMS, Chapter 5, Section 3 (incorporated by reference as specified in § 250.198);

(xii) API MPMS, Chapter 5, Section 4 (incorporated by reference as specified in § 250.198);

(xiii) API MPMS, Chapter 5, Section 5 (incorporated by reference as specified in § 250.198);

(xiv) API MPMS, Chapter 5, Section 6 (incorporated by reference as specified § 250.198);

(xv) API MPMS, Chapter 5.8 (incorporated by reference as specified in § 250.198);

(xvi) API MPMS, Chapter 6.1 (incorporated by reference as specified in § 250.198);

(xvii) API MPMS, Chapter 6, Section 6 (incorporated by reference as specified in § 250.198);

(xviii) API MPMS, Chapter 6, Section 7 (incorporated by reference as specified in § 250.198);

(xix) API MPMS, Chapter 7.1 (incorporated by reference as specified in § 250.198);

(xx) API MPMS, Chapter 7.3 (incorporated by reference as specified in § 250.198);

(xxi) API MPMS, Chapter 8.1 (incorporated by reference as specified in § 250.198);

(xxii) API MPMS, Chapter 8.2 (incorporated by reference as specified in § 250.198);

(xxiii) API MPMS, Chapter 8.3 (incorporated by reference as specified in § 250.198);

(xxiv) API MPMS, Chapter 9.1 (incorporated by reference as specified in § 250.198);

(xxv) API MPMS, Chapter 9.2 (incorporated by reference as specified in § 250.198);

(xxvi) API MPMS, Chapter 9.4 (incorporated by reference as specified in § 250.198);

(xxvii) API MPMS, Chapter 10, Section 1 (incorporated by reference as specified in § 250.198);

(xxviii) API MPMS, Chapter 10.2 (incorporated by reference as specified in § 250.198);

(xxix) API MPMS, Chapter 10.3 (incorporated by reference as specified in § 250.198);

(xxx) API MPMS, Chapter 10.4 (incorporated by reference as specified in § 250.198);

(xxxi) API MPMS, Chapter 10.9 (incorporated by reference as specified in § 250.198);

(xxxii) API MPMS, Chapter 11.1 (incorporated by reference as specified in § 250.198);

(xxxiii) API MPMS Chapter 12, Section 2, Part 4 (incorporated by reference as specified in § 250.198);

(xxxiv) API MPMS Chapter 12.2 (incorporated by reference as specified in § 250.198);

(xxxv) API MPMS Chapter 20, Section 1 (incorporated by reference as specified in § 250.198);

(xxxvi) API MPMS, Chapter 21, Section 2 (incorporated by reference as specified in § 250.198);

(xxxvii) API MPMS, Chapter 21, Addendum to Section 2 (incorporated by reference as specified in § 250.198);

(xxxviii) API Standard 2555 (incorporated by reference as specified in § 250.198);

(xxxix) API RP 2556 (incorporated by reference as specified in § 250.198);

(xl) API MPMS Chapter 2.2E, Part 1 (incorporated by reference as specified in § 250.198);

(xli) API MPMS Chapter 2.2F, Part 2 (incorporated by reference as specified in § 250.198);

(xlii) API MPMS Chapter 3.1A (incorporated by reference as specified in § 250.198);

(xliii) API MPMS Chapter 4, Section 2 (incorporated by reference as specified in § 250.198);

(xliv) API MPMS Chapter 4.5 (incorporated by reference as specified in § 250.198); and

(xlv) API MPMS Chapter 4, Section 7 (incorporated by reference as specified in § 250.198).

(3) Use procedures and correction factors according to the applicable chapters of the API MPMS or RP as incorporated by reference in § 250.198, including the following additional editions:

(i) API MPMS, Chapter 4.8 (incorporated by reference as specified in § 250.198);

(ii) API MPMS, Chapter 5, Section 6 (incorporated by reference as specified in § 250.198);

(iii) API MPMS, Chapter 5.8 (incorporated by reference as specified in § 250.198);

(iv) API MPMS Chapter 11, Section 1 (incorporated by reference as specified in § 250.198);

(v) API MPMS Chapter 11.2.2 (incorporated by reference as specified in § 250.198);

(vi) API MPMS Chapter 11, Section 2, Part 2 (incorporated by reference as specified in § 250.198);

(vii) API MPMS Chapter 12, Section 2, Part 4 (incorporated by reference as specified in § 250.198);

* * * * *

(d) * * *

(5) Use procedures and proving or meter factors according to API MPMS Chapter 4, Section 1 (incorporated by reference as specified in § 250.198).

* * * * *

(f) * * *

(1) Calibrate mechanical-displacement provers and tank provers at least once every 5 years according to the following API MPMS Sections:

(i) API MPMS, Chapter 4, Section 4 (incorporated by reference as specified in § 250.198);

(ii) API MPMS, Chapter 4.8 (incorporated by reference as specified in § 250.198);

(iii) API MPMS Chapter 12, Section 2, Part 4 (incorporated by reference as specified in § 250.198);

(2) Submit a copy of each calibration report to the Regional Supervisor within 15 days after the calibration.

* * * * *

(h) * * *

(5) Use procedures and proving or meter factors according to API MPMS Chapter 4, Section 6 (incorporated by reference as specified in § 250.198).

* * * * *

(l) * * *

(4) Obtain the volume and other measurement parameters by using corrections factors and procedures in the following API MPMS, as incorporated by reference in 30 CFR 250.198: API MPMS Chapter 2, Section 2A, API MPMS Chapter 2, Section 2B, API MPMS Chapter 3, Section 1B, API MPMS Chapter 11, Section 1.

■ 16. Amend § 250.1203 by revising paragraph (b)(2) to read as follows:

§ 250.1203 Gas measurement.

* * * * *

(b) * * *

(2) Design, install, use, maintain, and test measurement equipment and procedures to ensure accurate and verifiable measurement. You must follow the recommendations in the following API MPMS, RP, GPA, and AGA as incorporated by reference in § 250.198:

(i) AGA Report No. 7 (incorporated by reference as specified in § 250.198);

(ii) AGA Report No. 8, Part 1 (incorporated by reference as specified in § 250.198);

(iii) AGA Report No. 8, Part 2 (incorporated by reference as specified in § 250.198);

(iv) AGA Report No. 9 (incorporated by reference as specified in § 250.198);

(v) AGA Report No. 10 (incorporated by reference as specified in § 250.198);

(vi) AGA Report No. 11 (incorporated by reference as specified in § 250.198);

(vii) GPA Standard 2198–16 (incorporated by reference as specified in § 250.198);

(viii) GPA Standard 2261–20 (incorporated by reference as specified in § 250.198);

(ix) GPA Standard 2286–14 (incorporated by reference as specified in § 250.198);

(x) API MPMS Chapter 14.1 (incorporated by reference as specified in § 250.198);

(xi) API MPMS Chapter 14.3.1 (incorporated by reference as specified in § 250.198);

(xii) API MPMS Chapter 14.3.2 (incorporated by reference as specified in § 250.198);

(xiii) API MPMS Chapter 14.3.3 (incorporated by reference as specified in § 250.198);

(xiv) API MPMS Chapter 14.5/GPA Standard 2172–09 (incorporated by reference as specified in § 250.198);

(xv) API MPMS Chapter 14, Section 8 (incorporated by reference as specified in § 250.198);

(xvi) API MPMS Chapter 20, Section 1 (incorporated by reference as specified in § 250.198);

(xvii) API MPMS Chapter 20.3 (incorporated by reference as specified in § 250.198); and

(xviii) API MPMS Chapter 20.5 (incorporated by reference as specified in § 250.198).

(xix) API MPMS Chapter 21, Section 1 (incorporated by reference as specified in § 250.198).

* * * * *

§ 250.1629 [Amended]

■ 17. Amend § 250.1629, by removing the text ''ANSI/ASME Boiler and Pressure Vessel Code'' wherever it appears, and adding in its place, the text ''ASME Boiler and Pressure Vessel Code''.

[FR Doc. 2023–25734 Filed 11–29–23; 8:45 am]

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Part IV

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 North American Wolverine; Final and Interim Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2023–0216; FF09E21000 FXES11110900000 245]

RIN 1018–BH27

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for North American Wolverine

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule and interim rule with request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine threatened species status under the Endangered Species Act of 1973 (Act), as amended, for the distinct population segment (DPS) of the North American wolverine (*Gulo gulo luscus*) occurring in the contiguous United States. This rule adds the contiguous U.S. DPS of the North American wolverine to the Federal List of Endangered and Threatened Wildlife. We are also issuing an interim rule under the authority of section 4(d) of the Act (an ''interim 4(d) rule'') that provides the prohibitions, and exceptions to those prohibitions, necessary and advisable for the conservation of the contiguous U.S. DPS of the North American wolverine.

DATES:

Effective date: This rule is effective January 2, 2024.

Comments due: Comments on the interim 4(d) rule must be received or postmarked by January 29, 2024.

ADDRESSES:

Written comments on the interim 4(d) rule: You may submit comments on the interim 4(d) rule by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R6–ES–2023–0216, 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, click on the Rules box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* U.S. mail: Public Comments Processing, Attn: FWS–R6–ES–2023–0216; U.S. Fish and Wildlife Service; MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Public Comments Solicited on the Interim 4(d) Rule, below, for more information).

Availability of supporting materials: This document is available on the internet at *https://www.regulations.gov* and at *https://ecos.fws.gov/ecp/species/5123.* Supporting materials we used in preparing this rule, including the 2018 species status assessment (SSA) report and the 2023 addendum to the SSA report, are available on the Service's website at *https://ecos.fws.gov/ecp/species/5123,* at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2023–0216, or both.

FOR FURTHER INFORMATION CONTACT: Jodi Bush, U.S. Fish and Wildlife Service, Pacific Region, 911 NE 11th Ave., Portland, OR 97232; telephone: (503) 231–6131. 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:

Executive Summary

Final Rule To List the Contiguous U.S. DPS of the North American Wolverine

Why we need to publish a rule. The Act (16 U.S.C. 1531 *et seq.*) defines ''species'' as any subspecies of fish or wildlife or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife which interbreeds when mature. 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 DPS of the North American wolverine occurring in the contiguous United States (the ''contiguous U.S. DPS'') meets the Act's definition of a threatened species; therefore, we are listing 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. This document is both (1) a final rule listing the contiguous U.S. DPS of the North American wolverine as a threatened species under the Act; and (2) an interim rule issued under the authority of section 4(d) of the Act (an ''interim 4(d) rule'') providing the prohibitions, and exceptions to those prohibitions, that are necessary and advisable to provide for the conservation of the contiguous U.S. DPS of the North American wolverine.

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 contiguous U.S. DPS of the North American wolverine is a threatened species due primarily to the ongoing and increasing impacts of climate change and associated habitat degradation and fragmentation.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. We have not yet obtained the necessary economic information needed to develop a proposed critical habitat designation for the contiguous U.S. DPS of the North American wolverine. Therefore, we find that designation of critical habitat for the DPS is currently not determinable.

Interim 4(d) Rule

The need for the regulatory action and how the action will meet that need. Consistent with section 4(d) of the Act, this interim 4(d) rule provides measures that are tailored to our current understanding of the conservation needs of the North American wolverine.

Under section 4(d) of the Act, the Secretary of the Interior has discretion to issue such regulations as she deems necessary and advisable to provide for the conservation of the species. The Secretary also has the discretion to prohibit by regulation with respect to a threatened species, any act prohibited by section 9(a)(1) of the Act.

Summary of the major provisions of the regulatory action. This interim 4(d) rule will provide for the conservation of the contiguous U.S. DPS of the North American wolverine by prohibiting the following activities, unless they fall

within the specific identified 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.

The interim 4(d) rule will also provide for the conservation of the species by allowing exceptions to the general prohibitions against ''take'' of the species in support of conservation actions and otherwise lawful activities that could take wolverines but at minimal levels not likely to have a negative impact on the species' conservation. The exceptions include take due to scientific research conducted on wolverines by a Federal or Tribal biologist in the course of their official duties, incidental take resulting from forest management activities for the purposes of reducing the risk or severity of wildfire, and incidental take resulting from legal trapping conducted consistent with State and Tribal trapping rules or guidelines that contain steps to minimize the potential for capture of wolverine.

Supporting Documents

A team prepared a species status assessment (SSA) for the North American wolverine (*Gulo gulo luscus*) (Service 2018, entire) (hereafter referred to as the wolverine SSA report). The SSA team was composed of U.S. Fish and Wildlife Service (Service) biologists, who consulted with other species experts. The wolverine SSA report represented a compilation of the best scientific and commercial data available (known at that time) concerning the status of the North American wolverine, including the impacts of past, present, and future factors (both negative and beneficial) affecting the wolverine. The wolverine SSA report underwent independent peer review by scientists with experience with mesocarnivores and their conservation and management, genetics, population modeling, and climate change.

More recently, the Service prepared an SSA addendum for the North American wolverine (*Gulo gulo luscus*) (Service 2023, entire) (hereafter referred to as the wolverine SSA report addendum). The wolverine SSA report addendum contains a synthesis of relevant new information that has become available since the 2018 wolverine SSA report. The wolverine SSA report addendum underwent independent peer review by scientists with experience with mesocarnivores and their conservation and management, genetics, population modeling, and climate change. The wolverine SSA report addendum also underwent technical review by State, Federal, and Tribal biologists.

The wolverine SSA report, the wolverine SSA report addendum, and other materials relating to this rulemaking can be found at the Service's website at *https://ecos.fws.gov/ecp/species/5123,* and at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2023–0216.

Previous Federal Actions

On February 4, 2013, we published in the **Federal Register** (78 FR 7864) a proposed rule to list the DPS of the North American wolverine occurring in the contiguous United States as a threatened species under the Act, with a proposed rule under section 4(d) of the Act that outlined the prohibitions, and exceptions to those prohibitions, necessary and advisable for the conservation of the wolverine. Please refer to that February 4, 2013, proposed rule (78 FR 7864) for a detailed description of previous Federal actions concerning the wolverine prior to 2013. We published a separate proposed rule in the **Federal Register** on February 4, 2013 (78 FR 7890), to establish a nonessential experimental population (NEP) area for the North American wolverine in the Southern Rocky Mountains of Colorado, northern New Mexico, and southern Wyoming. On October 31, 2013, we reopened the comment period on the proposed listing rule for an additional 30 days (78 FR 65248).

Following publication of the 2013 proposed rules, there was scientific disagreement and debate about the interpretation of the habitat requirements for wolverines and available climate change information used to determine the extent of threats to the contiguous U.S. DPS of the North American wolverine. Based on this substantial disagreement regarding the sufficiency or accuracy of the available data relevant to the proposed listing, on February 5, 2014, we announced in the **Federal Register** (79 FR 6874) a 6-month extension of the final determination of whether to list the contiguous U.S. DPS of North American wolverine as a threatened species under the Act. That document reopened the comment period on the February 4, 2013, proposed listing rule for an additional 90 days.

On August 13, 2014, we published in the **Federal Register** (79 FR 47522) a document withdrawing both proposed rules published on February 4, 2013: (1) the proposed rule to list the contiguous U.S. DPS of the North American wolverine as a threatened species under the Act, including the provisions proposed under section 4(d) of the Act; and (2) the proposed NEP designation under section 10(j) of the Act for the North American wolverine in the Southern Rocky Mountains of Colorado, northern New Mexico, and southern Wyoming. These withdrawals were based on our conclusion that the factors affecting the DPS as identified in the listing proposed rule were not as significant as believed at the time of that proposed rule's publication in 2013.

In October 2014, three complaints were filed in the District Court for the District of Montana by Defenders of Wildlife, WildEarth Guardians, Center for Biological Diversity, and other organizations challenging the withdrawal of the February 4, 2013, proposed rule to list the contiguous U.S. DPS of the North American wolverine. Numerous parties intervened in the litigation. These three cases were consolidated, and on April 4, 2016, the court issued a decision. The court granted plaintiffs' motion for summary judgment with respect to the Service's determination regarding (1) the threat posed to the wolverine by the effects of climate change at the reproductive denning scale, (2) the threat posed to the wolverine by small population size and lack of genetic diversity, and (3) the application of the significant portion of the range policy to the wolverine. As a result of the court order, the August 13, 2014, withdrawal (79 FR 47522) of the February 4, 2013, proposed listing rule was vacated and remanded to the Service for further consideration consistent with the order.

In effect, the court's action returned the process to the proposed rule stage, and the status of the contiguous U.S. DPS of the North American wolverine under the Act reverted to that of a proposed species for the purposes of consultation under section 7 of the Act. On October 18, 2016, we published in the **Federal Register** (81 FR 71670) a document reopening the comment period on the February 4, 2013, proposed rule to list the DPS of the North American wolverine occurring in the contiguous United States as threatened under the Act (78 FR 7864). The October 18, 2016, publication also requested new information and announced that we were initiating a new and comprehensive status review of the North American wolverine, to determine whether the species meets the definition of an endangered or threatened species under the Act, or

whether the species is not warranted for listing. Both new and updated information and analyses presented in the wolverine 2018 SSA report, along with public comments, prompted us to reevaluate our previous assessment of the DPS (presented in our 2013 proposed listing rule (78 FR 7864), which in turn relied on the DPS analysis completed in our 2010 12-month finding (75 FR 78030)) with respect to the North American wolverine in the contiguous United States.

On October 13, 2020, we published in the **Federal Register** (85 FR 64618) another document withdrawing the February 4, 2013, proposed rule to list the DPS of the North American wolverine occurring in the contiguous United States as threatened under the Act. Our 2020 withdrawal decision was based on our conclusion that the factors affecting the North American wolverine occurring in the contiguous United States as identified in the 2013 proposed listing rule were not as significant as believed at the time of the proposed rule's publication in 2013. We also found that the North American wolverines occurring in the contiguous United States did not qualify as a DPS.

The Center for Biological Diversity and WildEarth Guardians filed lawsuits in the District Court for the District of Montana challenging the Service's 2020 decision to withdraw the February 4, 2013, proposal to list the contiguous U.S. DPS of the North American wolverine. The cases were consolidated, and the State of Idaho's motion to intervene was granted. On February 4, 2022, the Service filed a motion asking the court to voluntarily return (remand) the 2020 withdrawal decision to the Service to allow the Service to re-examine the decision in light of the intervening decision in *Center for Biological Diversity* v. *Haaland,* 998 F.3d 1061 (9th Cir. 2021) (''Pacific Walrus Decision'') and to reevaluate the decision in light of new scientific information that had become available since the completion of the 2018 SSA. The Service also requested that the 2020 withdrawal decision remain in effect pending that reevaluation. On May 26, 2022, the court granted the Service's request for a voluntary remand of the 2020 withdrawal decision, but the court decided to vacate the withdrawal decision (*Ctr. for Biological Diversity* v. *Haaland,* No. CV 20–181–M–DWM (D. Mont. May 26, 2022)).

The court's May 26, 2022, action returned the listing process for the North American wolverine to the proposed rule stage. On November 23, 2022, the Service published in the **Federal Register** (87 FR 71557) a document soliciting new information on the North American wolverine and notifying the public that the February 4, 2013, proposed rule to list the contiguous U.S. DPS of the North American wolverine as threatened under the Act (78 FR 7864) had been reinstated. As of May 26, 2022, for purposes of consultation under section 7 of the Act, the North American wolverine was again a species proposed for listing and subject to conferencing requirements.

The Service then completed the wolverine SSA report addendum (Service 2023, entire), which contains a synthesis of all relevant new information that has become available since the 2018 wolverine SSA report to inform this final listing rule and the associated interim 4(d) rule.

Peer Review

Our assessment of the status of the North American wolverine contained in this document is supported by information in both the 2018 SSA report (Service 2018, entire) and the 2023 wolverine SSA report addendum (Service 2023, entire). 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 actions under the Act, we solicited independent scientific review of the information contained in the 2018 wolverine SSA report. We sent the SSA report to four independent peer reviewers and received four responses; we incorporated the results of that review into the SSA report, as appropriate. More recently, we solicited independent scientific review of the 2023 wolverine SSA report addendum. We sent the wolverine SSA report addendum to six peer reviewers and received three responses; we incorporated the results of the peer review into the wolverine SSA report addendum, as appropriate. The peer reviews on the wolverine SSA report and the wolverine SSA report addendum can be found at *https://www.regulations.gov.*

Summary of Changes

Since the publication of the February 4, 2013, proposed listing rule (78 FR 7864), the development of the 2018 SSA report (Service 2018, entire), and the publication of the October 13, 2020, withdrawal document (85 FR 64618), a substantial number of new studies have become available, refining our understanding of wolverine biology and threats affecting North American wolverines in the contiguous United States. We incorporated this new information into the 2023 wolverine SSA report addendum. We summarize the information most salient to our determination in this final rule below. We also discuss these changes where appropriate in the remainder of the document to provide further detail and context.

Ecological Requirements

The snow model used in the climate change analysis in the 2018 SSA report and October 13, 2020, withdrawal document (85 FR 64618) projected snow loss out to year 2050 in only two modeling domains (Glacier National Park and the central Rocky Mountains) (Service 2018, p. 88). Results indicated a decline in spring snow in these areas due to climate change was likely, but we were unable to extrapolate those projections across the remainder of the North American wolverine's breeding range in the contiguous United States. Persistent spring snow (greater than or equal to 1 meter on May 1; see *Climate Change,* below) was not identified as an ecological requirement for wolverines, and we assumed that if snow was necessary for denning, there would be enough spring snowpack in the future to fulfill denning needs.

Our updated climate analysis reported in the 2023 wolverine SSA report addendum projects snow loss out to 2100 across five modeling domains that cover a much larger extent of the breeding range in the contiguous United States when compared to the 2018 SSA report. In our 2023 wolverine SSA report addendum, we found declines in spring snow due to climate change are likely across the North American wolverine's range and predicted losses will be greater in 2100 than in 2050. In general, when compared to historical amounts of snow cover, nearly every area modeled (except for the Mid-Rockies) sees a decrease in snow cover and that decrease becomes larger over time. In the Mid-Rockies, snow cover increases in the short term, but as with the other areas, it decreases over time.

New research indicates that areas characterized by persistent spring snow are likely important for wolverine survival (*e.g.,* caching food) in addition to denning and reproduction. One new study reported wolverines cache food year-round, indicating that warmer temperatures could impact the ability of wolverines to store food resources by decreasing the shelf-life (usability) of cached food, and increasing competition from pilferers that benefit from a warmer climate (van der Veen et al. 2020, p. 1). Another study found evidence to support a functional

relationship between North American wolverines and persistent spring snow that could be explained by the distribution of food, disturbance, or mortality risk (Kortello et al. 2019, p. 8).

Connectivity With Canada

Connectivity with Canada is essential to the long-term viability of North American wolverines in the contiguous United States (Cegelski et al. 2006, p. 209). In the 2018 SSA report and October 13, 2020, withdrawal document (85 FR 64618), we assumed that wolverines could move freely between Canada and the United States (Service 2018, p. 104). We also concluded that trapping of wolverines did not represent a barrier to wolverine movement and dispersal along the international border (Service 2018, p. 69). Additionally, we concluded that major highways did not represent a barrier to wolverine movement (Service 2018, p. 60).

In the 2023 wolverine SSA report addendum, we affirm that connectivity with Canada is essential to the long-term viability of North American wolverines in the lower 48 States. However, our understanding of the ability of wolverines to move between Canada and the United States in the Rocky Mountains has changed. New research found an estimated 41 percent decline in the wolverine population from 2011–2020 in a portion (7,583,417 acres (ac) (30,689 square kilometers (km^2))) of the southern Canadian Rockies, Purcell Mountains, and Selkirk Mountains important for wolverine connectivity with the United States; this decline could be attributed to one or more of the following causes: trapping, backcountry recreation, human development, and food availability (Barrueto et al. 2022, p. 4). In addition, new transboundary genetic research indicates the Trans-Canada Highway in southern British Columbia is impeding female dispersal from Canada to the United States, thereby limiting gene flow and the ability of dispersing wolverines to supplement the contiguous U.S. DPS (Sawaya et al. 2023, pp. 12, 17).

Genetic Diversity and Adaptive Capacity

In the October 13, 2020, withdrawal document (85 FR 64618), we found there was no available information to indicate that the current abundance of the North American wolverine across its range in the contiguous United States was at a level that was causing inbreeding depression or loss of genetic variation that would affect its ability to adapt to changing conditions.

New transboundary genetic research shows a sharp decline in genetic diversity and increasing population fragmentation at the southern extent of the North American wolverine's range in western North America (Sawaya et al. 2023, p. 17). As a result, there is potential for inbreeding given the relatively small population sizes and low levels of genetic diversity of wolverines in the contiguous United States, especially in the Cascade Mountains of Washington and southern British Columbia (Sawaya 2023, pers. comm.); however, inbreeding depression has not been observed. New analysis of the North American wolverine's adaptive capacity shows that their specialized habitat associations, low genetic diversity and population size, narrow ecological niche, low tolerance for human disturbance, and slow reproductive rate all contribute to the wolverine's relative difficulty in adapting in-place to future environmental change (Service 2023, p. 66).

Roads and Development

We analyzed the effects of roads and development (human disturbance) to North American wolverines in the 2018 SSA report (Service 2018, p. 62) and determined in our October 13, 2020, withdrawal document (85 FR 64618) that impacts to wolverines are small and narrow in scope and scale. We did not consider roads and development to be an impediment to wolverine movement and gene flow.

New habitat and landscape genetic research indicates multi-lane roads and human development in valley bottoms between core habitats may limit dispersal and population connectivity to some extent, especially for female wolverines. Connectivity among wolverine habitats appears to be particularly sensitive to housing developments (Balkenhol et al. 2020, p. 797). Also, new research indicates that human disturbance (road density) and food availability are major drivers of wolverine distribution in winter (Kortello et al. 2019, p. 1). Wolverine density and detection probability declined in areas with more human development (Barrueto et al. 2022, p. 4). Human development may also have cascading impacts of increasing competition from other mesocarnivores that are less affected by human disturbance (Frey et al. 2020, pp. 1136–1138; Chow-Fraser et al. 2022, p. 6; Milanesi et al. 2022, pp. 10–11).

Winter Recreation

In our 2018 SSA report and October 13, 2020, withdrawal document (85 FR 64618), we concluded that winter recreation is a low-level stressor for wolverines in the contiguous United States (Service 2018, p. 62). The limited research available at the time indicated some avoidance behavior exhibited by wolverines in areas with backcountry winter recreation, but not to the extent that we had concerns about population-level impacts.

In the 2023 wolverine SSA report addendum, we provide an updated assessment of the effects of winter recreation based on new studies. Research indicates winter recreation is negatively associated with North American wolverine habitat use, and that winter recreation is likely to increase and become more concentrated in the future as snow-covered areas decline due to climate change (Heinemeyer et al. 2019, p. 1). A large multi-State analysis of winter recreation impacts in the Northern Rocky Mountains was published in 2019, indicating greater concern for impacts to wolverines than we found in 2018 and showing a negative functional response to the level of recreation exposure within their home ranges (Heinemeyer et al. 2019a, pp. 13–14, 17–18). Additionally, new research found an incremental loss of wolverines in portions of central Idaho where winter recreation impacts are increasing (Mack and Hagan 2022, p. 13). Furthermore, forest roads used by snowmobilers in the Canadian Rockies were found to have a strong negative correlation with wolverine distribution (Kortello et al. 2019, p. 10). Wolverine detection probability in protected and non-protected habitat of southwestern Canada was found to be strongly and negatively correlated with nonmotorized recreation in summer and winter (Barrueto et al. 2022, p. 5).

Trapping

In our 2018 SSA and the October 13, 2020, withdrawal document (85 FR 64618), we concluded that overutilization does not currently represent a stressor to the North American wolverine in the contiguous United States at the individual, population, or species level. We also concluded that trapping in Canada has been and appears to be sustainable, and trapping or harvesting of wolverines along the contiguous U.S.–Canada border does not represent a stressor to wolverines migrating into the contiguous United States and does not represent a barrier to wolverine movement and dispersal along the international border (Service 2018, p. 71).

Legal trapping of wolverines has not occurred in the contiguous United States in the past 10 years, and lethal

incidental trapping of wolverines has been minimal (Service 2023, p. 38). We expect recent changes to wolf trapping regulations in Idaho and Montana to have little effect on wolverines at a population level, as long as trapping is done in a manner to limit wolverine bycatch (Idaho Department of Fish and Game (IDFG) 2023, in litt., p. 1; IDFG 2022, p. 40; Montana Fish, Wildlife and Parks (MFWP) 2023, in litt., p. 1; MFWP 2022, entire). Below, under *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes,* we provide an assessment of incidental trapping and the measures States are taking to reduce incidental trapping of wolverines.

Recent research on wolverine trapping in Southern Canada indicates that trapping may be having more of a negative effect on wolverine populations in Canada than previously thought (Kortello et al. 2019, pp. 1, 10; Mowat et al. 2020, entire; Barrueto et al. 2020, p. 296; Barrueto et al. 2022, entire). Unsustainable trapping levels in Canada could limit dispersal of individuals into the contiguous United States, where the dispersal of wolverines from Southern Canada is vital to the genetic and demographic health of the U.S. population (Sawaya 2023, pers. comm.).

Summary of Comments and Recommendations

Comments on the 2013 Proposed Listing Rule

Upon publication of our February 4, 2013, proposed rule to list the DPS of North American wolverine occurring in the contiguous United States as a threatened species (78 FR 7864), we opened a 90-day public comment period, ending May 6, 2013. After we withdrew the proposed rule, on October 18, 2016 (81 FR 71670), we again opened a public comment period on our 2013 proposed listing rule; that comment period was open for 30 days, ending November 17, 2016. At both times, we contacted appropriate Federal and State agencies, scientific experts and organizations, Tribes, and other interested parties and invited them to comment on the 2013 proposed listing rule. Many of the comments we received from State agencies during our 2016 reopened comment period (81 FR 71670) were similar to those we received during the initial 2013 public comment period (78 FR 7864). All substantive information provided during both comment periods on our 2013 proposed listing rule has either been incorporated directly into this final determination or is addressed below.

Below, we present the comments received on the 2013 proposed listing rule and a summary of our responses as presented in the October 13, 2020, withdrawal document (85 FR 64618). We also provide updated responses to several of the comments based on new information presented in the 2023 wolverine SSA report addendum and this final rule. Comments are numbered below as they were numbered in the October 13, 2020, withdrawal document (85 FR 64618). Several of the comments and responses from the October 13, 2020, withdrawal document did not require revision, and they are incorporated here by reference; those comments with responses that remain the same are comments 6, 7, 9, 11, 13, 20, 21, 22, 23, and 24 (85 FR 64618 at 64622–64626).

Public Comments

(1) Comment: We received several public comments claiming that the North American wolverine faces increasing threats from the effects of climate change, particularly habitat loss due to declining snowpack.

Our 2020 Response Summarized: Our climate assessment in the 2018 wolverine SSA report and October 13, 2020, withdrawal document focused on the impact of climate change to denning conditions for wolverines. We stated we recognize that current climate trends and future (2055 and later) climate model projections indicate warming temperatures for much of western North America and changes to snow-pack conditions. In general, models indicate higher elevations, where documented historical wolverine denning has occurred, will retain more snow cover than lower elevations, particularly in early spring (on April 30/May 1). We referenced a climate analysis that included two regions, Glacier National Park and Rocky Mountain National Park. Details of this climate analysis are presented in Ray et al. (2017) and are summarized in the 2018 SSA report. Climate models in Ray et al. (2017) built upon previous model projections presented in McKelvey et al. (2011), but with significant differences such as finer spatial resolution, incorporation of slope and aspect, snow depth estimates, additional years of historical data, and wider temporal analyses of snow persistence (April–June). Model projections from Ray et al. (2017) indicate significant areas (several hundred square kilometers (km^2)/square miles (mi^2) for each study area) of future snow (greater than 0.5 meters (m) (20 inches (in)) in depth) are likely to persist on May 1 at elevations currently used by wolverines for denning. This is true, on average, across the range of climate models used out to approximately year 2055.

Our 2023 Response: Our assessment of climate change impacts to North American wolverines in the 2023 wolverine SSA report addendum, and applied in this final rule, evaluates the impact of climate warming and changes in snowpack on various aspects of wolverine ecology, not just denning habitat (see *Climate Change,* below). We now consider habitats characterized by the presence of persistent spring snow for survival and reproduction to be a physical and ecological requirement for wolverines in the contiguous United States (see *Life-History Needs,* below). New evidence from around the world reinforces that snow—especially persistent spring snow—is an important predictor of broad-scale wolverine distribution and density (Aubry et al. 2023, pp. 15–16; Carroll et al. 2020, p. 8; Fisher et al. 2022, p. 10; Glass et al. 2021, entire; Mowat et al. 2020, p. 220). Snow cover appears to influence wolverine dispersal and resulting genetic structure (Balkenhol et al. 2020, pp. 798–799). Warming future conditions could make caching food more difficult for wolverines year-round (Van der Veen et al. 2020, pp. 8–10). Climate change also has the potential to exacerbate the impacts of other stressors, including effects from roads, winter recreational activity, development, low genetic diversity, and small populations (see *Threats,* below). Wolverines have denned outside of spring snowpack in the boreal forests of Canada and Scandinavia; however, the importance of spring snow for denning may vary among areas depending on the abundance of alternative den site structures, competitors, and food resources (Persson et al. 2023, p. 5810). Furthermore, there is no evidence that North American wolverines have denned in areas outside of spring snowpack in their alpine habitats in the contiguous United States. In light of this, we do not expect North American wolverines to continue to have the same or better resiliency in the contiguous United States in the future when cold and snowy conditions are expected to decrease, with spring snowpack decreasing as much as 50 percent in some areas. Although we are not seeing deleterious effects of climate change on the contiguous U.S. population of North American wolverines currently, we expect future impacts at the population level. For further detail, see the discussion under *Climate Change,* below.

(2) Comment: We received several public comments during our request for

information claiming that low population size (and small effective population size) warrant listing of the North American wolverine as threatened or endangered.

Our 2020 Response Summarized: We stated that wolverines are difficult animals to survey, and populations occur in naturally low densities across their North American range, due in large part to their need for large, exclusive territories. At that time (and still today), the only estimate of the number of wolverines that currently occupy the contiguous United States is the often-cited population estimate of 318 wolverines (range: 249–926) in the contiguous United States. This estimate was derived from habitat modeling presented in Inman et al. (2013). That publication also provided a modeled estimate of potential wolverine capacity in the contiguous United States of 644 wolverines (range: 506–1881). We also reported the preliminary results from the Western States Wolverine Conservation Project (WSWCP) occupancy study in four western States (Idaho, Montana, Washington, and Wyoming) and from a pilot occupancy study in Wyoming (2015–2016) (Service 2018, appendix B). Preliminary analysis of the study results indicated an average estimated probability of occupancy of 0.42, suggesting that wolverines used nearly half of all sites during the study period (MFWP 2017, pers. comm.). Although the sum of these reports cannot confirm the previous estimate of population size or verify population trends, they offer recent evidence that wolverines continue to be observed across a large area of the western United States.

We also discussed the estimated effective population size by Schwartz et al. (2009), which estimated a summed effective population size of 35, with credible limits from 28 to 52 (Schwartz et al. 2009, p. 3,226). We stated that the analysis missed two wolverine subpopulations as well as individuals, which would underestimate the results for this type of analysis. We went on to discuss the apparent connectivity between wolverines in the contiguous United States and Canada, and we considered the contiguous United States to be genetically continuous with wolverines in adjacent Canadian provinces. We concluded that a small effective population size would be more of a concern if the population was in isolation; however, wolverines in the contiguous United States are not genetically isolated from wolverines in Canada.

Our 2023 Response: The best available estimate of effective population size for the wolverine in the Northern Rocky Mountains continues to be 35 (credible interval = 28–52) (Schwartz et al. 2009, p. 3226). We estimated the effective population size of wolverines in the North Cascades to be four (Service 2023, p. 27). Overall, the effective population size estimates of wolverines in the contiguous United States are small compared to conservation guidelines, and the contiguous U.S. DPS of North American wolverines appear to be vulnerable to inbreeding and loss of genetic diversity when considered in isolation. However, only one or two effective migrants per generation (*i.e.,* the number of migrants that reproduce at the same rate as residents) are likely needed to achieve genetic population connectivity and maintain existing levels of genetic diversity (Cegelski et al. 2006, p. 209).

At the time we published the October 13, 2020, withdrawal document (85 FR 64618), we considered the contiguous U.S. population to be genetically continuous with Canada. We now know that wolverine populations in southern British Columbia and Alberta near the transboundary interface are less genetically connected to the contiguous United States than we found in our 2018 SSA. New information has revealed that female wolverines appear to avoid crossing major roadways, including the Trans-Canada Highway (Highway 1) and the Crowsnest Highway (Highway 3) in southern British Columbia (Sawaya et al. 2023, pp. 11–14). Substantially lower mitochondrial DNA diversity in the United States, as compared to mitochondrial DNA diversity in Canada, is consistent with the nuclear DNA signals of limited contemporary female gene flow between the countries and the wolverine's relatively recent recolonization at the southern edge of their range (Sawaya et al. 2023, p. 17). See ''Gene Flow Between the United States and Canada'' and ''Population Structure and Gene Flow Within Canada,'' below, for more detail. Given the new information on limited gene flow with Canada and the potential impacts of climate change to future dispersal, the low effective population size in the contiguous U.S. population of North American wolverines is a concern to future population viability.

(3) Comment: We received several public comments during our request for information claiming that the North American wolverine faces threats from indiscriminate trapping in the contiguous United States, or are negatively impacted by incidental trapping.

Our 2020 Response Summarized: In our October 13, 2020, withdrawal document (85 FR 64618), we stated that trapping or hunting of wolverines was not allowed in any State within the range of the wolverine in the contiguous United States, and we presented the legal protections afforded to wolverines in each State. We summarized what we knew at the time about incidental trapping. In the wolverine SSA report, we provided a summary of the number of wolverines that have been incidentally trapped in Idaho (18 since 1965, including 6 known to be released alive and 7 known mortalities), Montana (4 since 2013, 3 mortalities and 1 released unharmed), and Wyoming (2 since 1996, 1 mortality and 1 released unharmed) (Service 2018, p. 66). Both Idaho and Montana are implementing trapper education programs to minimize nontarget wolverine captures. We noted that regulated trapping and hunting of wolverines occurs in parts of Alaska and Canada, and appears to be sustainable based on population and density estimates.

Our 2023 Response: Legal trapping of wolverines has not occurred in the contiguous United States in the past 10 years. Wolverine trapping remains closed throughout the western United States, and wolverines have retained various protected status designations in the States within their current U.S. range (Service 2023, table 10). Therefore, legal direct trapping is no longer a stressor on wolverines in the contiguous United States. In the past 10 years, lethal incidental trapping of wolverines has been minimal (approximately 1 to 2 animals per year or fewer), primarily occurring in Idaho and Montana (see *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes,* below). New information suggests that recent overharvest from trapping has occurred in southern Canada in areas that could provide dispersing individuals to the contiguous United States (Mowat et al. 2020, entire). Trapping in southern Canada appears to have had a more negative effect on wolverine populations in Canada than previously thought. Legacy effects of recent unsustainable trapping levels in a portion of the southern Rocky Mountains of Canada could limit dispersal of individuals into the contiguous United States in an area where wolverine connectivity between the United States and southern Canada is vital to the genetic and demographic health of the U.S. wolverine population. See *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* and Provisions of the Interim 4(d) Rule, below, for further details.

(4) Comment: We received several public comments identifying potential threats to wolverines from winter recreation activities, such as snowmobiling and backcountry skiing.

Our 2020 Response Summarized: When we published our October 13, 2020, withdrawal document (85 FR 64618), there was little information on the effect of winter recreation on wolverines. We received a final report of a multiyear study on the effects of winter recreation on wolverines (Heinemeyer et al. 2017, entire) in mid-December 2017, and the results of this study were published (Heinemeyer et al. 2019a, entire) prior to the publication of our 2020 withdrawal document. The study found that wolverines were displaced from habitat by winter recreation but maintained multiyear home ranges, and the authors suggest that wolverines are able to tolerate winter recreation at some scales (Heinemeyer et al. 2017, p. iv; Heinemeyer et al. 2019a, p. 16). The study described habitat selection as complex for female wolverines and stated that habitat selection was likely driven by a combination of abiotic (snow, cold) and biotic (predator avoidance, food availability) factors (Heinemeyer et al. 2017, p. 36; Heinemeyer et al. 2019a, p. 16). This study did not assess demographic effects, fitness effects, or population-level effects of winter recreation on wolverines (Heinemeyer et al. 2019a, pp. 17, 19).

Our 2023 Response: There are multiple recent studies that indicate wolverines are negatively affected and displaced (at least temporarily) by various types of backcountry winter recreation (Barrueto et al. 2022, entire; Heinemeyer et al. 2019a, entire; Heinemeyer et al. 2019b, entire; Kortello et al. 2019, entire; Mack and Hagen 2022, entire; Regan et al. 2020, entire). The effect of winter recreation activity (of concern due to potential impacts to denning and survival), in isolation, represents a low threat to wolverines in the contiguous United States at the population level. However, in combination with other threats, including decreased snow availability (see *Climate Change,* below) and increased overlap with winter recreationalists in the future due to climate change, winter recreation could negatively affect wolverine population resilience in the future. See *Disturbance Due to Winter Recreational Activity,* below, for further details.

(5) Comment: We received public comments claiming that wolverines are dependent on deep snow for survival and expressing concern for future changes in snowpack due to the effects of climate change.

Our 2020 Response Summarized: Our response to this comment in our October 13, 2020, withdrawal document (85 FR 64618) focused on snow availability for denning and the wolverine's ability to cope with changing snow conditions in the denning context. We stated that wolverines can and have denned outside of heavy snowpack, multiple factors play a role in den site selection, females will move dens as young become mobile, and areas of significant snowpack will likely persist in the future the contiguous United States in areas where wolverines are known to den at levels that will continue to support wolverines. Our review of studies of wolverine denning activity found no quantitative data reporting snow depth at the den site when wolverines abandon the den. More importantly, wolverine reproductive success has not been studied relative to a number of abiotic and biotic conditions, including depth and temporal aspect of spring snow cover.

In our evaluation of the effects of climate change to snowpack (see Service 2018, pp. 73–99), we presented a finer-scale analysis (0.0625 km^2 (0.24 mi^2)) for two study areas (Glacier National Park and Rocky Mountain National Park) that focused directly on May 15, in addition to the presence or absence of snow on May 1 and April 15. These dates are more relevant to the North America wolverine's life-history needs. We also modeled the depth of ''significant'' snow (0.5 m (20 in)) on these dates. We found that large areas (several hundred km^2/mi^2 for each study area) of future snow cover (greater than 0.5 m (20 in) in depth) are projected to persist on May 1 at elevations currently used by wolverines for denning. This is true, on average, across the range of climate models used out to approximately year 2055.

Our 2023 Response: As discussed above in our response to *(1) Comment,* the wolverine is a snow-adapted species that utilizes cold and snowy habitats for multiple aspects of its life history. To inform our assessment of the wolverine's status in the contiguous United States, we updated our previous climate change analysis, the details of which are summarized in the wolverine SSA report addendum (Service 2023, pp. 47–60). Our analysis focuses on the expected loss of snowpack out to 2100 in five modeling domains that overlap with occupied and potential wolverine habitat in the contiguous United States across latitudinal, longitudinal, and elevation gradients. The Service chose a snow depth threshold of greater than or equal to 1 m (3.3 ft) to represent significant snow cover on May 1, which provides a more conservative estimate than was used in the 2018 SSA (*i.e.,* greater than or equal to 0.5 m (20 in.) on May 1). This updated analysis shows that cold and snowy conditions at high elevations are expected to decrease, with spring snowpack at denning elevations decreasing as much as 50 percent in some areas. As a result, we expect wolverine population resiliency in the contiguous United States to decrease in the future. For more information see *Climate Change,* below.

(8) Comment: We also received public comments recommending that the North American wolverine not be listed as threatened or endangered under the Act. One commenter stated that State wildlife agencies are capable of managing the species and are able to provide protections that ensure continued population growth towards population objectives established by these agencies and that mandates of various Federal resource management agencies provide a commitment to managing wildlife habitat in a way that benefits all wildlife species, including wolverines and other forest carnivores.

Our 2020 Response Summarized: We acknowledged that some members of the public supported our decision to withdraw our proposed rule to list the North American wolverine occurring in the contiguous United States as a threatened species under the Act. In the wolverine SSA report (Service 2018, appendix G), we provided a summary of the regulatory protections provided by western States and Federal agencies, as well as management measures being implemented, to conserve the wolverine and its habitat. Trapping or hunting of wolverines was prohibited in the contiguous United States when our October 13, 2020, withdrawal document (85 FR 64618) published.

Our 2023 Response: We appreciate the regulatory protections and management measures our State wildlife agency partners and Federal resource management agencies have enacted to conserve the North American wolverine and its habitat (Service 2018, appendix G). However, we have determined that the contiguous U.S. DPS of North American wolverine meets the Act's definition of a threatened species as described in this rule due to future threats, including the reduction in spring snowpack from climate change. This determination is not a reflection on the adequacy of State management or the capability of States to manage the species but rather an acknowledgement of the serious threat posed to the species

by climate change. Along with the listing, we are finalizing an interim 4(d) rule that will promote conservation of the contiguous U.S. DPS of North American wolverine by encouraging management of the landscape by our partners in ways that meet the conservation needs of the wolverine. The provisions of this 4(d) rule provide one of many tools we will use to promote the conservation of the contiguous U.S. DPS of North American wolverine.

(10) Comment: We received comments from several organizations that support the listing of the North American wolverine and designation of critical habitat. Threats cited include restricted migration, habitat loss and connectivity related to threats from effects of climate change, nontarget trapping pressures, road mortality and other effects of roads (*e.g.,* noise, pollution, fragmentation of habitat), motorized recreation and traffic in wildlife corridors, timber sales and associated roads, and effects of snowmobile traffic (habitat fragmentation and pollution, and change in behavior).

Our 2020 Response Summarized: We found that demographic risks to the species from either known or most likely potential stressors (*i.e.,* disturbance due to winter recreational activities, other human disturbances, effects of wildland fire, disease, predation, overutilization, genetic diversity, small population effects, climate change, and cumulative effects) were low based on our evaluation of the best available information at the time in relation to current and potential future conditions for the North American wolverine occurring in the contiguous United States and in the context of the attributes that affect the needs of the DPS (Service 2018, p. 103). Thus, we determined that the North American wolverine in the contiguous United States did not meet the definition of an endangered species or a threatened species under the Act.

Our 2023 Response: Our 2018 wolverine SSA report and 2023 SSA report addendum provide a thorough assessment of the threats affecting the North American wolverine in the contiguous United States. New information related to the threats affecting the contiguous U.S. DPS of the North American wolverine have led us to a different conclusion than the one we presented in our October 13, 2020, withdrawal document (85 FR 64618). In this final rule, we examine the best available information about threats to the wolverine, including effects from roads, disturbance due to winter recreational activity, other human disturbance, effects from wildland fire, disease, predation, overutilization (trapping), genetic diversity, small population effects, and climate change, including the cumulative effects of these threats. See Summary of Biological Status and Threats, below, for a complete discussion of threats affecting the DPS. After assessing the best available information, we conclude that the contiguous U.S. DPS of the North American wolverine is not currently in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

(12) Comment: We received comments from several industry groups supporting our August 13, 2014, withdrawal (79 FR 47522) of our February 4, 2013, proposed rule (78 FR 7864) to list the North American wolverine as threatened. In general, their support rests on the following: (1) The DPS determination presented in our previous proposed rules (both 2010 and 2013) was flawed; (2) the North American wolverine does not meet the definition of a threatened species; (3) the obligate relationship with denning and need for snow has not been adequately addressed (and may be a habitat preference); and (4) climate model projections do not support complete loss of snow. They also urged us to reaffirm prior findings that winter recreation (motorized and nonmotorized) is not a threat to wolverines.

Our 2020 Response Summarized: We reevaluated wolverines occurring in the contiguous United States under our Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (DPS policy; 61 FR 4722, February 7, 1996). See Distinct Population Segment in the October 13, 2020, withdrawal document (85 FR 64618 at 64628–64631) for more information. We provided our analysis of the status of wolverines in the contiguous United States under Determination of Species Status in the October 13, 2020, withdrawal document (85 FR 64618 at 64645–64647). The topic of denning behavior is discussed in the wolverine SSA report (see ''Use of Dens and Denning Behavior'' under *Reproduction and Growth* in the wolverine SSA report (Service 2018, pp. 23–28)). For our analysis of the effects of climate change to North American wolverines and denning habitat, see ''Climate Change and Potential for Cumulative Effects'' in the October 13, 2020, withdrawal document (85 FR 64618 at 64642–64644).

Our 2023 Response: In this final rule, we provide our revised evaluation of discreteness and significance under our DPS policy of the segment of the North American wolverine occurring in the contiguous United States considering new information available since the publication of our October 13, 2020, withdrawal document (85 FR 64618). We also explain how new information has led us to a different determination from previous DPS analyses. The analysis contained in this rulemaking supersedes and replaces any previous DPS analysis for the segment of the North American wolverine occurring in the contiguous United States. We conclude that the population of wolverines in the contiguous United States is discrete and significant in relation to the remainder of the species in North America. For more information, see Distinct Population Segment Analysis for Wolverine in the Contiguous United States, below.

The wolverine population in the contiguous United States is expected to decrease in resiliency, redundancy, and representation in the foreseeable future. The best available information suggests that habitat loss as a result of climate change, and the resulting exacerbating effect on other stressors, are likely to decrease the viability of wolverines in the contiguous United States within this century (see ''Summary of Future Condition'' and Determination of North American Wolverine's Status, below). Our review of the best scientific and commercial data available indicates that the contiguous U.S. DPS of the North American wolverine meets the Act's definition of a threatened species.

We acknowledge the precise causal mechanism(s) for the apparent association of wolverine distribution with persistent spring snow are not yet clear. The association could involve the importance of snow for denning or other aspects of the species' biology and ecology. We address uncertainties under *Areas of Uncertainty for Wolverine Habitat Needs,* below. That said, we know that wolverines are a species that is adapted to, and has a strong preference for, cold and snowy conditions and that these conditions will be reduced in the future. The commenter is accurate in that climate models do not predict a complete loss of snow within the North American wolverine's range in the contiguous United States. However, we expect climate change to reduce snowpack in areas used by wolverines by as much as 50 percent in some places (see our analysis under *Climate Change,* below). We conclude increasing temperatures and decreasing snowpack have the

largest potential to influence the population viability of the contiguous U.S. DPS of the North American wolverine in the future.

Regarding winter recreation, new information supports our understanding that some forms of winter recreation, backcountry motorized recreation especially, have the potential to negatively impact wolverines. See our response to *(4) Comment,* above, and *Disturbance Due to Winter Recreational Activity,* below, for further details.

Comments From Tribes

(14) Comment: We received comments from one consortium of Tribal nations stating that, based on the weight of evidence provided in our previous rules, the North American wolverine meets the Act's definition of endangered or threatened and is therefore warranted for listing. Specific threats mentioned in the comment letter included current population status, winter recreation activities, and effects of climate change. The Tribes also included comments documenting the cultural value of the wolverine and connection to cultural practices and concern for the loss of wolverine populations in the contiguous United States. The Tribes encouraged the Service to use sound and solid science in the listing determination and noted that additional population monitoring and Tribal climate change modeling efforts are under way to evaluate the status of the wolverine.

Our 2020 Response Summarized: We appreciate the unique perspective provided by the Tribal nations regarding the contribution of the North American wolverine to the Tribes' culture and spirituality. We also appreciate the commitment of the Tribal nations to continue studies of wolverines.

We used the best available scientific information to provide a detailed description of the North American wolverine's life history and ecology, including a detailed discussion of wolverine denning habitat and behavior. We conducted an analysis to assess the current population status. Conservation measures and regulatory mechanisms relative to the North American wolverine were also provided in the wolverine SSA report. This information was used to evaluate the current and future conditions of the DPS. We evaluated results from a fine-scale analysis of the potential effects of climate change to future snowpack conditions and found significant areas of snow (several hundred km^2/mi^2) will persist on May 1 at elevations used by wolverines for denning. We determined that, based on the best available information, the North American wolverine in the contiguous United States did not warrant listing as threatened or endangered under the Act in 2020.

Our 2023 Response: We appreciate the commitment of the Tribal nations to further our knowledge of this unique species. We have gathered the best available information on North American wolverines and used this information to assess the current and future population status of wolverines in the contiguous United States.

Regarding winter recreation, see our response to *(4) Comment,* above, and *Disturbance Due to Winter Recreational Activity,* below, for further details.

Regarding the effects of climate change to North American wolverines, see our response to *(1) Comment,* above, and *Climate Change,* below. We conclude that the contiguous U.S. DPS of the North American wolverine is not currently in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

(15) Comment: We received comments from one Tribe whose territory is occupied by the North American wolverine. The Tribe submitted a comment letter in 2013 supporting our proposed listing. The Tribe stated that the conservation and restoration of the wolverine and other species within this homeland is of great importance to the Tribe's subsistence, culture, religion, and economy. The letter also identified conservation and management plans currently under development and highlighted that the wolverine is designated as a species of concern in these current draft plans. Specific comments were provided relative to threats from climate change (including relative to demographic stochasticity), recreation and urban development, and incidental take. Included in those comments were references to other studies under way (*e.g.,* Adaptation Partners and climate change vulnerability assessments; winter recreation study) to evaluate these potential stressors.

Our 2020 Response Summarized: We appreciate the perspective provided regarding the importance of the North American wolverine and other species to the Tribe and its commitment to current and future conservation and management actions. We also appreciate and evaluated the information presented in the citations that were provided in the comment letter. The best available scientific information was used to evaluate the current conditions (*i.e.,* potential stressors, including winter recreation) and future conditions (*e.g.,* effects of climate change) of the DPS. Based on the best available information, we determined that the North American wolverine in the contiguous United States did not warrant listing as endangered or threatened under the Act in 2020.

Our 2023 Response: Information previously provided by the Tribe was considered in the 2018 SSA report. We include new and updated scientific information in the 2023 wolverine SSA report addendum, including information on the current conditions (*i.e.,* potential stressors, including winter recreation) and future conditions (*e.g.,* effects of climate change) of the DPS. Based on the best available information, we now determine that the contiguous U.S. DPS of the North American wolverine meets the Act's definition of a threatened species.

State Agency Comments

In our October 13, 2020, withdrawal document (85 FR 64618), we also addressed the extensive comments from several western States, including previously submitted comments in response to the February 4, 2013, proposed listing rule (78 FR 7864) as well as additional comments submitted in response to our October 18, 2016, document that reopened the public comment period on the 2013 proposed listing rule (81 FR 71670). These comments were grouped together and summarized as described below.

(16) Comment: We received detailed comments critical of our reliance on ''unverified'' climate model projections in our February 4, 2013, proposed listing rule, the lack of discussion of assumptions in adopting the model findings, the lack of evaluating alternative hypotheses, and the need to evaluate these effects at the den-site scale. One State agency recommended that, given the disagreements in the scientific community on the interpretation of these results, the Service solicit an independent, scientific review of the February 4, 2013, proposed listing rule.

Our 2020 Response Summarized: In preparing the 2018 SSA report for the North American wolverine, our foundational science document for informing the October 13, 2020, withdrawal (85 FR 64618), we reviewed available reports and peer-reviewed literature, incorporated survey information for the purpose of preparing updated maps of the known current and historical occurrences of the North American wolverine, and contacted species experts to collect additional unpublished information. We evaluated the appropriate analytical tools to

address data gaps and uncertainties. In some instances, we used publications and other reports of the Eurasian subspecies (*Gulo gulo gulo*) to fully inform our knowledge of the North American wolverine (*Gulo gulo luscus*).

Before finalizing the 2018 SSA report, the draft wolverine SSA report was submitted for peer review to four independent peer reviewers and submitted to our Federal, State, and Tribal partners for scientific review. We incorporated the results of these reviews in the 2018 wolverine SSA report, as appropriate.

We recognized that climate trends and future (2055 and later) climate model projections indicated warming temperatures for much of western North America, and changes to snowpack conditions. Our assessment of climate change impacts indicated that large areas (several hundred km^2/mi^2 for each study area) of future snow (greater than 0.5 m (20 in) in depth) would persist on May 1 at elevations currently used by wolverines for denning. This was true, on average, across the range of climate models used out to approximately year 2055.

Our 2023 Response: In the 2023 wolverine SSA report addendum, we expanded upon our climate analysis from the 2018 SSA report. Both SSA documents went through an independent, scientific peer review process. The assessment of the climate modeling results, presented below under *Climate Change,* and applied in the ''Summary of Future Condition'' discussion, replaces and supersedes the analysis of modeling results presented in the February 4, 2013, proposed listing rule (78 FR 7864) and the October 13, 2020, withdrawal document (85 FR 64618). We acknowledge there are uncertainties around the nature of the wolverine's relationship with cold and snowy conditions (see *Areas of Uncertainty for Wolverine Habitat Needs,* below). Cold and snowy conditions at high elevations favored by wolverines in the contiguous United States are expected to decrease, with spring snowpack at denning elevations decreasing as much as 50 percent in some areas.

(17) Comment: We received comments critical of our previous support for findings by Schwartz et al. (2009) regarding effective population size. Relatedly, several States commented on recent dispersal/movements of wolverines into California, Colorado, and Utah as evidence of population expansion.

Our 2020 Response Summarized: In the October 13, 2020, withdrawal document (85 FR 64618), we referred to our response to *(2) Comment* for a discussion of effective population size (85 FR 64618 at 64620). Regarding recent occurrences of wolverines in the contiguous United States, we noted that wolverines had recently been found in areas where they were once extirpated in the contiguous United States. See ''Population Abundance and Density'' in the October 13, 2020, withdrawal document (85 FR 64618 at 64634–64636) for more information.

Our 2023 Response: The best available estimate of effective population size for the Northern Rocky Mountains continues to be that provided by Schwartz et al. 2009 (p. 3226): 35 (credible interval = 28–52). We estimated the effective population size of wolverines in the North Cascades to be four (Service 2023, p. 27). We are not aware of any other estimates of the effective population size of North American wolverines in the contiguous United States. See also our response to *(2) Comment,* above, and *Effective Population Size in the Contiguous United States,* below, for more information.

We have gathered updated occurrence information in our 2023 wolverine SSA report addendum (Service 2023, figure 2). We acknowledge that there are recent occurrences of wolverines in the western United States in areas where they have not been reported for years or very rarely (California, Colorado, Oregon, and Utah). These occurrences outside of the known breeding distribution are encouraging, but there is no evidence of breeding population expansion into California, Colorado, Oregon, and Utah.

(18) Comment: We received comments from several western States presenting clarifications or updates to incidental trapping events and trapping regulations.

Our 2020 Response Summarized: We noted that trapping or hunting of wolverines was not allowed in any western State (with the exception of Alaska, which was not included in the DPS in our February 4, 2013, proposed listing rule (78 FR 7864)). Legal protections for wolverines are codified in western State laws and regulations concerning hunting and trapping. Since 2013, there has been a zero quota for trapping or harvest of wolverines in Montana. We described the documentation of incidental trapping of wolverines in the contiguous United States (as recently as December 2017) and noted that not all events resulted in mortality. We acknowledged that both Idaho and Montana are implementing trapper education programs to minimize nontarget wolverine captures.

Our 2023 Response: We gathered updated information from States within the North American wolverine's range about incidental trapping, trapping regulations, and measures taken by States to prevent incidental trapping of wolverines. Lethal incidental trapping of wolverines has been minimal (1 to 2 animals per year), primarily occurring in Idaho and Montana. In the *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* discussion, below, we provide an assessment of incidental trapping and the measures States are taking to reduce incidental trapping of wolverines.

(19) Comment: Several States provided comments in response to our February 4, 2013, proposed listing rule (78 FR 7864) and our October 18, 2016, reopening of the public comment period (81 FR 71670) indicating their disagreement with our determination of a wolverine DPS for the contiguous United States. Specifically, some commenters stated that the criteria of significance should be reevaluated, noting that the February 4, 2013, proposed listing rule did not provide any substantive information to support our conclusion that the loss of the wolverine in the contiguous United States would result in a significant gap in the range of the species; that is, our previous use of the loss of latitudinal range does not provide a rational basis for concluding that the loss of the wolverine in the contiguous United States would be significant in relation to the taxon. Another commenter stated that the wolverine population in the contiguous United States is connected geographically and genetically to the Canada/Alaska populations and these northern populations were likely the source of recolonization during the 20th century. Further, this commenter stated there is not a difference in control of exploitation and conservation status between the United States and Canada.

Another commenter noted that, throughout the February 4, 2013, proposed listing rule, the Service acknowledged that, historically, the wolverine population in the contiguous United States was markedly reduced by systematic predator control programs and unregulated trapping. The commenter pointed out that areas of suitable habitat in the North Cascades, where trapping has been minimal or nonexistent for decades, and northern Rockies were recolonized by animals from Canada, where relatively liberal trapping is still allowed. The commenter asserted that our characterization in the February 4, 2013, proposed listing rule of ''liberal''

Canadian regulations as sufficient to ''maintain the robust conservation status of the Canadian population,'' does not comport with our characterization that the very limited trapping in the contiguous United States (Montana only) is insufficient to maintain the rebounding population designated as a DPS.

Our 2020 Response Summarized: In light of the updated analysis and new information included in the 2018 wolverine SSA report, we reevaluated wolverines in the contiguous United States under our DPS policy. We concluded that the population of wolverines in the contiguous United States was not discrete in relation to the remainder of the species in North America. As a result, in 2020, the population of wolverines in the contiguous United States was not a listable entity under section 3(16) of the Act. See Distinct Population Segment in the October 13, 2020, withdrawal document (85 FR 64618 at 64627–64631) for more information.

Our 2023 Response: As stated above, in this final rule we provide our revised evaluation of discreteness and significance under the DPS policy of the segment of the North American wolverine occurring in the contiguous United States considering new information. We also explain how new information has led us to different conclusions from previous DPS analyses. The analysis contained in this rulemaking supersedes and replaces any previous DPS analysis for the segment of the North American wolverine occurring in the contiguous United States.

Regarding the commenter's concern with the significance analysis, we have determined, as we did in the February 4, 2013, proposed listing rule, that there is evidence that the loss of the wolverine in the contiguous United States would result in a significant gap in the range of the taxon. Based upon the loss of approximately 58,998,140 acres (238,757 km^2) of high-quality wolverine habitat from the southern extent of the range and the adaptive potential that part of the range provides against oncoming climate change impacts, and the 12-degree latitudinal gap in the wolverine's range that would result if the U.S. population was lost, we determine that the loss of the contiguous U.S. wolverine population would result in a significant gap in the range of the taxon. Thus, the DPS meets the definition of significant in our DPS policy. For more information see *Analysis of Significance,* below.

Regarding the commenter's assertion that wolverines in the contiguous United States are connected to Canada, which relates to the discreteness analysis of our DPS policy, we do not consider wolverines in the contiguous United States to be genetically or morphologically discontinuous from wolverines in Canada (McKelvey et al. 2014, entire; Pilgrim and Schwartz 2018, entire; Sawaya et al. 2023, entire). Therefore, wolverines in the contiguous United States are not discrete based on marked separation from other populations of the same taxon. However, we determined that the wolverine meets the discreteness criterion in our DPS policy (61 FR 4722; February 7, 1996), as delimited by the international boundary with Canada and given differences in control of exploitation, conservation status, and regulatory mechanisms that are significant in light of section 4(a)(1)(D) of the Act. See *Analysis of Discreteness,* below, for more information.

Finally, regarding the commenter's point about our characterization in the February 4, 2013, proposed listing rule of trapping in Canada versus the contiguous United States, we have considered updated trapping information in our DPS analysis. New information available since the publication of our October 13, 2020, withdrawal document (85 FR 64618) indicates that overharvest from trapping in Canada was likely causing more of an impact than previously thought. Recent studies show that harvest levels in portions of southeastern British Columbia and southwestern Alberta were unsustainable and causing population declines (Mowat et al. 2020, entire; Barrueto et al. 2022, entire) and could negatively impact movement of individuals from Canada to the contiguous United States (Sawaya 2023, pers. comm.). We now conclude that the differences between Canada and the United States in control of exploitation are significant in light of section 4(a)(1)(D) of the Act and the wolverine population in the contiguous United States meets the DPS policy's standard for ''discreteness.'' See *Analysis of Discreteness,* below, for more information.

We conclude that the population of wolverines in the contiguous United States is discrete and significant in relation to the remainder of the species in North America. For our complete DPS analysis, see Distinct Population Segment Analysis for Wolverine in the Contiguous United States, below.

Comments Received in Response to Our November 23, 2022, Publication

As stated above, on November 23, 2022, we published a document in the **Federal Register** (87 FR 71557) soliciting new information to update the wolverine SSA so that we could reevaluate whether the North American wolverine occurring in the contiguous United States is a distinct population segment and, if so, whether the distinct population segment meets the definition of an endangered or threatened species under the Act. This document also notified the public that the February 4, 2013, proposed listing rule (78 FR 7864) had been reinstated as a result of court action. In response to the November 23, 2022, publication, we received additional information including survey results, reports, documented mortalities, management efforts, and recent wolverine literature that we evaluated and incorporated as appropriate into our wolverine SSA report addendum. Although not requested, we also received comments from submitters on topics related to determinations regarding wolverine, including whether the wolverine should or should not be listed as an endangered or threatened species under the Act. The comments we received are similar to those we present and respond to above.

Peer Reviewer Comments on the 2023 Wolverine SSA Report Addendum

We received comments from three peer reviewers on the draft wolverine SSA report addendum. We reviewed all comments we received from the peer reviewers for substantive issues regarding the information contained in the wolverine SSA report addendum, as well as any new information. The peer reviewers generally provided additional references, clarifications, and suggestions, including further definitions of some of the terms used in the wolverine SSA report addendum. We updated the wolverine SSA report addendum based on the peer reviewers' comments, including revising some of our adaptive capacity scores, clarifying specific points where appropriate, and adding additional details and suggested references where needed. Peer reviewer comments are addressed in the following summary.

(PR1) Comment: Regarding our climate change analysis, one peer reviewer did not agree with our initial characterization of the shared socioeconomic pathway (SSP) 5–8.5 emissions scenario as worst case, and stated there are possible scenarios that could be more extreme. They also recommended the wolverine SSA report addendum more clearly point out the uncertainty around the climate models and emissions scenarios by stating the scenarios are representative of a large

portion of plausible outcomes, but not all.

Our Response: We addressed the peer reviewer's concern by removing mention of likelihood when discussing specific emissions scenarios. We also modified the text to include the latest guidance from the White House Office of Science and Technology Policy on Selecting Climate Information to Use in Climate Risk and Impact Assessments (OSTP 2023, entire), which recommends using SSP5–8.5 as an upper bounding scenario. We applied SSP5–8.5 as the upper bound to estimate future snow cover available for wolverines within the selected domains.

(PR2) Comment: A peer reviewer questioned why we used the SSP2–4.5 and SSP5–8.5 emissions scenarios for our future condition analysis. They suggested we use SSP1–1.9 instead of SSP2–4.5 since it is the opposite extreme of SSP5–8.5.

Our Response: For our future analysis, we used SSP2–4.5 because that emissions scenario is closest to the current emissions trajectory we are on now, which provides a plausible lower boundary estimate of future snow cover available for North American wolverines. The Intergovernmental Panel on Climate Change (IPCC) has recently deemed our ability to limit warming to 1.5 °C (2.7 °F) (SSP1–1.9) as ''impossible'' with no or limited overshoot in its 2022 gap analysis (Riahi et al. 2022, p. 298). Scenario SSP5–8.5 reflects a no-emissions mitigation policy, which provides a plausible upper boundary estimate of available future snow cover.

(PR3) Comment: A peer reviewer was concerned that the wolverine SSA report addendum did not list snow as an important attribute when studies have shown dens are concordant with spring snow coverage. The peer reviewer disagreed with our reasoning for excluding snow, which was because we do not know how it impacts survival and reproduction, and stated we should also remove food habits, physical features, and home range size since it is not clear how any of these impact survival and reproduction. They believe the case for snow is much stronger than any of these other factors.

Our Response: We considered the information provided and addressed the peer reviewer's concern by updating the wolverine SSA report addendum to include snow as an important attribute of wolverine habitat.

(PR4) Comment: One peer reviewer was concerned about the use of spring snow cover for distribution. They questioned our use of the term ''persistent spring snow'' and the May 15 end date that is often associated with the term. The peer reviewer recommended analyzing snow cover between February and March, when young are newborn and most in need of thermal cover in natal dens. The reviewer believed that any analysis of climate change effects at those more critical times for denning would not likely show impacts.

Our Response: We used the term ''persistent spring snow'' in the wolverine SSA report addendum because it is a term frequently used in the scientific literature for wolverines and appears to be correlated to the wolverine's circumpolar distribution. Snow model outputs for May 1 are presented in the 2023 wolverine SSA report addendum. May 1 was used based on previous studies documented in the 2018 SSA (Service 2018, p. 26), indicating wolverine den site abandonment generally occurs before May 1. We acknowledge that young kits are in natal dens usually from mid-February to mid-March, so the use of May 1 snow projections is a conservative approach, but one which is consistent with the literature.

As described in the wolverine SSA report addendum, there are a number of hypotheses for why wolverines prefer cold and snowy habitats, and not all of them are limited to denning (*i.e.,* easier to get food, more food caching sites, etc.). These things could be important for adults throughout the breeding cycle or for juveniles as they become more independent from their mothers. We also discuss the possibility of other factors that are correlated to persistent spring snow, such as low temperatures (also analyzed in Copeland et al. 2010, entire), being the causal mechanisms for the observed relationship. In the wolverine SSA report addendum, we acknowledge wolverines have been documented denning in areas without persistent spring snow (Aronsson and Persson 2017, p. 266; Copeland et al. 2010, pp. 240–242; Fisher et al. 2022, p. 8; Jokinen et al. 2019, pp. 6–8; Persson et al. 2023, entire; Webb et al. 2016, pp. 1466–1467); however, this phenomenon appears to be associated with cold, high-latitude boreal or arctic forests rather than the alpine habitats used by wolverines in the contiguous United States. In the contiguous United States, there is no evidence that wolverines have denned in areas without persistent spring snow.

(PR5) Comment: One peer reviewer recommended including potential ways wolverines could adapt their denning behavior or use smaller or shallower patches of snow for denning in response to effects from climate change.

Our Response: We added language to the wolverine SSA report addendum to address this comment and we also included additional text that snow may be important for more than just denning. As stated above, there is no evidence that wolverines have denned in areas without persistent spring snow in the contiguous United States.

(PR6) Comment: A peer reviewer pointed out that future recreation will not just increase due to an increase in the human population, but also because snow-dependent recreational activities will be constrained to a smaller area that still contains quality snow in the future.

Our Response: We included text in the wolverine SSA report addendum reflecting the reviewer's comment.

(PR7) Comment: One peer reviewer suggested adding Colorado's wolverine reintroduction plan to the wolverine SSA report addendum as a voluntary conservation measure.

Our Response: We updated the wolverine SSA report addendum to include a description of Colorado Parks and Wildlife's previous consideration of reintroducing wolverines to Colorado as a nonessential experimental population (see 78 FR 7890, February 4, 2013). We also describe how this proposal was subsequently withdrawn in 2014 (see 79 FR 47522, August 13, 2014), when we withdrew the February 4, 2013, proposed listing rule (78 FR 7864), and that there is currently no formal proposal to reintroduce wolverines to Colorado.

(PR8) Comment: Two peer reviewers provided additional documentation regarding roads acting as a barrier to wolverine dispersal. Both provided different situations where at least one wolverine was seen crossing roadways, including a multiple-lane highway. One peer reviewer also mentioned regularly seeing wolverine tracks crossing roadways.

Our Response: We updated the wolverine SSA report addendum to reflect these observations and modified the text to clarify that highways can limit female gene flow in some situations, but they are not complete barriers to wolverine movements.

(PR9) Comment: One peer reviewer questioned how the artificial cutoff of the U.S.-Canada international border influenced the results of the 2009 effective population size analysis (Schwartz et al. 2009, entire).

Our Response: The effective population size estimate was only for the U.S. portion of the Northern Rockies, and there were no samples taken from Canada. As we stated in the wolverine SSA report addendum, connectivity to larger source

populations can alleviate the adverse effects of small effective population sizes (Frankham et al. 2014, entire). We also added a paragraph to the wolverine SSA report addendum to explain that because effective population size estimates for wolverine are small, connectivity with populations in Canada to allow for migration and gene flow is crucial to maintaining genetic diversity.

(PR10) Comment: One peer reviewer was concerned that current data for the wolverine are not being compared to what is known historically. They specifically called out the comparison of population sizes, the distribution and abundance of wolverines in the contiguous United States, and the results of genetic studies.

Our Response: As the peer reviewer mentioned, there is a lack of historical data to compare to current conditions. However, our assessment is a forward-looking one, based on current and future conditions, and not the change from historical conditions to current conditions.

(PR11) Comment: One peer reviewer questioned the 40 percent decline in wolverine abundance within a national park complex in southwestern Canada (Mowat et al. 2020, entire; Barrueto et al. 2022, entire).

Our Response: The Barrueto et al. (2022) effort is a decade-long research project that was peer reviewed and published in a scientific journal. We note that the initial population estimate was approximately 50 wolverines at the start of the study, so a 40 percent decline over 10 years results in the loss of approximately 15–20 wolverines. The wolverine SSA report addendum has been updated to provide this additional detail.

(PR12) Comment: A peer reviewer suggested including additional detail on how species-specific trapping and snaring reduce the likelihood of incidentally capturing a wolverine.

Our Response: We updated the wolverine SSA report addendum to include how trappers use pan tension, site selection, and snare height to reduce the likelihood of incidental capture. We also included additional information we received from the States on their efforts to reduce incidental trapping of wolverines.

(PR13) Comment: One peer reviewer suggested that the median and quartiles presented in our modeling may not accurately capture the variability in environmental conditions. The reviewer suggested that in addition to calculating the lower-quartile, median, and upper-quartile at each individual grid cell and timestep, we should also calculate the maximum and minimum bracketing response.

Our Response: We did not conduct the additional suggested analysis. The additional analysis would require significant work and time, and we conclude our approach includes the majority of plausible future outcomes and incorporates the best available information to inform our listing determination.

I. Final Listing Determination

Background

A comprehensive review of the life history, population trends, and ecology of the North American wolverine is presented in the wolverine SSA report (Service 2018, pp. 3–44) and wolverine SSA report addendum (Service 2023, entire). The Service recognizes the North American wolverine as the subspecies *Gulo gulo luscus* (Service 2018, p. 8). Wolverines are a medium-sized (about 1 m (3.3 feet (ft)) in length) carnivore, with a large head, broad forehead, and short neck (Service 2018, p. 4). Wolverines have heavy musculature and relatively short legs, and large feet with strong, curved claws for digging and climbing (Service 2018, p. 4). Their feet are adapted for travel through deep snow and, during the winter, dense, stiff, bristle-type hairs are found between the toes and around the foot pad. This characteristic becomes diminished in the summer (Service 2018, p. 4). The wolverine is the largest terrestrial member of the Mustelidae family, which includes weasel, fisher, mink, marten, and others, and resembles a small bear with a bushy tail (Service 2018, p. 1). Wolverines possess a number of morphological and physiological adaptations that allow them to travel long distances, and they maintain large territories in remote areas (Service 2018, p. 1). They have been described as curious, intelligent, and playful but cautious animals, though their social behavior and social organization has not been well-studied (Service 2018, p. 1). In North America, wolverines are found in Alaska, much of Canada, and the western-northwestern United States.

During the late 1800s and early 1900s, the wolverine population declined or was extirpated in much of the contiguous United States (lower 48 States), which was most likely the result of unregulated trapping and predator poisoning campaigns. Following regulation of trapping and restrictions on the use of poison, the wolverine population rebounded to some extent, and their distribution expanded to refill a portion of their previously extirpated range. In the contiguous United States, wolverines are known to reproduce in Washington, Idaho, Montana, and Wyoming (Service 2023, figure 3). Solitary individuals or lone dispersing individuals have been observed in other western States (Oregon, Colorado, Utah, and California), but there is no evidence of reproduction in the contiguous United States outside of the Northern Rocky Mountains in Idaho, Montana, and Wyoming and the Cascade Mountains of Washington.

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. In 2019, jointly with the National Marine Fisheries Service, the Service issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and the criteria for designating listed species' critical habitat (84 FR 45020; August 27, 2019). On the same day, the Service also issued final regulations that, for species listed as threatened species after September 26, 2019, eliminated the Service's general protective regulations automatically applying to threatened species the prohibitions that section 9 of the Act applies to endangered species (84 FR 44753; August 27, 2019).

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 now and in the foreseeable future.

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. The term ''foreseeable future'' extends only so far into the future as we can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define the foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The wolverine SSA report and SSA report addendum document the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the North American wolverine, including an assessment of the potential threats to the subspecies occurring in the contiguous United States. The wolverine SSA report and SSA report addendum do not represent our decision on whether the North American wolverine should be listed as an endangered or threatened species under the Act. However, they do 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 viability of the North American wolverine occurring in the contiguous United States, 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, pathogen). 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 subspecies' ecological requirements for survival and reproduction at the individual, population, and species 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 subspecies' 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 species 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 a species (which, under the Act, includes any subspecies of fish or wildlife or plants, and any DPS of any species of vertebrate fish or wildlife which interbreeds when mature) to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Later in this document, we present a summary of the key results and conclusions from the 2018 wolverine SSA report and 2023 wolverine SSA report addendum; the full SSA report and SSA report addendum can be found at Docket No. FWS–R6–ES–2023–0216 on *https://www.regulations.gov* and at *https://ecos.fws.gov/ecp/species/5123.*

Distinct Population Segment

Pursuant to the Act, we must consider for listing any species, subspecies, or, for vertebrates, any DPS of these taxa, if there is sufficient information to indicate that such action may be warranted. To interpret and implement the DPS provision of the Act and Congressional guidance, the Service and the National Marine Fisheries Service published, on February 7, 1996, an interagency Policy Regarding the Recognition of Distinct Vertebrate Population Segments under the Act (DPS policy; 61 FR 4722, February 7, 1996). The DPS policy addresses the recognition of DPSs for potential listing actions. The DPS policy allows for more refined application of the Act that better reflects the biological needs of the taxon being considered, and avoids the inclusion of entities that do not require its protective measures.

Under our DPS policy, three elements are considered in a decision regarding the status of a possible DPS as endangered or threatened under the Act. These are applied similarly for additions to the Lists of Endangered and Threatened Wildlife and Plants (Lists), reclassification, and removal from the Lists. They are: (1) Discreteness of the

population segment in relation to the remainder of the taxon; (2) the biological or ecological significance of the population segment to the taxon to which it belongs; and (3) the population segment's conservation status in relation to the Act's standards for listing (*i.e.,* whether the population segment is, when treated as if it were a species or subspecies, an endangered or threatened species). Discreteness refers to the degree of isolation of a population from other members of the species, and we evaluate this factor based on specific criteria. If a population segment is considered discrete, we must consider whether the discrete segment is ''significant'' to the taxon to which it belongs by using the best available scientific and commercial information. When determining if a potential DPS is significant, our policy directs us to sparingly list DPSs while encouraging the conservation of genetic diversity. If we determine that a population segment is both discrete and significant, we then evaluate it for endangered or threatened species status based on the Act's standards.

We have conducted several DPS analyses of wolverines in the contiguous United States since 2010 in response to new information and legal challenges. We first found that the population qualified as a DPS in our 2010 12-month finding (75 FR 78030; December 14, 2010) on a petition to list the population as a DPS. We reaffirmed and summarized this finding in our February 4, 2013, proposed listing rule (78 FR 7864). In 2020, we reversed our previous finding, based on information at the time which suggested the population was not discrete from wolverine populations in Canada (85 FR 64618; October 13, 2020). Below, we provide our revised evaluation of discreteness and significance under the DPS policy of the segment of the North American wolverine occurring in the contiguous United States. Where necessary and appropriate below, we explain how new information has led us to different conclusions from previous DPS analyses. The analysis contained in this rulemaking supersedes and replaces any previous DPS analysis for the segment of the North American wolverine occurring in the contiguous United States. We determined that the contiguous U.S. population of the North American wolverine meets the discreteness criterion in our DPS policy; it is delimited by the international boundary with Canada, and there are differences between the United States and Canada regarding control of exploitation, conservation status, and regulatory mechanisms that are significant in light of section 4(a)(1)(D) of the Act. We then determined that the North American wolverine population occurring in the contiguous United States is significant because its loss would result in a significant gap in the range of the taxon.

Distinct Population Segment Analysis for Wolverine in the Contiguous United States

Analysis of Discreteness

Under our DPS policy, a population segment of a vertebrate species may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation); or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act (inadequacy of existing regulatory mechanisms).

Discreteness Based on Marked Separation

In our February 4, 2013, proposed listing rule (78 FR 7864), we did not find marked separation from other populations to support discreteness of the contiguous U.S. wolverine population. We also did not find marked separation to support discreteness in our October 13, 2020, withdrawal (85 FR 64618). Our review of the new information presented in the 2023 wolverine SSA report addendum has not altered that conclusion; we continue to find that there are no physical, physiological, ecological, or behavioral factors separating wolverines in the contiguous United States from wolverines in Canada. We do not consider wolverines in the contiguous United States to be genetically or morphologically discontinuous from wolverines in Canada based on genetic information that supports that Canadian wolverines repopulated the contiguous United States over the past several decades and there are no unique haplotypes in the contiguous U.S. population (McKelvey et al. 2014, entire; Pilgrim and Schwartz 2018, entire; Sawaya et al. 2023, entire). Therefore, wolverines in the contiguous United States are not discrete based on marked separation from other populations of the same taxon.

We next evaluate whether the wolverine population in the contiguous United States is discrete based on the international boundary with Canada. We separately consider below whether there is discreteness based on differences between the two countries in terms of control of exploitation, management of habitat, conservation status, or regulatory mechanisms that are significant in light of section 4(a)(1)(D) of the Act (inadequacy of existing regulatory mechanisms).

Discreteness Based on the International Border—Differences in Control of Exploitation

In our 2010 12-month finding (75 FR 78030; December 14, 2010) and 2013 proposed listing rule (78 FR 7864; February 4, 2013), we noted that differences in control of exploitation exist between the United States and Canada, but concluded those differences did not result in discreteness because the differences favored the contiguous U.S. population, the population that is at risk. In the wolverine 2018 SSA report, we noted that trapping or hunting of wolverines is currently prohibited in the contiguous United States and is allowed in Canada (Service 2018, pp. 68–69). In that 2018 SSA report, we included an analysis of trapping efforts in southern Canada and trapping effort along the U.S.–Canada border, and based on that analysis, we found trapping to be limited. We again concluded in our October 13, 2020, withdrawal document (85 FR 64618) that the differences in exploitation were not significant in light of section 4(a)(1)(D) of the Act (inadequacy of existing regulatory mechanisms).

However, new information available since the publication of the October 13, 2020, withdrawal document indicates that trapping in Canada was likely causing more of an impact than previously thought. Recent studies show that harvest levels in portions of southeastern British Columbia and southwestern Alberta were unsustainable and causing population declines (Mowat et al. 2020, entire; Barrueto et al. 2022, entire). The areas evaluated are close enough to the international border that dispersing individuals would be likely to provide important genetic diversity and demographic rescue to the population in the contiguous United States. Harvest levels in Canada could negatively impact movement of individuals from Canada because, with reduced populations in Canada, there is less pressure on individuals to move south to areas in the United States to find suitable vacant home ranges (Sawaya

2023, pers. comm.). Furthermore, female wolverines appear less likely to disperse long distances or across major roadways compared to males (Sawaya et al. 2019, pp. 621–23). According to the latest genetic analyses, virtually all of the recent movement of wolverines from Canada to the United States appears to be by males (Sawaya et al. 2023, pp. 12–14, 17). Although there is now a trapping moratorium in southeastern British Columbia (British Columbia 2022, p. 76), it is unclear how long the moratorium will be in place or what the legacy effects of recent overharvest in southern British Columbia will be. In addition, trapping continues to be allowed in portions of southern Alberta. We conclude that harvest in Canada will continue to be an impediment to effective dispersal of wolverines into the United States. This, in turn, is likely to impact future genetic integrity of the population in the contiguous United States and limit the ability for demographic rescue should wolverines decline in number within the contiguous United States. Thus, we now conclude, based on new information, that the differences between Canada and the United States in control of exploitation are significant in light of section 4(a)(1)(D) of the Act. Existing regulations in Canada have been inadequate to address this exploitation. Alberta continues to allow trapping in areas important for potential dispersing wolverines, and there is uncertainty on the length and effectiveness of the trapping moratorium in British Columbia and the long-term population effects of the recent overharvest there. As a result, we conclude the wolverine population in the contiguous United States meets the standard of ''discreteness'' and we use the international border between the United States and Canada to define the northern boundary of the contiguous U.S. wolverine discrete population.

Discreteness Based on the International Border—Differences in Management of Habitat

In the 2013 proposed listing rule (78 FR 7864; February 4, 2013) and October 13, 2020, withdrawal document (85 FR 64618), we stated that management activities (*e.g.,* timber harvest, wildland firefighting, prescribed fire, and silviculture) can modify wolverine habitat, but this species appears to be little affected by changes to the vegetative characteristics of its habitat. However, recent research in Canada indicates that wolverines and other carnivores can be displaced from habitat that is subject to human disturbance that includes harvest cut-blocks in forested habitat (Frey et al. 2020, entire). That said, most wolverine habitat in the contiguous United States occurs at high elevations in rugged terrain that is not usually conducive to intensive forms of silviculture and timber harvest. Although recent information indicates wolverines may be affected by disturbance from some types of habitat management, these disturbances occur in both the contiguous United States and southern Canada, where forested alpine habitats are managed in relatively similar ways and are relatively limited in scope and scale in wolverine habitat. Therefore, there are no significant differences in management of habitat between the United States and Canada pursuant to 4(a)(1)(D) of the Act.

Discreteness Based on the International Border—Differences in Conservation Status

In the December 14, 2010, 12-month finding (75 FR 78030), which is summarized in the February 4, 2013, proposed listing rule (78 FR 7864), we found that the wolverine population in the contiguous United States met the second DPS discreteness condition because of differences in conservation status as delimited by the U.S.-Canada international governmental boundary. We found that those differences were substantial and significant in light of section 4(a)(1)(D) of the Act. We stated that in the remaining current range in Canada and Alaska, wolverines exist in well-distributed, interconnected, large populations. We added that, conversely, wolverine populations in the remaining contiguous U.S. range appear to be at numbers so low that their continued existence could be at risk, especially in light of the threats to the subspecies. In the 2010 12-month finding, we stated that risks come from three main factors: (1) Small total population size; (2) effective population size below that needed to maintain genetic diversity and demographic stability; and (3) the fragmented nature of wolverine habitat in the contiguous United States that results in smaller, isolated patches separated by unsuitable habitat. As a result, we concluded that the contiguous U.S. population of the wolverine met the discreteness criterion in our DPS policy. Consequently, we used the international border between the United States and Canada to define the northern boundary of the contiguous U.S. DPS of the North American wolverine in our December 14, 2010, 12-month finding (75 FR 78030) and our February 4, 2013, proposed listing rule (78 FR 7864).

In our October 13, 2020, withdrawal document (85 FR 64618), based on new information at the time, we concluded there were not significant differences in control of exploitation, conservation status, and management of habitat, nor other threats to the wolverine requiring regulatory mechanisms to address them, and we concluded that there are no differences in regulatory mechanisms between the United States and Canada that are significant in light of section 4(a)(1)(D) of the Act. As a result, we concluded that the contiguous U.S. population of the North American wolverine did not meet the discreteness criterion in our DPS policy. Below, we revisit discreteness based on the international border and differences in conservation status considering new information presented in the wolverine SSA report addendum.

Small Total Population Size—Wolverine population densities vary across North America and have been described as naturally low (van Zyll de Jong 1975, p. 434) given the species' large home range, wide-ranging movements, and solitary characteristics (Service 2018, p. 56). There are far fewer wolverines in the contiguous United States (around 300) than there are in Canada (more than 15,000) and Alaska (likely in the thousands) (Committee on the Status of Endangered Wildlife in Canada (COSEWIC) 2014, pp. 36, 47; Inman et al. 2013, p. 282; Service 2018, p. 71), but this is largely a reflection of the amount of suitable habitat available within the contiguous United States (both currently and historically) for a species that needs large, exclusive territories. Even if wolverines occupied all available habitat in the contiguous United States, their populations would still be relatively small compared to Canada (*i.e.,* the population capacity estimate was 644 (95% confidence interval (CI) = 506–1881) (Inman et al. 2013, p. 282). A small population in the contiguous United States would be less of a conservation concern if there were greater connectivity with the larger populations in Canada.

Recent genetic information indicates wolverines from Canada have slowly repopulated the contiguous United States over the past century since the era of unregulated predator removal (Service 2018, pp. 45–50; Sawaya 2023, pers. comm.). We stated in the December 14, 2010, 12-month finding (75 FR 78030) that differences in population sizes between the contiguous United States and Canada were reflective of a difference in conservation status. In our October 13, 2020, withdrawal document (85 FR 64618), based on new information, we concluded that the contiguous U.S. wolverines represent a peripheral

population at the southern extent of the North American wolverine's range. Thus, we considered the small population size of wolverines in the United States to be a natural result of the limited habitat available and not reflective of a difference in conservation status. Our 2020 determination on this point was made with the understanding that there was sufficient connectivity with Canada such that dispersing wolverines could bolster the small population in the contiguous United States. However, new information on wolverine dispersal and genetic connectivity indicates that wolverines appear to be impacted by recent overharvest in Canada, barriers to female wolverine dispersal, and development in dispersal corridors between suitable habitat (Barrueto et al. 2022, p. 4; Sawaya et al. 2023, pp. 12–14; Balkenhol et al. 2020, p. 799). Because of this, the small population in the contiguous United States is more at risk from future threats impacting population resiliency. We now conclude that the difference in population size on the contiguous U.S. side of the international border is a significant difference in conservation status in light of section 4(a)(1)(D) of the Act as it applies to discreteness.

Effective Population Size—In our December 14, 2010, 12-month finding (75 FR 78030) and February 4, 2013, proposed listing rule (78 FR 7864), in support of our conclusion that differences in conservation status between the United States and Canada exist that are significant in light of section 4(a)(1)(D) of the Act, we discussed the difference in wolverine effective population size between the contiguous United States and Canada. The 2013 proposed listing rule presented an effective population size estimate for wolverines in the contiguous United States from a publication by Schwartz et al. (2009), which estimated a summed effective population size of 35, with credible limits from 28 to 52 (Schwartz et al. 2009, p. 3,226). As provided in our SSA report (Service 2018, pp. 46–47), effective population sizes (N_e) are typically smaller than census population sizes. N_e is the number of individuals in a population that would result in the same loss of genetic diversity, inbreeding, and genetic drift, if they behaved in the manner of an idealized population (equal sex ratio, random mating, all adults producing offspring, equal numbers of offspring per parent, and a constant number of breeding individuals across generations) (Frankham 1995, p. 96). The concept of effective population size relates to population viability because, as a general rule, closed populations with random mating that have effective population sizes (1) below 50 are at higher risk of inbreeding depression, and (2) below 500 are more likely to lose genetic variation important to maintaining long-term evolutionary potential. In addition, small, isolated populations are more vulnerable to extinction through interactions between environmental, genetic, and demographic factors (Caughley 1994, pp. 221–227). Importantly, the concept and guidelines for genetically effective population size were developed for a single, isolated population (Laikre et al. 2016, p. 280). Fragmentation can further exacerbate inbreeding depression and genetic loss, while connectivity to larger source populations can alleviate the adverse effects of small effective population sizes (Frankham et al. 2014, p. 60).

In our October 13, 2020, withdrawal document (85 FR 64618), we acknowledged the low effective population size of wolverines in the contiguous United States but found this was not a concern given the evidence of genetic connectivity between the United States and Canada. We stated the currently known spatial distribution of genetic variability in wolverines in North America appeared to be a reflection of a complex history where population abundance has fluctuated since the time of the last glaciation and insufficient time has passed since human persecution for a full recovery of wolverine densities (Cardinal 2004, pp. 23–24; Zigouris et al. 2012, p. 1,554). Zigouris et al. (2012, p. 1,545) posit that the irregular distribution of wolverines in the southwestern periphery and the genetic diversity observed in those analyses is a result of population bottlenecks that were caused by range contractions from a panmictic (random mating) northern core population approximately 150 years ago coinciding with human persecution. We stated that very few successful migrants are needed per generation to maintain at least 95 percent of the genetic variation in the next 100 generations (approximately 750 years) in the contiguous United States (Cegelski et al. 2006, p. 209). We concluded that this level of migration from the north had already been occurring following the end of intense predator removal campaigns that affected this subspecies. Given observations of wolverines moving vast distances over varied terrain and across the U.S.–Canada border, our assessment of the low levels of trapping mortality in Canada near the border, and further confirmation of Canada as the source of wolverine genetics present in contiguous U.S. wolverines, we believed that wolverines in the contiguous United States were not separated genetically from the larger population in Canada. In our October 13, 2020, withdrawal document (85 FR 64618), we concluded that wolverines in the contiguous United States exhibit genetic and phenotypic similarities with wolverines in Canada that implied connectivity with Canada. As such, we concluded in that withdrawal document that it was not biologically appropriate to consider the low effective population size of wolverines on the contiguous U.S. side of the border as a difference in conservation status that is significant in light of section 4(a)(1)(D) of the Act as it applies to discreteness.

In our 2023 wolverine SSA report addendum, we summarized our evaluation of the available information related to the effective population size of wolverines in the contiguous United States, recent trapping/harvest in Canada, and genetic connectivity of wolverines between the United States and Canada. We are not aware of any new estimates of effective population size for wolverines in the contiguous United States; therefore, the N_e estimate of the wolverine population in the Northern Rocky Mountains (35) provided by Schwartz et al. (2009) represents the best available scientific information regarding effective population sizes in the U.S. portion of the Northern Rocky Mountains (Service 2023, p. 27). In the 2023 wolverine SSA report addendum, we estimated the effective population size of the wolverine population in the North Cascade Mountains, resulting in an estimate of $N_e = 4$ (Service 2023, p. 27). When viewed in isolation, the overall effective population sizes for wolverines in the contiguous United States are under the conservation thresholds for short- and long-term genetic health (50 and 500, respectively). New information suggests recent trapping harvest in southwestern Canada resulted in population declines in some areas that may be important sources of dispersing individuals to the contiguous United States (Service 2023, pp. 41–42). Furthermore, new information shows that female wolverine movement is influenced by major transportation corridors and that the Trans-Canada Highway could be an impediment to female movement (Service 2023, p. 28). Overall, the effective population size estimates of wolverines in the contiguous United States are small

compared to conservation rules-of-thumb and presumably smaller than the effective population size of wolverines in Canada. Only one or two migrants per generation are likely needed to achieve genetic population connectivity (Cegelski et al. 2006, p. 13); however, based on new information on gene flow and dispersal, we cannot assume this level of immigration from Canada is occurring. The contiguous U.S. population may be at risk of impacts from low effective population size without sufficient gene flow with Canada. We now conclude that the difference in effective population size on the U.S. side of the international border results in a significant difference in conservation status in light of section 4(a)(1)(D) of the Act as it applies to discreteness.

Habitat Fragmentation—In our December 14, 2010, 12-month finding (75 FR 78030) and February 4, 2013, proposed listing rule (78 FR 7864), we stated that wolverine habitat in the contiguous United States consists of small, isolated areas of high-elevation habitat separated from each other by low valleys of unsuitable habitat. We also described that these 'habitat islands' are represented by areas containing spring snow, citing Copeland et al. (2010). We concluded that the fragmented nature and distribution of wolverine habitat in the contiguous United States results in a population that is highly vulnerable to extirpation because of lack of connectivity between subpopulations, and this also makes them more vulnerable to external threats (75 FR 78030; December 14, 2010). This was used to support our justification for discreteness.

The breeding range of wolverines in the contiguous United States largely exists in high-elevation alpine forested habitats. Those alpine areas with established wolverine home ranges are separated by expanses of lower elevation valley habitats that are not conducive to wolverine home range establishment but do provide varying levels of connectivity between home ranges or subpopulations. In Canada and Alaska, habitats are more contiguous and much less fragmented than wolverine habitat in the contiguous United States. The fragmented nature and distribution of wolverine habitat in the contiguous United States puts wolverines occurring in the contiguous United States at higher risk of impacts from climate change and other stressors compared to wolverines occurring in Canada and Alaska. We conclude that the difference in habitat fragmentation on the contiguous U.S. side of the international border results in a significant difference in conservation status in light of section 4(a)(1)(D) of the Act as it applies to discreteness.

Discreteness Based on the International Border—Differences in Regulatory Mechanisms

Wolverines are currently protected under various State regulatory designations in the States where the species occurs in the western United States (Service 2023, table 10). In Canada, provincial designations for the wolverine include endangered in Labrador, and threatened in Ontario and Québec (''threatened'' is equivalent to endangered in Québec), with the remaining provincial designations ranging from no ranking to sensitive or special concern to the Vancouver Island population's designation as imperiled (COSEWIC 2014, p. 44).

Current regulatory mechanisms prohibit trapping or harvest of wolverines in the contiguous United States, while trapping is legal in Canada and occurs in parts of the range that could be a source of important dispersers to the contiguous United States. We acknowledge that there is currently a trapping moratorium in a portion of British Columbia resulting from studies showing population declines in that area related to trapping (Service 2023, pp. 44–45). However, that moratorium is temporary and only covers a portion of the Canadian range (*e.g.,* it does not include Alberta). As discussed above, there are significant differences in control of exploitation that may be impeding movement of wolverines, from Canada to the contiguous United States. We conclude that there are differences in regulatory mechanisms related to control of exploitation between the United States and Canada that are significant in light of section 4(a)(1)(D) of the Act.

Discreteness Conclusion

Based on our updated analysis described above and supported by information in the wolverine SSA report and the wolverine SSA report addendum, the contiguous U.S. population of the North American wolverine meets the discreteness criterion in our DPS policy (61 FR 4722; February 7, 1996). It is delimited by the international boundary with Canada, given differences in control of exploitation, conservation status, and regulatory mechanisms that are significant in light of section 4(a)(1)(D) of the Act. After determining that a vertebrate population is discrete, we are required to complete an analysis to determine if the population in question is significant according to our DPS policy; that analysis follows.

Analysis of Significance

If we determine a population segment is discrete, its biological and ecological significance will then be considered in light of Congressional guidance that the authority to list DPSs be used sparingly while encouraging the conservation of genetic diversity. In carrying out this examination, we consider available scientific evidence of the population's importance to the taxon to which it belongs (*i.e.,* the North American wolverine). Our DPS policy states that this consideration may include, but is not limited to: (1) persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; or (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics. Below, we address considerations 1, 2, and 4. Consideration 3 does not apply to the continental U.S. wolverine population because North American wolverines are distributed widely across Alaska and Canada.

In our December 14, 2010, 12-month finding (75 FR 78030), we conducted an exhaustive analysis of the significance of the contiguous U.S. population of the North American wolverine; this analysis was incorporated by reference into our February 4, 2013, proposed listing rule (78 FR 7864). In the analysis, we concluded that the wolverine population in the contiguous United States is significant because its loss would result in a significant gap in the range of the taxon. In our October 13, 2020, withdrawal document (85 FR 64618), we did not present an assessment of significance under the DPS policy because, at that time, we determined that the wolverine population in the contiguous United States was not discrete, and thus there was no need to assess significance. Because we have now determined the wolverine population in the contiguous United States is discrete, we reviewed and present an update to our 2010 and 2013 assessment of the significance of the wolverine population occurring in the contiguous United States using the best available information.

Unusual or Unique Ecological Setting

Wolverines occupy a variety of habitats within North America, including Arctic tundra, subarctic-alpine tundra, boreal forest, mixed forest, redwood forest, and coniferous forest (Banci 1994, p. 114). Wolverines in the contiguous United States exist in an ecosystem that includes high-elevation, remote, rugged, alpine forested terrain and non-forested habitats around the tree line that retain snowpack into the spring. The ecoregions inhabited by wolverines in the contiguous United States are also present in large portions of their occupied range in Canada and Alaska (Service 2018, appendix A).

Wolverines in the contiguous United States appear to use habitat attributes that are similar to wolverine populations in Canada and Alaska, where wolverines also use alpine habitats, and do not appear to exist in an unusual or unique ecological setting. Thus, we again do not rely on this factor when determining that the wolverine in the contiguous United States is significant to the taxon as a whole.

Significant Gap in the Range of the Taxon

Wolverines once lived throughout the North American Rocky Mountains from Alaska and Canada, south through Colorado and into New Mexico, and in the North Cascades of Washington and the Sierra Nevada Range of California. During the late 1800s and early 1900s, the wolverine population declined or was extirpated in much of the contiguous United States (Service 2018, p. 1). Wolverines have since recolonized parts of the contiguous United States, and the current breeding range includes the Southern Rocky Mountains of Idaho, Montana, and Wyoming and the Cascades of Washington (Service 2023, figure 3). Individual wolverines have been documented in California, Colorado, Oregon, and Utah; however, breeding populations are not known to exist in these areas. The contiguous United States represents the southernmost extent of the wolverine's range in North America.

Our significance determination in the December 14, 2010, 12-month finding (75 FR 78030) concluded that the loss of wolverines in the contiguous United States would result in a significant gap in the range of the taxon. This determination was based on an estimate of the historical range (not current range) of wolverine in the contiguous United States. This relied on a latitudinally-based interpretation of historical range in the contiguous United States, the majority of which was unoccupied at the time the estimation was made and remains unoccupied by wolverines. We stated in 2010 that the loss of the population in the contiguous United States would be significant because it would substantially curtail the range of the wolverine by moving the southern range terminus approximately 15 degrees latitude to the north (or approximately 40 percent of the presumed latitudinal extent of the wolverine's range in North America). For reference, the U.S. border with Canada is 49 degrees North latitude. Fifteen degrees south of the border (at 34 degrees North latitude), the assumed 15-degree gap in latitude (49 degrees North minus 34 degrees North) presented in the DPS analysis in the December 14, 2010, 12-month finding (75 FR 78030), lands on 34 degrees North latitude, which runs through western States, including southern California and approximately the middle of Arizona and New Mexico, significantly south of the currently occupied range of wolverine in United States.

During the development of our 2018 wolverine SSA report and 2023 SSA report addendum, we conducted an extensive analysis of the recent and historical occurrence records for wolverines in the contiguous United States (Service 2018, pp. 12–16; Service 2023, pp. 3–14). Our updated significance analysis is based on an updated, spatially explicit assessment of the current range of wolverines in the contiguous United States. We used the current range (Service 2023, figure 2) to provide a more accurate reflection of the range currently being used by populations of wolverines in the contiguous United States supported by the best available information. By focusing on the current range, and not the historical range, we avoid including large sections of the western United States that do not have high-quality wolverine habitat (southern California and northern Arizona and New Mexico) in our significance analysis, and thus we are able to better assess the significance of the population in the contiguous United States relative to the larger taxon. The current range of wolverines in the contiguous United States covers approximately 58,998,140 acres (238,757 km^2) of high-quality wolverine habitat with recent wolverine occurrences (from 2009–2023) (Service 2023, figure 2), the loss of which would move the southern range terminus approximately 12 degrees latitude to the north.

Furthermore, the southernmost portion of the range may be important for conservation, as it may allow for unique adaptive potential in the face of a changing global climate and future reduction in cold and snowy conditions. Populations on the periphery of species' ranges tend to be given lower conservation priority because they are thought to exist in low-quality habitats and are also thought to be the populations that are least likely to survive a reduction in range (Wolf et al. 1996, p. 1147). However, this tendency presumes that the ultimate cause of the species' extinction will be one that operates by eroding away the species' range beginning at the periphery and progressing to the center. This presumption is based on biogeographical information that habitat and population densities of species are highest near the center of the species' range and decline near the edge (Brown and Lomolino 1998, figure 4.16). Data from documented range collapses of species from around the world, however, illustrate that species' ranges tend to collapse to peripheral areas rather than to the center of their historical ranges (Lomolino and Channell 1995, p. 342; Channell and Lomolino 2000, pp. 84–86). Of 96 species whose last remnant populations were found either in the core or periphery of their historic ranges (rather than some in both core and periphery), 91 (95 percent) of the species were found to exist only in the periphery, and 5 (5 percent) existed solely in the center (Channell and Lomolino 2000, p. 85). Available scientific data support the importance of peripheral populations for conservation (Fraser 1999, entire; Lesica and Allendorf 1995, entire).

Based upon the loss of approximately 58,998,140 acres (238,757 km^2) of high-quality wolverine habitat from the southern extent of the range and the adaptive potential that part of the range may provide against oncoming climate change impacts, and a 12 degree latitudinal gap in the North American wolverine's range that would result if the U.S. population was lost, we determine that the loss of the contiguous U.S. wolverine population would result in a significant gap in the range of the taxon. Thus, the DPS meets the definition of significant in our DPS policy.

Marked Genetic Differences

In the contiguous United States, small, isolated wolverine populations are likely dependent on gene flow from Canada for population persistence (Cegelski et al. 2006, pp. 208–209; McKelvey et al. 2014, entire). In the Northern Rocky Mountains, the best available genetic data indicate genetic

structuring of populations despite some dispersal (Cegelski et al. 2006, pp. 204–205, 208; Sawaya et al. 2023, pp. 12–14). Genetic structuring reflects the amount of interbreeding between different groups of an organism where more structure indicates less interaction between groups, increased genetic isolation, increased potential for inbreeding, and lower genetic diversity. Given the relatively recent recolonization of wolverines in the contiguous United States from Canada (within the last 60–70 years), nuclear genetic diversity was lower in the southern periphery of the subspecies' range in the south (Sawaya et al. 2023, pp. 9–11). Nuclear DNA analyses indicated differences in allele frequencies between the United States and Canada along the Rocky Mountains, with some areas of overlap in wolverine populations straddling the border due to male-mediated gene flow. Females appear to be segregated near the international border due to their higher rates of philopatry (the tendency of an animal to remain in or return to the area of its birth) than males and their apparently greater tendencies to avoid crossing major roadways, including the Trans-Canada Highway (Highway 1) and the Crowsnest Highway (Highway 3) in southern British Columbia (Sawaya et al. 2023, pp. 12, 17). Both highways were opened in the 1960s (British Columbia Ministry of Transportation and Highways 2001, pp. 16, 20). Since then, they have been widened in many areas, and traffic volumes have substantially increased (British Columbia Ministry of Transportation and Highways 2001, pp. 7–11, 16–21). Mitochondrial DNA patterns in the Rocky Mountains showed no unique contemporary maternal lineages detected south of the international border, which is consistent with observational data indicating that wolverines recolonized the contiguous United States from Canada within the last 60–70 years (Sawaya et al. 2023, pp. 2, 16–17). Substantially lower mitochondrial DNA diversity in the United States, as compared to mitochondrial DNA diversity in Canada, is consistent with the nuclear DNA signals of limited contemporary female gene flow between the countries along the Northern Rocky Mountain range and the wolverine's relatively recent recolonization at the southern edge of their range (Sawaya et al. 2023, p. 17).

In the North Cascades, global positioning system (GPS) tracking data show that wolverines in western Washington and southern British Columbia form a small transboundary population (Aubry et al. 2023, p. 4). Preliminary results from a large population genetics study of this transboundary population show that wolverines in the North Cascades are genetically isolated from other wolverine populations in the United States and Canada and likely went through a genetic bottleneck with few founders (Sawaya 2023, pers. comm.). The population has low heterozygosity (less than 0.5) and could be experiencing some level of inbreeding (Sawaya 2023, pers. comm.). However, there are no indications or evidence that individuals or population dynamics are being adversely affected by inbreeding depression (Sawaya 2023, pers. comm.).

As part of the multi-State wolverine occupancy surveys in 2016–2017, researchers obtained 240 wolverine DNA samples (Lukas et al. 2020, p. 846). These samples represented 26 unique females and 24 unique males (Lukas et al. 2020, p. 846). Analyses of the mitochondrial DNA control region revealed regional structuring (*i.e.,* regional grouping), with all of the samples in Idaho, Montana, and Wyoming assigned to Haplotype Wilson A (the most abundant haplotype in North America) and all of the samples in Washington assigned to Haplotype Wilson C (Lukas et al. 2020, p. 846). These results are consistent with the latest genetic analysis from the large transboundary study (Sawaya et al. 2023, entire) and previous mitochondrial DNA studies showing that the Northern Rocky Mountains and North Cascades do not appear to share any contemporary haplotypes (McKelvey et al. 2014, p. 328).

The genetic differences between the contiguous United States and Canada consist of lower genetic diversity in the United States, a difference that is a reflection of the recent recolonization of wolverines into the contiguous United States from Canada over the last century. There are no unique haplotypes present in contiguous U.S. wolverines that are not already present in larger populations in Canada and Alaska. As we noted in our analysis in the December 14, 2010, 12-month finding (75 FR 78030), this is not the kind of genetic difference that would lead us to conclude that a population is significant under our DPS policy. The DPS policy is designed to ensure the protection of important components of a species' evolutionary legacy rather than populations that simply have lower genetic diversity due to recent recolonization from a larger source population. Therefore, as in our 2010 analysis, we do not find marked genetic differences as a basis for determining significance for this DPS.

Summary for Significance

We evaluated whether the discrete population segment of wolverines in the contiguous United States is also significant, considering factors such as whether the population segment is in an ecological setting unusual or unique for the taxon; whether the loss of the discrete population segment would result in a significant gap in the range of a taxon; whether the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; or whether the discrete population segment differs markedly from other populations of the species in its genetic characteristics. We conclude that the wolverine population in the contiguous United States is significant because its loss would result in a significant gap in the range of the taxon.

DPS Conclusion

Based on the best available information, we conclude that the population of wolverines in the contiguous United States is discrete and significant in relation to the remainder of the subspecies in North America. As a result, the population of wolverines in the contiguous United States is a listable entity under section 3(16) of the Act.

The DPS policy sets forth a three-step process for determining whether a vertebrate population as a separate entity warrants listing: (1) Determine whether the population is discrete; (2) if the population is discrete, determine whether the population is significant to the taxon as a whole; and (3) if the population is both discrete and significant, then evaluate the conservation status of the population to determine whether it is endangered or threatened. We have determined that wolverines in the contiguous United States qualify as a DPS and, therefore, are a listable entity. Below, we provide a status determination of the wolverine DPS in the contiguous United States.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the DPS and its resources, and the threats that influence the DPS's current and future condition, in order to assess the DPS's overall viability and the risks to that viability.

In preparing the 2018 wolverine SSA report and the 2023 SSA report addendum, we reviewed available reports and peer-reviewed literature, incorporated survey information, and

contacted species experts to collect additional unpublished information for the North American subspecies (*Gulo gulo luscus*). We identified uncertainties and data gaps in our assessment of the current and future status of the subspecies. We also evaluated the appropriate analytical tools to address these gaps, consulted with species experts, prepared updated maps of the known subspecies' distribution and breeding range in the contiguous United States, and evaluated new models of spring snow. In some instances, we used publications and other reports (primarily from Fenno-Scandinavia) of the Eurasian subspecies (*G. g. gulo*) as a surrogate in completing our status assessment.

Since the publication of the October 13, 2020, withdrawal document (85 FR 64618), more than 180 new publications have been issued (see list of citations in the 2023 wolverine SSA report addendum). This is a substantial amount of new information for a difficult-to-study animal like the wolverine and has added significantly to our understanding of wolverine biology. This new information has also highlighted new insights into the subspecies' biological needs, threats, and the wolverine's interactions with abiotic and biotic habitat features.

We also conducted an updated geospatial analysis to map verified wolverine occurrences and approximate breeding ranges in the contiguous United States. This was informed by recent multi-State monitoring data (Lukas et al. 2020, entire; Mosby et al. 2023, entire).

Our updated analyses, since the publication of the October 13, 2020, withdrawal document, of the current and predicted future condition for the wolverine is presented in the wolverine SSA report addendum and summarized here. Our future-condition analysis includes the potential conditions that the subspecies or its habitat may face in the future. This includes consideration of threats most likely to impact the subspecies at the population or rangewide scales in the future, including potential cumulative impacts. The spatial expansion to our climate analysis is a major improvement from the snow projections used in our 2018 SSA report, which focused only on Rocky Mountain National Park (Colorado) and Glacier National Park (Montana). We now focus on five modeling domains that overlap with occupied and potential wolverine habitat in the contiguous United States across latitudinal, longitudinal, and elevation gradients. These include: (1) Cascades (Washington); (2) Northern Rocky West (Washington, Idaho, and Montana); (3) Northern Rocky (Idaho and Montana); (4) Mid-Rocky (Idaho, Montana, and Wyoming); and (5) Southern Rocky (Colorado and New Mexico) (Service 2023, p. 49). In our updated climate assessment, we use a timeframe out to end of century for assessing future effects to North American wolverine viability from climate change and other threats. Beyond 2100, climate modeling uncertainty increases substantially. Our previous assessment considered in the October 13, 2020, withdrawal document (85 FR 64618) looked at a timeframe 50 years into the future. We conclude that end of century is a reasonable timeframe, as it includes the potential for observing these effects over several generations of the wolverine.

As discussed above in *Analytical Framework,* we consider what the subspecies needs to maintain viability by characterizing the status of the subspecies in terms of resiliency, redundancy, and representation (Wolf et al. 2015, entire). Resiliency is having sufficiently large populations for the subspecies to withstand stochastic events (arising from random factors). We can measure resiliency based on metrics of population health (for example, birth versus death rates and population size). Resilient populations are better able to withstand disturbances such as random fluctuations in birth rates (demographic stochasticity), variations in rainfall (environmental stochasticity), or the effects of anthropogenic activities.

Redundancy is having a sufficient number of populations for the subspecies to withstand catastrophic events (such as a rare destructive natural event or episode involving many populations). Redundancy is about spreading the risk and can be measured through the duplication and distribution of populations across the range of the subspecies. The greater the number of populations a subspecies has distributed over a larger landscape, the better it can withstand catastrophic events.

Representation is having the breadth of genetic makeup of the subspecies to adapt to changing environmental conditions. Representation can be measured through the genetic diversity within and among populations and the ecological diversity (also called environmental variation or diversity) of populations across the subspecies' range. The more representation, or diversity, a subspecies has, the more it is capable of adapting to changes (natural or human-caused) in its environment. In the absence of subspecies-specific genetic and ecological diversity information, we evaluate representation based on the extent and variability of habitat characteristics within the geographical range.

Life-History Needs

Wolverine populations are characterized by naturally low densities. The species is highly territorial, with very little overlap between same-sex adults. Wolverines occupy a variety of habitats, but generally select habitat in locations away from human settlements and activities. The wolverine is a snow-adapted, cold-climate animal in its physiology and morphology (Telfer and Kelsall 1984, p. 1830); phylogeography (historical processes that may be responsible for past and present geographic distributions of genealogical lineages); and behavior and habits (Fisher et al. 2022, p. 7).

Wolverines consume a variety of food resources, and seasonal switching of prey is commonly observed. Unlike wolverine populations in Eurasia, wolverines in the contiguous United States rarely prey on livestock. During our extensive literature review in preparing the 2023 wolverine SSA report addendum, we discovered only two instances of wolverine depredation in the United States since our 2018 SSA report; one wolverine that had depredated sheep in Utah, and another that was caught in a chicken coop in Washington (Service 2023, pp. 10, 38).

Wolverine reproduction includes the following characteristics: polygamous behavior (*i.e.,* male mates with more than one female each year), delayed implantation (up to 6 months), a short gestation period (30–40 days), denning behavior (only observed in snow in the contiguous United States), and several additional months of maternal care (Service 2018, p. 22). The reproductive behavior in wolverines is temporally adapted to take advantage of the availability of food resources, limited interspecific competition, and snow cover in the winter.

In our 2018 wolverine SSA report, we defined the physical and ecological requirements of wolverine in the contiguous United States (see (1), (2), and (3), below). In light of new information regarding wolverine habitat associations that provides support for the wolverine's strong preference for areas with cold and snowy conditions, we have added a fourth ecological requirement (see (4), below). The requirements are:

(1) Large territories in relatively inaccessible landscapes, at high elevation (1,800 to 3,500 m (5,906 to 11,483 ft));

(2) Access to a variety of food resources that vary with seasons;

(3) Physical/structural features (*e.g.,* talus slopes, rugged terrain) linked to reproductive behavioral patterns; and

(4) Habitats characterized by the presence of persistent spring snow (of greater than or equal to 1 meter on May 1) for survival and reproduction.

Our 2023 wolverine SSA report addendum affirms these requirements and the species characterization in our 2018 SSA report.

Habitat

Research published since our 2018 wolverine SSA report confirms that broad-level habitat selection (subspecies' range, individual home range) at the southern edge of the wolverine's distribution can be accurately predicted using a small number of high-elevation variables and terrain features (Carroll et al. 2021a, pp. 1470–1471; Aubry et al. 2023, p. 7). New evidence from around the world reinforces that snow—especially persistent spring snow—is an important predictor of broad-scale wolverine distribution and density (Aubry et al. 2023, pp. 15–16; Carroll et al. 2020, p. 8; Fisher et al. 2022, p. 10; Glass et al. 2021, entire; Mowat et al. 2020, p. 220). Within home ranges, the precise nature of the relationship between wolverine space-use and snow is complex, involving multiple snow characteristics (*e.g.,* density, depth, and melt), various phases of the wolverine lifecycle (*e.g.,* denning, feeding and food caching, within-territory movements, and dispersal) and sex-specific habitat selection (Carroll et al. 2021, p. 1469; Glass et al. 2021, entire; Heinemeyer et al. 2019, p. 16). While wolverines appear capable of occupying and reproducing in areas without persistent spring snow in some ecological contexts, at a continent-wide scale, wolverine dens outside of areas with persistent spring snow have thus far only been documented to occur in colder boreal or arctic environments in Canada and Alaska (Aronsson and Persson 2017, p. 266; Copeland et al. 2010, pp. 240–242; Fisher et al. 2022, p. 8; Jokinen et al. 2019, pp. 6–8; Webb et al. 2016, pp. 1466–1467).

In the Greater Yellowstone Ecosystem, distance to high-elevation talus, snow water equivalent (a surrogate for snow depth), and latitude-adjusted elevation were the most important environmental factors explaining selection of wolverine home ranges and habitats within home ranges (Service 2023, p. 16). These habitat variables are also known to be important in defining the wolverine's distribution (Inman et al. 2013, p. 278).

Results from dispersal suitability models developed for wolverines indicate that isolation by landscape resistance (areas that individuals are less likely to traverse due to high energy, mortality, or other biological costs) explained more of the variation in wolverine genetic differences than did isolation by distance (Balkenhol et al. 2020, pp. 795–797). This means that wolverines are moving non-randomly across the landscape in association with specific landscape features. Snow depth (average 1-year snow depth at 1-km^2 resolution), terrain ruggedness (measure of how jagged or flat the terrain is on average), and housing density (census block housing density per 1 km^2) best predicted gene flow in wolverines (Balkenhol et al. 2020, pp. 795–797). Snow depth was the most important variable for explaining variation in genetic differences overall (Balkenhol et al. 2020, p. 790). At broad spatial scales, housing density and terrain ruggedness were the most important factors, where wolverines avoided areas of high housing density and preferred areas of terrain ruggedness, which explains the variation in wolverine genetic differences (Balkenhol et al. 2020, p. 790).

In the Cascade Range in southern British Columbia and Washington, three climatic variables (proximity to the transitional zone near the alpine tree line, number of frost-free days per year, and annual precipitation as snow) were correlated with wolverine location data (Aubry et al. 2023, p. 10). Wolverine distribution in the Cascades is constrained by climatic conditions; snowy, cold environments delimit the areas that are ''overwhelmingly associated with resident wolverines'' (Aubry et al. 2023, p. 16). The highest-use areas were on the eastern side of the Cascades, where alpine habitats had fewer frost-free days (Aubry et al. 2023, p. 15). This is consistent with other models, indicating that wolverines rely on the transitional zone between the tree line, below which environmental conditions become too warm, and upper elevations of permanent ice and snow, where there is insufficient food and cover to support basic life-history requirements for wolverines (Aubry et al. 2023, pp. 13–14).

A study using GPS location data on 38 wolverines from 2001 to 2010 analyzed wolverine home range habitat selection across the western United States by identifying landscape variables that were highly correlated with wolverine home ranges (Carroll et al. 2020, entire). The resource selection function model included landform (*e.g.,* ridges and peaks), vegetation classification, distance to high-elevation talus, latitude-adjusted elevation, average monthly snow water equivalent, and human modification (Carroll et al. 2020, p. 8). Core areas were identified, and connectivity was assessed, between these core areas using a landscape resistance model, validated with GPS location data from dispersing wolverines (Service 2023, figure 3). Results showed that resident wolverines in core habitats are far more sensitive to low-quality habitat than are dispersing individuals, but that dispersers still follow lower-resistance pathways that connect higher quality core habitats (Carroll et al. 2020, p. 9). Another study modeled within-home range habitat selection by wolverines in areas of the Northern Rocky Mountains with high amounts of winter backcountry recreation and found significant differences in male and female habitat selection (Heinemeyer et al. 2019a, p. 9). The best model for male wolverines included distance to roads and proportion of lower elevation grass and shrub cover, while the best model for female wolverines included talus, persistent spring snow cover (defined in the cited studies as snow cover present between April 24 and May 15), and forest edge-to-area covariates (Heinemeyer et al. 2019a, p. 9). Best models for both sexes included covariates for topographic position index, quadratic form of slope, distance to forest edge, solar insulation, and percentage cover of forest, riparian, and montane open cover types. This study also showed that wolverines are negatively affected by winter recreation (see *Disturbance Due to Winter Recreational Activity,* below).

Multiple recent studies in Canada have provided further evidence of the influence of snow cover and human development/disturbance on wolverine distribution. Wolverine density in and around a national park complex in the southern Canadian Rocky Mountains was three times higher within these national parks than outside them, increased with spring snow cover, and decreased with increasing night light intensity (a measure of human development) (Barrueto et al. 2022, p. 4). Along the Front Range of the Canadian Rocky Mountains, wolverines selected areas with natural land-cover and high snow cover and avoided anthropogenic features and heterospecific competitors (Heim et al. 2019, pp. 2499–2502). In the Rocky Mountains of Alberta, wolverine occurrence in space and time was best explained by coyote (*Canis latrans*) occurrence and the density of linear

disturbance features (*e.g.,* roads, pipelines, seismic lines, motorized and nonmotorized recreational trails), with both of these factors decreasing the likelihood of wolverine occurrence (Chow-Fraser et al. 2022, pp. 4–5). In the southern Canadian Rockies, wolverine density was found to be positively correlated with the number of years of persistent spring snow cover and negatively correlated with road density (Clevenger 2019, p. 62; Mowat et al. 2020, pp. 218–219). Female densities in areas with more cumulative years of persistent spring snow were higher than male densities, which suggests there may be a preference for snowy areas when denning. An additional study, also in the Canadian Rockies, found that food availability and human disturbance were major drivers of wolverine distribution in winter (Kortello et al. 2019, p. 7). Persistent spring snow was an important factor in explaining the variation in female wolverine distribution in winter and overall wolverine distribution at coarse scales (Kortello et al. 2019, p. 8). The researchers concluded that their results ''do not reject the hypothesis that wolverine occurrence is constrained by an obligate association with persistent spring snow'' (Aubry et al. 2007, p. 2154; Copeland et al. 2010, p. 244), ''but do suggest the alternative explanation that the relationship between spring snow and wolverine distribution could be functionally related to the distribution of food, disturbance or mortality risk'' (Kortello et al. 2019, p. 8). We agree with their assessment and acknowledge the precise causal mechanism(s) for the apparent association of wolverine distribution and persistent spring snow are not yet clear. There may be a number of factors acting in concert to drive the wolverine's preference for cold and snowy conditions, and we have attempted to account for this in our analysis presented in this rule.

A habitat selection study of 21 adult, non-denning wolverines (11 female, 10 male) fitted with GPS collars in the Alaskan Arctic found that wolverines generally selected more rugged areas closer to streams, rivers, and lakes (Glass et al. 2021, p. 893). This study also showed that snow characteristics are important to wolverines for reasons other than solely creating reproductive dens. Specifically, they found that non-denning wolverines select deeper, denser snow, but only when that snow is not undergoing melt (Glass et al. 2021, pp. 894–895). The wolverine's observed preference for denser snow might be a function of both ease of movement across the surface, as well as the ability of denser snow to maintain snow cavities and tunnels (Glass et al. 2021, p. 895).

Denning Habitat—Denning habitat has been a focus for wolverine conservation because wolverines have naturally low reproductive rates. Impacts to denning habitat could have important consequences for demographic rates (Fisher et al. 2022, p. 8). There is growing evidence that wolverines rely on subnivean space (the environment between snow and terrain) for thermoregulation, to escape predation risk, and/or to cache food (van der Veen et al. 2020, pp. 8–10; Fisher et al. 2022, p. 10). Although wolverines have been documented denning in areas without persistent spring snow (Fisher et al. 2022, p. 8; Persson et al. 2023, entire), this phenomenon appears to be associated with cold, high-latitude boreal or arctic forests rather than the alpine habitats used by wolverines in the contiguous United States. In the contiguous United States, there is no evidence that wolverines have denned in areas without persistent spring snow.

Den-shifting behavior represents a tradeoff between moving—and risking potential energy loss and harm to offspring—versus staying in the original den site and risking exposure to disturbance or changed conditions, such as melting snow, that might make the original den site unsuitable (Heeres 2020, p. 9). In a study in northern Sweden focusing on 18 adult female wolverines fitted with GPS collars over an 11-year period and occupying 271 den sites, Heeres (2020, p. 15) determined that a female used an average of 12 den sites during a single denning season (range: 4–28; median: 10). Additionally, female wolverines had a higher probability of shifting den sites in forested habitats, compared to alpine habitats, which is likely a result of earlier snow melt in forests that may make den sites uninhabitable early in the season (Heeres 2020, p. 20). Other factors related to den-shifting behavior included the level of denning experience of the female wolverine, which was quantified as the number of previous reproductive attempts by an individual (lower den-shift probability), temperature (higher den-shift probability in the warmer forested habitats; nonsignificant den-shift probability in alpine habitat), food resource availability (higher den-shift probability, which could be related to accessing food or increased human presence), and cub age (more shifting as cubs mature and are able to move to food resources) (Heeres 2020, pp. 20–22).

In certain ecological contexts, individual wolverines and reproductive dens can exist in areas without substantial spring snowpack (Persson et al. 2023, p. 10; Jokinen et al. 2019, pp. 4–9). For example, Jokinen et al. (2019, pp. 6, 10) observed seven of eight wolverine dens (three primary and five secondary dens) in hollows of uprooted trees and not in snow; however, the researchers acknowledged that sample sizes were small and limited their ability to draw robust conclusions. Jokinen et al. (2019, p. 12) speculated that wolverines, in the absence of spring snow in Alberta, were able to meet their physiological needs through locally available features such as the cavity created by partially uplifted root masses, the thermal properties of thick moss, and the caching opportunities provided by deep peat accumulations. Wolverines are resourceful and may be more flexible in their denning requirements than documented by studies in other landscapes (Persson et al. 2023, p. 10; Jokinen et al. 2019, p. 12; Glass et al. 2021, entire); however, it is also apparent that boreal forest communities have a series of unique properties conducive to wolverine denning, including cold spring temperatures and dense peat layers that might aid in insulating the den (Jokinen et al. 2019, p. 12).

At present, it remains uncertain whether the alpine ecosystems in the contiguous United States contain environmental conditions that would allow wolverines to switch denning behavior or use smaller or shallower patches of snow in response to changes in future snow under a changing climate. Even if they were able to make this shift, snow may be important to wolverines for more than just denning.

Food Caching—Wolverines are physiologically and behaviorally adapted to caching perishable food in snow, boulders, and peat bogs for short- or long-term storage (van der Veen et al. 2020, pp. 2–3). In Scandinavia, wolverines cached food all year from scavenging and predation events, with the locations of food caches widely distributed across their home ranges (van der Veen et al. 2020, pp. 6–8). When caching, wolverines selected steep and rugged terrain in unproductive habitat types (habitats with fewer plants and animals) or in forest, indicating a preference for less-exposed sites that can provide cold storage or protection against pilferage. The observed year-round investment in caching by wolverines suggests that food predictability is important for their

survival and reproductive success. Increasing temperatures caused by climate change may provide new challenges for wolverines in at least two ways: (1) by decreasing the shelf-life of cached food, and (2) by increasing competition from pilferers that benefit from a warmer climate (van der Veen et al. 2020, pp. 8–10).

Areas of Uncertainty for Wolverine Habitat Needs

The precise causal mechanism(s) for the apparent association of wolverine distribution and persistent spring snow are not yet clear. Hypotheses for this association include the importance of snow to create dens (Copeland et al. 2010, entire), the advantages of snow for catching prey within a wolverine's metabolic limits (Young et al. 2012, pp. 224–226), competitive advantages over other scavengers and predators in snow-covered areas (Service 2018, p. 6), thermoregulation (Service 2018, pp. 7–8), food storage and refrigeration (Inman et al. 2012, p. 640), or some combination of these factors. The interplay of temperature and persistence of spring snow and the point at which temperature becomes limiting is also unknown.

There is presumably some limit in appropriate habitat availability at which wolverines will not cross certain habitats or traverse certain barriers, but that threshold is not known. Understanding this threshold for females is particularly important because they often disperse shorter distances than males and appear to be more affected by potential barriers to movement, such as large multi-lane highways (*e.g.,* Sawaya et al. 2019, pp. 621–623).

Recent studies from Canada and Alaska have shown that apex predators and sympatric mesocarnivores (small to mid-sized carnivores that occur in the same area) can influence wolverine space use (*e.g.,* Heim et al. 2019, pp. 2499–2504; Frey et al. 2020, pp. 1133–1137; Bell 2021, pp. 46–47; Klauder et al. 2021, p. 569; Chow-Fraser et al. 2022, p. 4). In addition, it is possible that competitors such as coyotes that thrive within human-dominated landscapes could potentially displace wolverines in areas with substantial anthropogenic disturbance (Chow-Fraser et al. 2022, pp. 4–5). However, the influence of apex predators and intraguild competition on wolverine distribution, abundance, and dispersal in the contiguous United States remains largely unstudied.

Threats

A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (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. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Threats evaluated for the wolverine in the contiguous United States include climate change (Factors A and E), effects from roads (Factors A and E), disturbance due to winter recreational activity (Factors A and E), other human disturbance (Factors A and E), effects from wildland fire (Factor A), disease (Factor C), predation (Factor C), overutilization (trapping) (Factor B), genetic diversity (Factor E), and small population effects (Factor E). We found that habitat loss as a result of climate change is the primary threat to the wolverine's future viability in the contiguous United States. We expect climate change to exacerbate effects from multi-lane roads, backcountry winter recreation, and human development, all of which could then impact genetic diversity and small population dynamics. A summary of the threats affecting the North American wolverine in the contiguous United States is presented below; for a full description of our evaluation of the effects of these stressors, refer to the wolverine SSA report (Service 2018, pp. 57–101) and the 2023 wolverine SSA report addendum (Service 2023, pp. 30–47).

Climate Change: The wolverine's evolutionary and phylogeographic history suggest a species adapted to cold and snowy climate conditions (Fisher et al. 2022, p. 7; Service 2023, pp. 24–25). The wolverine is a snow-adapted, cold climate animal in its physiology, morphology (Telfer and Kelsall 1984, p. 1,830), behavior, and habits. Wolverines have been classified as a ''chionphile'' or those animals with adaptations for snow (*e.g.,* increased surface area on feet, pelt characteristics) (see definitions in Pruitt 1959, p. 172; Cathcart 2014, p. 22). We find that impacts from climate change (increasing temperatures and decreasing snowpack) have the largest potential to influence the North American wolverine's population viability in the future.

To inform our assessment of the North American wolverine's status in the contiguous United States, we updated our previous climate change analysis, the details of which are summarized in the wolverine SSA report addendum (Service 2023, pp. 47–59). The spatial expansion to our climate change analysis is a major improvement from the snow projections used in our 2018 SSA report, which focused only on Rocky Mountain National Park (Colorado) and Glacier National Park (Montana). We now focus on five modeling domains that overlap with occupied and potential wolverine habitat in the contiguous United States across latitudinal, longitudinal, and elevation gradients: (1) Cascades (Washington); (2) Northern Rocky West (Washington, Idaho, and Montana); (3) Northern Rocky (Idaho and Montana); (4) Mid-Rocky (Idaho, Montana, and Wyoming); and (5) Southern Rocky (Colorado and New Mexico) (Service 2023, p. 49). Central Idaho was not modeled due to constraints of time and resources. In our updated climate assessment, we use a timeframe out to year 2100 for assessing future effects to the North American wolverine's viability from climate change and other threats. Beyond 2100, climate modeling uncertainty increases substantially due to the inability to predict human behavior, policy changes, and, by extension, future greenhouse gas emissions. Our previous assessment in the October 13, 2020, withdrawal document (85 FR 64618) looked at a timeframe of 38 to 50 years into the future. We find that end of century is a reasonable timeframe to consider, as it includes the potential for observing these effects and the wolverine's responses over several generations of the wolverine.

Two scenarios were chosen from the Intergovernmental Panel on Climate Change (IPCC) Sixth Assessment Report to bracket the uncertainty regarding future greenhouse gas emission scenarios (Tebaldi et al. 2021, p. 258). The two emission scenarios used in the analyses are referred to as SSP2–4.5 and SSP5–8.5; SSPs replace representative concentration pathways (RCPs) from prior IPCC reports. The numerical suffixes (*e.g.,* 2–4.5 and 5–8.5) represent the approximate level of radiative forcing (the change in energy flux in the atmosphere caused by natural or anthropogenic factors of climate change) in 2100 (compared to preindustrial levels) in units of watts per meter squared (W/m^2). The SSP2–4.5 pathway (modest mitigation) used in this analysis is similar to the RCP 4.5 scenario used in past reports, whereas the SSP5–8.5 pathway represents one of the most pessimistic estimates of future greenhouse gas emissions, a future with no mitigation policy. The SSP5–8.5

pathway was included in this analysis to provide a lower-boundary estimate of future snow cover available for wolverines within the selected domains (OSTP 2023, p. 11). We chose a snow depth threshold of greater than or equal to 1 m (40 inches) to represent persistent spring snow cover on May 1 based on published literature, our prior analyses in the 2018 SSA, and studies indicating that den site abandonment generally occurs before May 1 (see the *Use of Dens and Denning Behavior* discussion in the *Reproduction and Growth* section of the 2018 SSA (Service 2018, pp. 25–27). There is no known snow depth threshold for successful wolverine denning on any date. However, based on historical den site melt-out dates (when there was no snow at the den sites) and hindcasted (historical) snow models for Glacier National Park, the 2018 SSA used greater than 0.5 m (20 inches) on May 1. We received criticism from some wolverine researchers that the use of the 0.5-m snow depth threshold on May 1 was not conservative enough based on prior studies (*e.g.,* Copeland et al. 2010, entire; McKelvey et al. 2011, entire) that considered snow depth out to June. Others would argue (based on the importance of snow for denning) that snow depth at May 1 is not as important since young wolverine kits are usually out of their natal dens by mid-March (Inman 2023, pers. comm.). To address the criticism, and to acknowledge that snow is likely important to the wolverine for more life behaviors than just denning, for our updated analysis we increased the snow depth measure representing persistent snow cover to greater than or equal to 1 m (3.3 ft) but retained the May 1 end date. This provides a reasonable but more conservative estimate than we used in the 2018 SSA.

Results from this updated climate change analysis are consistent with earlier studies predicting greater snow loss at lower elevations across all domains. Similar elevational patterns were reported for Rocky Mountain and Glacier National Parks with greater reductions in future snow cover at lower elevations (Barsugli et al. 2020, pp. 8–10). This is partially explained by a greater percentage of future precipitation falling as rain due to higher temperatures, earlier snowmelt onset, and warmer conditions. Snowpack in the high country is not as affected by projected temperature increases but is likely more strongly controlled by projected precipitation changes (Barsugli et al. 2020, pp. 6–11; Scalzitti et al. 2016, p. 5367; Sospedra-Alfonso et al. 2015, p. 4429).

The elevational distribution of historical den sites varies by latitude, with a general trend of dens being found at higher elevations the farther south they are found. For example, dens in the Northern Rocky domain are found at elevations ranging from approximately 1,500–2,400 m (4,921–7,874 ft) (Service 2023, figure 12), while dens in the Mid-Rocky domain are found from approximately 2,400–3,000 m (7,874–9,843 ft) (Service 2023, figure 13). Additional den sites outside of the modeling domains could expand these elevational bands. The majority of historical dens across the domains are located in elevational bands that are predicted to experience relatively small decreases in future snow cover at the higher denning elevations and moderate decreases for lower denning elevations. The percentage change in future snow depth threshold (greater than or equal to 1 m (3.3 ft)) on May 1 (median) for SSP2–4.5 (2076–2095) for the upper denning elevations in Northern Rocky West, Northern Rocky, and Mid-Rocky domains is predicted to be a less than 10 percent decrease, whereas the percentage change for the Cascades domain is predicted to be a less than 25 percent decrease. The percentage change in future snow depth threshold (greater than or equal to 1 m (3.3 ft)) on May 1 (median) for SSP2–4.5 (2076–2095) for the lower denning elevations in Northern Rocky is predicted to be a 10–50 percent decrease, and for Mid-Rocky is predicted to be a 10–25 percent decrease, while the percentage change for the Cascades domain is predicted to be a less than 25 percent decrease.

Elevations above historical den elevations are predicted to have small decreases (less than 10 percent) in the future area with snow depth exceeding the threshold (greater than or equal to 1 m (3.3 ft)) on May 1 (median) for SSP2–4.5 (2076–2095) across the domains and in some cases (*e.g.,* Northern Rocky and Mid-Rocky domains), there are increases in predicted future area with snow exceeding the greater than or equal to 1 m (3.3 ft) May 1 threshold. This is driven by the increases in future precipitation expected in all five domains, and elevations with temperatures sufficiently cold enough to sustain snowfall, even with future warming. The lowest elevation areas within all domains (the lowest approximately 500 m (1,640 ft) of domains modeled) are predicted to have the greatest decreases in the future snow depth threshold (greater than or equal to 1 m (3.3 ft)) on May 1. For example, the Northern Rocky domain is predicted to experience decreases of 50 to 100 percent at 1,000–1,500 m (3,281–4,921 ft) of elevation (Service 2023, figure 13). Similar patterns are seen in the other four domains, including predicted changes (mostly negative) in the future snow depth threshold (greater than or equal to 1 m (3.3 ft)) on May 1. While decreases are projected across the domains, the specific thresholds that could impact wolverine persistence at the population level are not known.

Central to our assessment of future conditions is the degree to which changes in persistent spring snow, other snow dynamics (*e.g.,* volume, duration, condition, spatial and temporal variability, etc.), and other climate-related factors will impact wolverines at the population level in the contiguous United States. Key uncertainties that remain regarding these relationships include: (1) the extent to which wolverine population connectivity and gene flow will be affected by these changes; (2) the impacts of climate change on ecosystem drivers of wolverine persistence (*i.e.,* changes in community dynamics, including prey availability and competition with other predators that might impact wolverine demographic rates); (3) the volume and duration of snow required for wolverines to successfully acquire and cache food for future use; (4) the impacts of climate change on the ability of wolverines to thermoregulate, and whether wolverines might experience any sublethal effects from changes in temperature (*e.g.,* impacts to reproduction) (see Thiel et al. 2019, entire); (5) whether the observed associations of the wolverine's distribution with snowy and cold environments are driven by reproductive denning needs, other ecological requirements, or physiological constraints (Aubry et al. 2023, p. 16); (6) the adaptive capacity of wolverines to move to higher elevations for denning given predicted snow loss at lower elevations within their historical denning range (assuming snow is required for denning); and (7) the importance of snow and the impact of decreases in future snow within historical denning elevations on reproductive success. In summary, specific thresholds regarding snow dynamics and how changes in these factors will impact wolverines in the future at the population level remain uncertain.

That said, we know that wolverines are a species that is adapted to, and has a strong preference for, cold and snowy conditions and that these conditions occur in the contiguous United States at high elevations. As explained before,

there are uncertainties as to the exact mechanism(s) by which spring snowpack is important to wolverines or when it may become limiting. Although wolverines have been shown to den outside of spring snowpack in Canada and Scandinavia, we continue to have no evidence of this behavioral ability in the contiguous United States. Furthermore, new research on wolverine habitat use continues to reinforce that cold and snowy conditions are a strong predictor of wolverine occurrence on the landscape (Aubry et al. 2023, pp. 15–16; Carroll et al. 2020, p. 8; Fisher et al. 2022, p. 10; Glass et al. 2021, entire; Mowat et al. 2020, p. 220). Furthermore, deep, persistent snow cover has been shown to be an important predictor of successful wolverine dispersal and resulting genetic structure (Balkenhol et al. 2020, pp. 798–799). New research on food caching indicates that warming future conditions could make caching food, a year-round behavior, more difficult for wolverines (Van der Veen et al. 2020, pp. 8–10). As climate change reduces the preferred habitat conditions for wolverine, it has the potential to exacerbate other stressors discussed above including effects from roads, winter recreational activity, effects from development, low genetic diversity, and small population effects. When taken together, we have no reason to conclude that wolverines will somehow continue to have the same or better resiliency in the contiguous United States in the future when those cold and snowy conditions at high elevations are expected to decrease, with spring snowpack at denning elevations decreasing as much as 50 percent in some areas. Although we are not seeing deleterious effects of climate change on the contiguous U.S. DPS of North American wolverines currently, we expect future impacts at the population level.

Effects from Roads: In our 2018 SSA and the October 13, 2020, withdrawal document (85 FR 64618), we concluded that roads present a low stressor to wolverines at the individual and population level in most of the wolverine's current area of occupancy within the contiguous United States. New information on the effects of roads on the North American wolverine's distribution, density, reproduction, and connectivity and gene flow are presented below.

Since 2018, we were made aware of four wolverine mortalities from collisions with vehicles in the contiguous United States, at least three of which were males (Service 2023, p. 30). Overall, young, inexperienced male wolverines have a greater risk of road mortality during dispersal compared to adults and immature females that are less prone to long-distance dispersal (*e.g.,* Krebs et al. 2004, pp. 497–498). The small number of mortalities observed since 2018, if biased toward males, are unlikely to have substantial impacts to the resiliency of the DPS overall.

New studies available in southwestern Canada and the western United States since the 2018 SSA have found that North American wolverine distribution and density are negatively related to road density (Service 2023, pp. 31–32). In southwestern Canada, consistency of spring snow and road density are the two most important variables correlated with wolverine density (Clevenger 2019, p. 52; Mowat et al. 2020, p. 220). Wolverine population estimates derived from models based on snow and road density predicted that wolverine abundance would be 44 percent higher without the depressing effect of the road covariate (Clevenger 2019, p. 52; Mowat et al. 2020, p. 220). As most roads are concentrated in areas of human development at lower elevations with less snow, correlations between wolverine distribution and road density can be confounded by other collinear variables (Copeland et al. 2007, pp. 2210–2211). In southeastern British Columbia, the density of forest roads that extended into high-elevation wolverine habitat was a strong negative predictor of wolverine distribution in winter, especially for females (Kortello et al. 2019, p. 10). The most likely explanation for this negative relationship is the use of these high-elevation forest roads by snowmobilers, rather than predator avoidance or trapping pressure (Kortello et al. 2019, p. 10). Other possible explanations are increased trapping access or less abundant food resources near roads (Mowat et al. 2020, p. 224). While the statistical significance of the relationship between roads and wolverine densities has been demonstrated in some areas, the mechanisms behind this relationship require further study (Mowat et al. 2020, p. 224).

Large transportation corridors (*e.g.,* multi-lane highways with substantial traffic volume) can have a significant impact on wolverine population connectivity and gene flow. The mechanisms for reducing connectivity and gene flow are road mortality and reduced habitat permeability (avoidance of crossing roads). Mitochondrial and nuclear DNA measures of genetic population structure found that the Trans-Canada Highway corridor in the Canadian Rockies, as well as other natural and anthropogenic barriers to movement, fragmented the North American wolverine population by restricting female movement (Sawaya et al. 2019, pp. 621–622). This restricted movement resulted in male-biased dispersal and gene flow (Sawaya et al. 2019, pp. 621–622). This highway is approximately 150 miles north of the U.S.–Canada border, and the study area for analyzing wolverine movement across the Trans-Canada Highway was in the lower Bow River Valley, which is a human-dominated landscape containing the Trans-Canada Highway, a town with approximately 10,000 residents, a golf course, three ski areas, the Canadian Pacific Railway, and a secondary highway. This transportation corridor was not an absolute barrier to female movement (4 of 20 female wolverines crossed the highway during the study); however, females traversing the transportation corridor did not translate to gene flow (Sawaya et al. 2019, p. 622). The differences between male and female dispersal across this highway were likely due to the exacerbating effects of linear anthropogenic barriers on the strong natural tendencies for female wolverine philopatry (tendency to return to or remain near a particular area or site) (Sawaya et al. 2019, p. 623). (See *Genetic Diversity,* below, for more discussion of the effects of roads on gene flow and genetics of wolverines within the contiguous United States and genetic connectivity to Canada).

Wildlife crossing structures spanning the Trans-Canada Highway along the crest of the Continental Divide may improve wolverine connectivity across this highway. Evidence suggests that female wolverines may be starting to use wildlife crossings to cross the Trans-Canada Highway (Service 2023, p. 32). However, the efficacy of these structures in restoring gene flow has not yet been measured (Sawaya et al. 2019, p. 623). There are few wildlife crossing structures spanning major highways in the contiguous United States; a series of three under-crossings and one dedicated wildlife overpass on I–90 in the Washington Cascades (connecting the northern and southern Cascades) were completed in 2019 (Sugiarto 2022, p. 9). To date, however, no wolverines have been detected using these relatively new crossings.

Habitats in the contiguous United States outside of the known breeding distribution of wolverines, including the Sierra Nevada in California and the central Rocky Mountains in Colorado, are separated from occupied habitats by

large expanses of high-resistance habitats, anthropogenic features, and highways (*e.g.,* Carroll et al. 2020, pp. 9–10; Bjornlie et al. 2021, pp. 116–117). While highways are not an absolute barrier to movement (wolverines have been documented crossing multi-lane highways), they can apparently limit female wolverine gene flow in some situations (*e.g.,* Sawaya et al. 2019, pp. 621–622). The wolverine's capacity to traverse large expanses of high-resistance habitats, anthropogenic features, and highways and naturally recolonize and establish a population in some relatively isolated habitats in the contiguous United States (*e.g.,* Oregon Cascades, Sierra Nevada, and central Rocky Mountains) remains unclear.

Based on the best available scientific and commercial information, the effect of roads, in isolation, represents a relatively low threat to wolverines in the contiguous United States at the population level, although some individuals are affected. However, in combination with other threats discussed below, roads, in particular multi-lane, high-traffic roads, and high road density in core habitats could negatively affect the North American wolverine's population resilience, distribution, and gene flow in the future.

Disturbance Due to Winter Recreational Activity: In our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618), we concluded that the effect of winter recreational activity represents a low stressor to wolverines in the contiguous United States at the individual and population levels. New information on winter recreation impacts on North American wolverines is presented below and adds significantly to our understanding of this factor as highly relevant to the DPS.

The response of North American wolverines to various levels of backcountry winter recreation (motorized and nonmotorized) was recently studied in four areas in Idaho, Montana, and Wyoming (Heinemeyer et al. 2019a, p. 8). The study found that wolverines temporarily avoided areas within their home range where winter recreation (motorized and nonmotorized) was occurring (Heinemeyer et al. 2019a, p. 16). Wolverines increasingly avoided these areas as the amount of off-road winter recreation increased, resulting in indirect habitat loss or functional degradation of moderate- or high-quality habitats in winter (Heinemeyer et al. 2019a, p. 16). However, wolverines did demonstrate the ability to maintain multi-year home ranges despite the presence of winter recreation activity within those home ranges. Some resident animals had more than 40 percent of their home range within the footprint of winter recreation, suggesting that, at some scale, wolverines tolerate winter recreation (Heinemeyer et al. 2019a, p. 16).

Dispersed or off-road winter recreation appears to elicit more of an avoidance response than recreation along roads and groomed routes with females showing more sensitivity than males (Heinemeyer et al. 2019a, p. 15). Females exhibited more of a negative response to motorized recreation, which occurred at higher intensity across a larger footprint than did nonmotorized recreation.

In a study evaluating the strength of aerial survey metrics in predicting wolverine responses to motorized and nonmotorized backcountry winter recreation, higher recreation intensity showed stronger avoidance coefficients and were the most important modelled predictors of female wolverine absence (Heinemeyer et al. 2019b, pp. 18–20). Given the likelihood that, under climate change, both wolverines and backcountry winter recreation will be impacted by declining snow extent and depth and an abbreviated snow season, there is the potential for increased overlap between winter recreation and wolverine distribution (Heinemeyer et al. 2019a, p. 18).

The impacts of motorized and nonmotorized backcountry winter recreation on wolverines in the Nez Perce-Clearwater, Sawtooth National Recreation Area, and Salmon-Challis National Forests of Idaho were recently evaluated (Regan et al. 2020, entire). Preliminary results showed that recreational impacts, in both area and intensity, are increasing over time. In the Sawtooth-Boulder White Cloud Mountains, researchers compared the current extent of winter recreation with known historical wolverine home ranges and found that most of these home ranges contained little or no backcountry recreation at this time (Regan et al. 2020, p. 4). In contrast, recent surveys on the Payette National Forest in central Idaho revisited a portion of a previous winter recreation study and found that there had been an incremental loss of resident wolverines from 2010 to 2014, and that previously documented territories appeared to be vacant (Mack and Hagen 2022, p. 13). The authors suggest that ''what was considered to be a stable core subpopulation area could, in fact, be more tenuous'' and ''that the change in wolverine abundance in this area might be attributed to changes in habitat quality from direct or indirect influences including dispersed recreation,'' although the cause for the decline in wolverine abundance requires further study (Mack and Hagen 2022, p. 13).

Both motorized and nonmotorized recreation can affect wolverine habitat use. Forest roads that are used by snowmobilers appear to have a strong negative correlation with wolverine distribution (Kortello 2019, p. 10). Nonmotorized recreation can also impact wolverines. Remote camera-based surveys from 2011–2020 in protected and non-protected habitat in southwestern Canada found that wolverine detection probability was strongly negatively correlated with the amount of nonmotorized human recreation (Barrueto et al. 2022, pp. 4–8). This pattern was consistent in both winter and summer, and mirrored the findings of Heinemeyer et al. (2019a, p. 18). Further research is necessary to determine the specific causal mechanisms most responsible for these declines (Barrueto et al. 2022, p. 8).

In the winter recreation studies we considered, winter recreation activities varied in the number of recreationists and types of recreation, and each study area had a unique combination of backcountry recreation including snowmobile, skiing (including snowboards), snowmobile-accessed ski/snowboard, cat-ski, heli-ski, yurt-supported skiing, and snowshoeing. Backcountry motorized and nonmotorized winter recreation that occurs in areas that do not overlap with wolverine home ranges is not expected to impact the DPS. Additionally, developed ski slopes and resorts that are already on the landscape and other developed winter recreation sites that do not occur in the backcountry are not expected to be a concern for wolverines, as wolverines are likely already avoiding these areas. Backcountry winter recreational activities that do occur in wolverine home ranges could negatively impact wolverines by displacing them from high-quality habitat. Developed ski resorts that allow for backcountry or out-of-bounds skiing in areas that overlap wolverine home ranges may also displace wolverines. Backcountry areas where wolverines reside in winter are largely difficult for recreationalists to access without snowmobiles or forest roads that facilitate access, and the intensity of recreational activity is correlated with accessibility.

Based on the best available scientific and commercial information, the effect of winter recreation activity (of greatest concern because of potential to impact denning), in isolation, represents a low

threat to North American wolverines in the contiguous United States at the population level, although some individuals are affected. However, in combination with other threats, including decreased snow availability (see *Climate Change,* above) and increased overlap with winter recreationalists in the future of climate change, winter recreation could negatively affect wolverine population resilience in the future.

Other Human Disturbance and Development: In our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618), we concluded that human infrastructure may affect individual wolverine behavior (*e.g.,* avoidance) or result in the loss or modification of wolverine habitat. We further stated these effects are small or narrow in scope and scale and appear to represent a trade-off between foraging opportunities in areas that provide minimal risk of predation and avoidance of open areas and/or higher predation risk. We discuss below new information related to the impacts of human disturbance and development on North American wolverine populations.

North American wolverine density in and around a national park complex in the southern Canadian Rocky Mountains was three times higher within these national parks than outside them, increased with spring snow cover, and decreased with increasing night light intensity (a measure of human development) (Barrueto et al. 2022, p. 4). An approximately 40 percent decline in wolverine abundance was observed between 2011 and 2020, likely from one or more of the following causes: trapping, backcountry recreation, human development, and food availability (Barrueto et al. 2022, pp. 4, 6–8). This pattern is consistent with telemetry-based data that wolverines avoid infrastructure (May et al. 2006, entire; Scrafford et al. 2018, entire). Along the Front Range of the Canadian Rocky Mountains, wolverines selected areas with natural land-cover and high snow cover, and avoided anthropogenic features and heterospecific competitors (Heim et al. 2019, pp. 2499–2502). It is thought that competition from other carnivores that more readily exploit anthropogenic change may exacerbate the habitat loss and displacement impacts of such changes on North American wolverines (Heim et al. 2019, pp. 2503–2504).

Connectivity among North American wolverine habitats appears to be particularly sensitive to housing developments and other human impacts in rugged areas located between typical wolverine habitats (Balkenhol et al. 2020, p. 799). Housing density was found to be an important predictor of long-distance wolverine dispersal and population structure in the Northern Rocky Mountains (Balkenhol et al. 2020, p. 799). Even if areas between wolverine primary alpine habitats are not typically inhabited by wolverines, they may be used during dispersal and can, therefore, offer crucial pathways for gene flow across broad spatial scales (Balkenhol et al. 2020, p. 799).

The extent of the impacts of human presence and actions on the landscape have been collectively called ''the human footprint'' (Janzen 1998, entire). In an analysis of the human footprint in the western United States, Leu et al. (2008, p. 1125) found that the physical effect area of 14 anthropogenic features they analyzed (human habitation, interstate highways, Federal and State highways, secondary roads, railroads, irrigation canals, powerlines, linear feature densities, agricultural land, campgrounds, highway rest stops, landfills, oil and gas development, and human-induced fires) covered 13 percent of the land area in the western United States. Accounting for the indirect effects radiating out from the direct human footprint, Leu et al. (2008, p. 1125) categorized 52 percent of the western United States as having medium- or high-intensity impacts from the human footprint (both direct and indirect impacts), while low-intensity impact areas covered the remaining 48 percent of the landscape (Leu et al. 2008, pp. 1125–1127). When modeled North American wolverine core areas are overlaid across the western United States with the human footprint, less than 1 percent was in the high-intensity category, 12 percent in the medium-intensity category, and 88 percent in the low-intensity category. We also overlaid the current breeding distribution of the North American wolverine with the human footprint map and found that only 1 percent of the current breeding range was within the high-intensity category, 31 percent in the medium-intensity category, and 68 percent in the low-intensity category (Service 2023, figure 4). As expected, wolverine core areas are concentrated in high-elevation areas with little human infrastructure (Service 2023, figure 4). However, within their current breeding distribution in the contiguous United States, wolverines must navigate across lower elevation areas with greater amounts of human infrastructure to disperse from one habitat core to another (Service 2023, figure 4).

In addition to effects on wolverine density and connectivity, human infrastructure can also affect wolverines through shifts in community dynamics that precipitate from changes in the behavior and temporal use of habitats by apex predators. Wolverines and other carnivores may shift their daily behavior patterns in response to the presence of human landscape disturbance (Frey et al. 2020, pp. 1133–1138). Indirect effects can also include range expansion of other carnivores into wolverine habitat facilitated by human infrastructure. While wolverine and coyotes are generally segregated, the probability of co-occurrence increases with the proportion of linear disturbance features (Chow-Fraser et al. 2022, p. 4). Using a study area in Alberta (Frey et al. 2020, p. 1130), the authors found that while wolverines favored areas of low disturbance (low proportion of linear features) and coyotes favored areas of high disturbance (high proportion of linear features), co-occurrence probability increased 3 times for each increase of linear feature unit (Chow-Fraser et al. 2022, p. 4). Modeling showed that competition exhibited the strongest effect on wolverine distribution, with wolverine occurrence best explained by coyote occurrence at the same sites (Chow-Fraser et al. 2022, p. 4). These results suggest that anthropogenic disturbance and resulting coyote range expansion may be contributing to wolverine population declines in the Canadian Rocky Mountains (Chow-Fraser et al. 2022, p. 6).

A recent study estimated the independent and cumulative effects of landscape features, human disturbance (distance to human settlements and roads, night light brightness, human population density), and prey availability on wolverines and other large carnivore occurrences in Fennoscandia (region in Europe that includes the Scandinavian peninsula, the Kola Peninsula, mainland Finland, and Karelia) (Milanesi et al. 2022, entire). Contrary to the other carnivores they evaluated, variation in the ''permanent'' occurrence of wolverines was best explained by human disturbance and the shared effect between landscape attributes and human disturbance. This same relationship was observed for ''sporadic'' wolverine occurrences, but with a considerably lower level of explained variance. The researchers concluded that, ''the wolverine showed higher sensitivity to human disturbance compared to the other large carnivores, and spatial segregation patterns between wolverines and humans were found, as large carnivore home ranges are usually at high elevation (often covered by

snow), far from the lowlands where density of human settlements and roads is high'' (Milanesi et al. 2022, p. 10). It appears that wolverines select den sites mainly away from infrastructure, indicating that successful reproduction may be influenced by human activities. However, wolverines also appear to be able to cross artificial barriers to some degree. Therefore, wolverines appear to have a relatively low tolerance of human disturbance, with an ability to exhibit more flexible behavior during dispersal in some circumstances.

Human disturbance and development effects are limited in scope and scale within the wolverine DPS's core habitats and breeding range in the contiguous United States. However, in lower elevations and valleys bottoms between core habitats, wolverines must traverse through areas of human disturbance and infrastructure to maintain connectivity in the contiguous United States, where habitat is often fragmented. Wolverines have shown avoidance of disturbed areas and human infrastructure and a preference for habitats devoid of these features. Based on the best available scientific and commercial information, we find that human disturbance and development, especially coupled with major roads (see *Effects from Roads,* above), could limit wolverine connectivity and dispersal in the future.

Effects from Wildland Fire: In our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618), we found that wildland fire was neither a population- nor species-level stressor to North American wolverines in the contiguous United States. Our assessment of wildland fire effects to wolverines has not changed. Wildland fire can produce both direct and indirect effects to wildlife. Direct effects include injury and mortality, as well as escape or emigration movement away from fires (Lyon et al. 2000, pp. 17–21). Wildland fire is likely to temporarily displace wolverines, which could affect home range dynamics. Given that wolverines can travel long distances in a short period of time, individuals would be expected to move away from fire and smoke (Luensmann 2008, p. 14). In addition, because young wolverines are born in underground or otherwise sheltered dens during winter months and in locations where wildland fire risk is low due to snow cover or increased moisture (Luensmann 2008, p. 14), the potential effects of fire at that critical life stage is very low (Luensmann 2008, p. 14). Indirect effects of wildland fire can include habitat-related effects or effects to prey and competitors/predators; however, we are unaware of empirical studies evaluating these potential effects as they relate to wolverines.

Given the diversity of habitats occupied by wolverines, their opportunistic foraging habitats and seasonal switching of food sources, their occupancy of high elevations, and their extensive mobility, wildland fire does not represent a stressor to North American wolverines in the contiguous U.S. range (Service 2018, pp. 63–64) and is not expected to have population-level impacts.

Disease and Predation: In our 2018 SSA, we found that disease and predation were neither population- nor species-level stressors to the North American wolverine in the contiguous United States. Our assessment of these stressors has not changed.

There has been considerable localized research on diseases and parasites in wolverines since the 2018 SSA was published; however, we lack data on the specific effects to wolverine populations. It is conceivable that disease-induced mortality could contribute to population declines, but this remains understudied south of the Arctic (Fisher et al. 2022, p. 9). The types of bacteria or parasites that could lead to disease in wolverines are still unknown (Watson 2020, pp. 62, 65). Many authors have discovered new viruses in the United States and Canada, some of which were previously unrecognized species of parasites (Sharma et al. 2020, p. 277; 2021, p. 1; Watson et al. 2020, p. 43; Bandoo et al. 2021, p. 1). This new information pertains to how wolverines act as primary hosts for some parasites, such as *Trichinella* spp., and how those parasites could increase infection risk to humans and other vertebrates (Sharma et al. 2021, pp. 1, 7). Considering the global coronavirus pandemic in recent years and instances of human-animal cross-infections, researchers are beginning to use genomic data to evaluate the wolverine's susceptibility to these pathogens (Lok et al. 2022, pp. 16–18). Although no coronavirus cases have been reported in wolverines, and an initial evaluation of the wolverine's genome to determine susceptibility to coronaviruses was inconclusive, there is potential risk of infection from their prey or from researchers handling captured wolverines that they release back into the wild (Lok et al. 2022, pp. 16, 18, 20).

Since our 2018 SSA, we found no substantive new information on predation. In North America, there was one new report of two wolverines being predated upon in the boreal ecosystem of Canada. One was the result of wolf predation, and the other was the result of an unknown predator (Scrafford et al. 2021, p. 9).

Based on the best available scientific and commercial information, disease and predation are not threats to North American wolverines in the contiguous United States at the individual or population level.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes: In our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618), we concluded that overutilization does not currently represent a stressor to the wolverine in the contiguous United States at the individual, population, or species level. We also concluded that trapping in Canada had been and appeared to be sustainable, and trapping or harvesting of wolverines along the contiguous U.S.–Canada border did not represent a barrier to wolverine movement and dispersal along the international border (Service 2018, p. 71). Below, we present new information on incidental captures of wolverines in the contiguous United States, where regulated wolverine trapping remains closed (Service 2018, pp. 70–72), and new information on the effects of trapping mortality on wolverine populations in southwestern Canada. New information suggests that wolverine trapping in southwestern Canada has impacted connectivity across the international border.

Since 2012, there have been 10 nontarget wolverine captures (average = fewer than 1 per year (1/year)) in Montana, resulting in 3 mortalities (1 in a conibear (a body gripping trap), 1 in a foothold, and 1 in a snare); the remainder were released (MFWP 2023, in litt., p. 1). In Idaho, 14 nontarget captures (0.7/year) of wolverines have occurred during licensed trapping activities, with no demonstratable trend in capture rates over the past 20 years (IDFG 2022, in litt., p. 3). Nine wolverines were incidentally trapped in Idaho between November 2017 and August 2022, with two resulting in known mortalities (IDFG 2022, in litt., pp. 5, 16–22).

The Idaho legislature revised the Idaho Code (IC) in 2021 to: (1) authorize a year-round trapping season for wolves on private property (IC 36–201(3)); (2) authorize additional methods of take previously prohibited (inclusive of the use of snares in 97 out of 99 management units) (IC 36–201(2)); (3) remove any limit to the number of wolf tags an individual may purchase (IC 36–408(1)); (4) allow a livestock or domestic animal owner to use a private contractor to kill wolves (IC 36–1107(c)); (5) allow the Idaho Wolf Depredation Control

Board to enter into agreements with private contractors, in addition to State and Federal agencies, to implement the provisions of Idaho Senate Bill 1211 (IC 22–5304(2)); and (6) direct wolf control assessments ($110,000 annually) collected from the Idaho livestock industry to be combined with $300,000 the State will transfer from the IDFG fund annually beginning on July 1, 2021 (IC 22–5306).

In Montana, new laws were also passed in 2021 to reduce the wolf population through, among other things: (1) authorizing the use of snares to take wolves by licensed trappers (Montana Code Annotated (MCA) 87–1–901(2)(b)); (2) allowing the Montana Fish, Wildlife, and Parks (MFWP) Commission authority to extend trapping season dates (MCA 87–1–304(8)); and, (3) allowing the reimbursement of costs incurred to harvest a wolf or wolves in Montana (MCA 87–6–214(1)(d)).

These regulation changes may increase the amount of wolf trapping and the risk of incidental trapping of wolverines because of the use of snares, extended trapping seasons, and financial incentives. However, because wolverines differ from wolves in size, distribution, and behavior, trappers use pan tension, site selection, and snare height to reduce the likelihood of incidental capture. In addition, year-round wolf trapping seasons in Idaho are limited to private lands, where there is very little core wolverine habitat. Although the wolf trapping regulations have been in effect for a limited time, we do not anticipate a significant increase in wolverine incidental trapping due to the measures Idaho and Montana are taking to limit wolverine capture. Across the contiguous U.S. range, wolverine mortality from incidental trapping has historically been very low, and States within the DPS's range are actively taking measures to limit incidental capture and mortality. Below, we present a summary of incidental trapping risk and measures to limit wolverine capture for each State within the current range in the contiguous United States.

California

The wolverine is listed as both a threatened species and as a fully protected mammal in California; these designations provide wolverines broad protection from being trapped, killed, or otherwise taken in the State (CDFW 2023, in litt., p. 2). Recent detections of lone animals have indicated the occasional presence of wolverines in the State (CDFW 2023, in litt., p. 2). Recreational and commercial trapping of fur-bearing and nongame animals has been illegal in California since 2019 (CDFW 2023, in litt., p. 2). While furbearers and nongame species can be trapped for other reasons (*e.g.,* the protection of property), existing regulations likely preclude the serious injury or mortality of incidentally captured wolverines (CDFW 2023, in litt., p. 2). The use of snares, conibear-type traps, and deadfall traps is prohibited in large areas of the State, including in the most recently estimated historical range of the wolverine (CDFW 2023, in litt., p. 2). The use of steel-jawed leghold traps is prohibited throughout the State (CDFW 2023, in litt., p. 2). All traps must be checked daily, and all captured animals that are not legal to trap should be immediately released (CDFW 2023, in litt., p. 2).

Colorado

Recreational trapping of wildlife in Colorado is limited to live cage traps (CPW 2023, in litt., p. 1), and any wolverines incidentally trapped could be released unharmed. However, there are currently no wolverines known to be present in Colorado, and, therefore, there should be no incidental trapping of wolverines occurring (CPW 2023, in litt., p. 1).

Idaho

IDFG has multiple guidelines that are shared with the trapping community to reduce the nontarget capture of wolverine (IDFG 2023, in litt.; IDFG 2022, p. 40). The guidelines, developed with the assistance of technical experts familiar with the wolverine, include recommendations on the types of traps used, trap tension, trap placement, avoiding areas with wolverine tracks observed, selecting habitats less likely to have wolverines, and contacting IDFG or a local sheriff's office to assist with the safe release of wolverines incidentally trapped. These guidelines help minimize nontarget wolverine captures (IDFG 2023, in litt., p. 3). Capture rates of wolverine during trapping activities for other species are low. In Idaho, 14 nontarget captures (0.7/year) of wolverines have occurred during licensed trapping activities, with no demonstratable trend in capture rates over the past 20 years (IDFG 2022, in litt., p. 3). Between November 2017 and August 2022, IDFG reported that nine wolverines were incidentally trapped, with two resulting in mortalities (IDFG 2022, in litt., pp. 5, 16–22).

Montana

Montana FWP has multiple trapping regulations that help mitigate the nontarget capture of wolverines by recreational trappers (MFWP 2023, in litt., p. 1). The regulations include requirements for trappers to take an education course, that wolf traps must be checked every 48 hours, and that wolf trap tension and snare height are set to limit wolverine capture (MFWP 2023, in litt., p. 1). There are also a number of regulations required to mitigate the nontarget capture of the federally listed Canada lynx (*Lynx canadensis*) that are also applicable to wolverines, including the prohibition of wolf snares on public lands in lynx protected zones, which overlap much of the wolverine habitat in Montana (MFWP 2023, in litt., p. 5).

The last legal harvest season for wolverines in Montana was in 2012 (MFWP 2023, in litt., p. 1). The nontarget capture of a wolverine is very rare, and these incidents do not pose any population-level effects on wolverines (MFWP 2023, in litt., p. 1). There have been 10 nontarget wolverine captures (average = less than 1/year), resulting in 3 mortalities in Montana (MFWP 2023, in litt., p. 1). This also provides evidence of the efficacy of the trapping regulations in place to mitigate the nontarget capture of wolverines and other animals (MFWP 2023, in litt., p. 1).

Oregon

There is no open season for wolverine (or other protected species), and any incidental capture or other take of wolverines must be reported to the Oregon Department of Fish and Wildlife (ODFW) within 48 hours (ODFW 2023, in litt., p. 4). Regulations that also reduce any incidental captures or take include a 48-hour trap check (which limits the ability for traps to be set in the wolverine's range and allows for prompt trap set modification or removal if signs of wolverine presence are detected) and a prohibition on medium-sized and larger body-grip traps (such as the conibear trap) being set on land (ODFW 2023, in litt., p. 4). In practice, other traps successfully deployed for the capture of wolverines simply are not used by Oregon trappers (ODFW 2023, in litt., p. 4). For example, foothold traps (#4 coil springs, Minnesota Brand 750s) used for wolverine in Canada and Alaska are too large for targeted Oregon species like bobcats (*Lynx rufus*) and coyotes (ODFW 2023, in litt., p. 4). No wolverines have been incidentally captured by licensed furtakers in Oregon over the last half-century (ODFW 2023, in litt., p. 4).

Utah

There are no regulations specific to wolverines in Utah, but the Utah Division of Wildlife Resources (UDWR)

regulates trapping and the use of trapping devices to reduce the capture of nontargeted protected species (UDWR 2023, in litt., p. 2). Any protected wildlife found alive in a trapping device must be immediately released unharmed (UDWR 2023, in litt., p. 2). UDWR also provides trappers with multiple recommendations that can help avoid catching nontarget species in traps set for bobcats and other furbearers, including recommendations on the type of traps used, placement of traps, and baits used (UDWR 2023, in litt., p. 2).

Washington

Information on the wolverine is in Washington's trapping education manual, and all trappers must pass a trapper education test (or a similar one in another State) prior to obtaining their first license (Washington Department of Fish and Wildlife (WDFW) 2023, in litt., p. 2). Due to Washington's trap-type regulations banning body gripping traps, the likelihood of accidental capture of a wolverine is very unlikely, and injury or death from these traps even more unlikely (WDFW 2023, in litt., p. 2). In Washington, the most commonly trapped animal in habitats that wolverines occupy is the marten (*Martes americana*) but marten traps are too small for wolverines (even young wolverines) to be captured (WDFW 2023, in litt., p. 2). Larger cage traps that are used for bobcat and other larger animals could potentially capture a wolverine, but these are not commonly set in areas that wolverines occupy, and if a wolverine were incidentally captured, it could be released from the trap unharmed (WDFW 2023, in litt., p. 3). The past several years of trapper reports (2017–2022) do not show any records of a wolverine being trapped.

Wyoming

The Wyoming Game and Fish Department (WGFD) addresses the incidental capture of animals classified as protected, like wolverines, in their Furbearing Animal Hunting or Trapping Seasons Brochure (WGDF 2023, in litt., p. 4). All protected animals that are trapped shall be released unharmed and mortalities reported to the WGFD (WGDF 2023, p. 14). Large areas of Wyoming within the distribution of wolverines are closed to trapping, including Yellowstone National Park and Grand Teton National Park.

The WGFD is not aware of any wolverines trapped incidentally in Wyoming in recent history (WGDF 2023, in litt., p. 1). Trap types with the potential to capture wolverines are largely restricted to private lands, must be partially submerged in water (where there would be low likelihood of wolverine capture), or are required to have break-away devices to limit bycatch (WGDF 2023, in litt., p. 2). Trapping that occurs in areas that overlap with wolverine habitat in Wyoming is primarily by marten trappers that use smaller cubby trap sets, and it is unlikely these would capture a wolverine (WGDF 2023, in litt., p. 2).

Since our 2018 SSA, there is substantial evidence demonstrating that direct trapping of wolverines has impacted wolverine densities in southern British Columbia and Alberta over the last decade (*e.g.,* Kortello et al. 2019, pp. 1, 10; Mowat et al. 2020, entire; Barrueto et al. 2020, p. 296; Barrueto et al. 2022, entire). In addition, there appear to be edge effects from trapping, with impacts to wolverine densities extending into protected areas in southern Canada (Barrueto et al. 2020, p. 296; Barrueto et al. 2022, p. 4). In the most expansive study of wolverine trapping and density to date—and encompassing southern British Columbia and Alberta's zone of connectivity with the Northern Rocky Mountains of the United States—wolverine trapping mortality was found to be unsustainably high at approximately 8.4 percent per year (Mowat et al. 2020, p. 221). Kill rates were higher in the southern British Columbia portion of the study area, with the best estimate of trapping mortality there approaching 10 percent per year (Mowat et al. 2020, p. 223). This contrasts with the maximum sustainable harvest of approximately 8 percent after accounting for the influence of higher trap vulnerability of juveniles and males and stochasticity in juvenile recruitment rates (Mowat et al. 2020, p. 221). Uncertainties in the stochasticity of reproduction, however, had large effects on the estimates of maximum sustainable harvest, causing it to vary between 0 and 8.1 percent (Mowat et al. 2020, p. 221). Based on their analyses, Mowat et al. (2020, p. 224) recommended reducing trapping mortality to no more than 4 percent per year (and perhaps even lower than that for an interim period) across their study area to promote wolverine population recovery. In response to the emerging information that trapping rates were unsustainable in southern British Columbia, the British Columbia Ministry of Forests, Lands, Natural Resource Operations and Rural Development closed a portion of the province along the U.S.-Canada border to wolverine trapping in 2020. New research published since that closure has confirmed population declines of approximately 40 percent (approximately 20 individuals) in the wolverine population in a portion of the Canadian Rocky Mountains over the decade before the closure (Barrueto et al. 2022, p. 6).

Legal trapping of wolverines has not occurred in the contiguous United States in the past 10 years, and lethal incidental trapping of wolverines has been minimal (1 to 2 animals per year across the contiguous United States). As described above, States within the wolverine's range have implemented measures to limit the incidental trapping of wolverines during legal trapping of other wildlife. We expect that, as long as trapping is done in a manner to limit wolverine bycatch, recent changes to wolf trapping regulations in Idaho and Montana will have little effect on wolverines at a population level.

Based on a recent analysis of an area in Canada that was experiencing population declines related to overharvest, Mowat et al. (2020, p. 224) recommended reducing direct trapping mortality to no more than 4 percent per year across their study area to promote wolverine population recovery. In the contiguous United States, where there is no direct trapping, incidental trapping rates have been well below this recommended rate. If we assume there are approximately 300 wolverines in the contiguous United States and assume 2 wolverine mortalities per year from incidental trapping (a conservative estimate from the incidental trapping mortalities we know of since 2012), that would amount to only 0.67 percent of the population per year. This minimal level of loss will not significantly impact the contiguous U.S. population of North American wolverines and will not inhibit conservation of the DPS.

As noted, trapping in southern Canada appears to be having more of a negative effect on wolverine populations in Canada than previously thought. Unsustainable trapping levels in Canada could limit dispersal of individuals into the contiguous United States, where the dispersal of wolverines from southern Canada is vital to the genetic and demographic health of the U.S. wolverine population. Based on the best available scientific and commercial information, the effect of overutilization (trapping) in the contiguous United States is not a threat to wolverines at the population level because there is no trapping of wolverine allowed, and the incidence of bycatch of wolverine resulting from other lawful trapping activities is small

and not expected to impact the DPS's population levels. However, in combination with other threats that limit dispersal (roads, infrastructure development, climate change), overharvest of wolverines in southern Canada could negatively affect the wolverine's population resilience, distribution, and gene flow in the contiguous United States in the future.

Genetic Diversity: In our October 13, 2020, withdrawal document (85 FR 64618), we conclude that loss of genetic diversity is not a threat for wolverines in the contiguous United States now or within the foreseeable future. Since our 2018 SSA and October 13, 2020, withdrawal decision, new genetic research has become available. Below, we assess new information on genetics relevant to our status assessment of wolverines in the contiguous United States, including estimates of effective population size and measures of gene flow and population connectivity.

Effective Population Size in the Contiguous United States

As reported in our SSA report (Service 2018, pp. 46–47), effective population sizes (N_e) are typically smaller than census population sizes. Scientists use the N_e concept as the number of individuals in a population that would result in the same loss of genetic diversity, inbreeding, and genetic drift if they behaved in the manner of an idealized population (equal sex ratio, random mating, all adults producing offspring, equal numbers of offspring per parent, and a constant number of breeding individuals across generations) (Frankham 1995, p. 96). The concept of effective population size relates to population viability because, as a general rule, closed populations with random mating that have effective population sizes (1) below 50 are at higher risk of inbreeding depression, and (2) below 500 are more likely to lose genetic variation important to maintaining long-term evolutionary potential. Fragmentation can further exacerbate inbreeding depression and genetic loss, while connectivity to larger source populations can alleviate the adverse effects of small effective population sizes (Frankham et al. 2014, p. 60). In addition, small, isolated populations are more vulnerable to extinction through interactions between environmental, genetic, and demographic factors (Caughley 1994, pp. 221–227).

The only available estimate of effective population size in wolverines in the contiguous United States is from the Northern Rocky Mountains (inclusive of the Greater Yellowstone Ecosystem, Idaho, and Montana). This is where the bulk of the wolverine population in the contiguous United States resides (Service 2023, table 4). In 2009, the N_e estimate for the Northern Rocky Mountains was 35 (credible interval = 28–52), and N_e did not change significantly from 1989–2006 (Schwartz et al. 2009, p. 3226). There are no published estimates of effective population size for wolverines in the North Cascades. Therefore, we estimated the effective population size of wolverines in the North Cascades, and the result was an estimate of N_e = 4 for the North Cascades (Service 2023, p. 27).

Overall, the effective population size estimates of wolverines occurring in the contiguous United States are small compared to conservation guidelines. Therefore, wolverines in the contiguous United States appear to be vulnerable to inbreeding and loss of genetic diversity when considered in isolation. However, only one or two migrants per generation are likely needed to achieve genetic population connectivity (Cegelski et al. 2006, p. 13). If populations were connected with a sufficient level of gene flow to offset the random loss of genetic variation in small populations, it would be more appropriate to evaluate the effective population size of the transboundary, interconnected population for the purposes of using conservation genetic rules-of-thumb.

Gene Flow Between the United States and Canada

In the contiguous United States, small, isolated wolverine populations are likely dependent on gene flow from Canada for population persistence (Cegelski et al. 2006, pp. 208–209; McKelvey et al. 2014, entire). Based on simulation analyses of gene loss, a census population of approximately 2,400 adult wolverines in the Northern Rocky Mountains and Greater Yellowstone Ecosystem would be needed to maintain 95 percent of the genetic variation over 100 wolverine generations (Cegelski et al. 2006, pp. 12–13). Because there is not likely sufficient habitat for that number of wolverines in the entire contiguous United States (Inman et al. 2013, p. 282), gene flow on the order of one or two wolverines per generation from Canada is critical to maintaining genetic diversity in wolverines in the contiguous United States (Cegelski et al. 2006, p. 13).

The best available genetic data indicate genetic structuring of populations despite some dispersal in the Northern Rocky Mountains (Cegelski et al. 2006, pp. 204–205, 208; Sawaya et al. 2023, pp. 12–14), indicating reduced gene flow. Nuclear genetic diversity was lower in the southern periphery of the subspecies' range where the recent recolonization from Canada occurred (Sawaya et al. 2023, pp. 9–11). Differences in allele frequencies between the United States and Canada along the Rocky Mountains are observed, with some areas of overlap in wolverine populations straddling the border due to male-mediated gene flow. Females appear to be segregated near the international border due to their higher rates of philopatry than males, and their apparently greater tendencies to avoid crossing major roadways, including major highways (Highway 1 and 3) in southern British Columbia (Sawaya et al. 2023, p. 12, 17). Traffic volumes have substantially increased since these highways were opened in the 1960s (British Columbia Ministry of Transportation and Highways 2001, pp. 7–11, 16–21).

No unique contemporary maternal lineages have been detected south of the international border, which is consistent with wolverines recolonizing the contiguous United States from Canada within the last 60–70 years (Sawaya et al. 2023, pp. 2, 16–17). Substantially lower mitochondrial DNA diversity in the United States, compared to Canada, is consistent with limited contemporary female gene flow between the countries along the Northern Rocky Mountain range and the North American wolverine's relatively recent recolonization at the southern edge of their range (Sawaya et al. 2023, p. 17).

Wolverines in western Washington and southern British Columbia form a small transboundary population in the North Cascades (Aubry et al. 2023, p. 4). Wolverines in the North Cascades are isolated from other wolverine populations in the United States and Canada and likely went through a genetic bottleneck with few founders (Sawaya 2023, pers. comm.). The population has low heterozygosity (less than 0.5) and is likely experiencing some level of inbreeding (Sawaya 2023, pers. comm.). However, there are currently no indications of inbreeding depression (Sawaya 2023, pers. comm.).

Population Structure and Gene Flow Within Canada

In our 2018 SSA, we stated that wolverines in Canada are considered to occur as a single large group because they are easily able to move between areas of good habitat and because wolverine habitat is relatively contiguous. New scientific information now shows that certain anthropogenic

features (*e.g.,* multi-lane highways) limit gene flow in southwestern Canada and supports previous research showing a pattern of decreasing genetic diversity in wolverines from north to south (*e.g.,* Sawaya et al. 2019, pp. 621–623; Sawaya 2023, pers. comm.). Human infrastructure and other anthropogenic and natural barriers also have the potential to impede dispersal and affect wolverine population distribution and gene flow in Canada (Lofroth and Ott 2007, pp. 2194–2195). These impediments are more prevalent in the southern portions of Canada (*e.g.,* Lofroth and Ott 2007, p. 2194). Additionally, the best available genetic data indicate substantial female population genetic isolation in wolverines (McKelvey et al. 2014, pp. 328–332; Schwartz et al. 2009, appendix A; Zigouris et al. 2012, pp. 1520–1522; Sawaya et al. 2023, p. 17), with the possibility that the Trans-Canada Highway represents a ''continental barrier to female wolverine movement'' (Sawaya et al. 2019, p. 623). There is also new information that Highway 3 in southern British Columbia likely limits female wolverine gene flow (Sawaya et al. 2023, pp. 17). Therefore, wolverine populations in southern British Columbia and Alberta near the transboundary interface are less genetically connected to the contiguous United States than we found in our 2018 SSA.

Gene Flow Within the Contiguous United States

Previous studies found wolverines have a strong association with areas that have persistent spring snow cover (Copeland et al. 2010, entire). Snow depth was the most important variable for predicting genetic structure overall in a new landscape genetics study in the Northern Rockies and at smaller spatial scales (up to about 230 km between genetic samples); however, at broad spatial scales (more than 430 km between genetic samples), housing density and terrain ruggedness explained the most variability in wolverine population genetic structure (Balkenhol et al. 2020, p. 799). These data highlight the importance of maintaining dispersal corridors for wolverines outside of core habitats, as they represent critical pathways for gene flow across broad spatial scales (Balkenhol et al. 2020, p. 799).

Analyses of the mitochondrial DNA revealed regional structuring (*i.e.,* regional grouping), with all of the samples collected in Idaho, Montana, and Wyoming assigned to Haplotype Wilson A (the most abundant haplotype in North America) and all of the samples in Washington assigned to Haplotype Wilson C (Lukas et al. 2020, p. 846). Haplotypes are groups of genes within an organism that are inherited together from a single parent. These results are consistent with the latest transboundary genetic analysis (Sawaya et al. 2023, entire) and previous mitochondrial DNA studies showing that the Northern Rocky Mountains and North Cascades do not appear to share any contemporary haplotypes (McKelvey et al. 2014, p. 328). New information also suggests that wolverines in the Greater Yellowstone Ecosystem have relatively low genetic diversity and high genetic distance from other wolverine populations in Idaho and Montana (Sawaya et al. 2023, pp. 8–9, 15–16).

The low effective population size and low genetic diversity present is likely the result of the recent colonization of the contiguous United States by wolverines from Canada. Relatively few migrants per generation would be needed to maintain the genetic health of wolverines in the contiguous United States. New genetic information indicates that gene flow across the landscape has been impeded by various barriers to wolverine (particularly female) movement. There is currently no evidence of inbreeding depression or any deleterious genetic effects in the contiguous U.S. population. Based on the best available scientific and commercial information, the low genetic diversity present in the contiguous United States is not currently a threat to the contiguous U.S. DPS of North American wolverine at the population level. However, in combination with other threats that limit dispersal of wolverines (roads, infrastructure development, climate change, trapping in Canada), the gene flow from Canada that is critical to maintaining genetic diversity in wolverines in the contiguous United States could be compromised and lead to future deleterious genetic effects to the contiguous U.S. DPS of North American wolverine.

Small Population Effects: The number of North American wolverines in the contiguous United States is relatively small compared to the remainder of the range in Canada and Alaska, in large part due to limited habitat and previous persecution and unregulated trapping pressures. In our 2018 finding and October 13, 2020, withdrawal document (85 FR 64618), we considered wolverines in the contiguous United States to be genetically connected to wolverines in Canada, and that wolverines in the contiguous United States were not separated from the larger North American wolverine population to the North (Canada and Alaska). We concluded that small population effects are not a stressor for wolverines in the contiguous United States now or within the foreseeable future.

Wolverine populations in the contiguous United States are small, fragmented, and relatively isolated from larger populations in Canada (Sawaya 2023, pers. comm.). Although male-mediated dispersal shows some level of wolverine population connectivity between the United States and Canada along the Rocky Mountains, female wolverines appear to have virtually no recent population connectivity based on genetic analyses (Sawaya 2023, pers. comm.). Small, isolated populations are more vulnerable to extinction through interactions of environmental, genetic, and demographic factors (Caughley 1994, pp. 221–227). Stochasticity in demographic rates at small population sizes causes outsized impacts to vital rates, even in a constant environment, which can greatly increase extinction risk. The repopulation of wolverines in the contiguous United States from Canada post-unregulated trapping over the last approximately 100 years has demonstrated the resiliency of the North American wolverine population to recover from extreme persecution and unprecedented direct mortality. We do not currently foresee any stochastic or catastrophic events that could result in a similar population-level effect on wolverines in the contiguous United States. However, the resiliency of the contiguous U.S. population to future catastrophic events is predicated on the ability of dispersing wolverines from Canada to repopulate the contiguous United States. As discussed above, connectivity with Canada is more limited than previously thought, especially considering the lack of female dispersal, which would be necessary for continued repopulation. Based on the best available scientific and commercial information, the small population size present in the contiguous United States is not currently a threat to wolverines at the population level. However, in combination with other threats, the small population size of wolverines in the contiguous United States could lead to a reduced ability of the population to withstand catastrophic events in the future.

Conservation Efforts and Regulatory Mechanisms

Federal Regulatory Mechanisms

Management of the wolverine and its habitat on Federal lands is crucial to

wolverine conservation, as Federal lands make up approximately 96 percent of modeled wolverine habitat, the majority of which are U.S. Forest Service lands (Service 2018, p. 103). The U.S. Forest Service manages the National Forest System lands in accordance with local land and resource management plans (Forest Plans). In 2012, the U.S. Forest Service published rules for revising Forest Plans (see 77 FR 21162, April 9, 2012, and 36 CFR part 219). The 2012 planning rule adopts a complementary ecosystem (coarse filter) and species-specific (fine filter) approach to maintaining the diversity of plant and animal communities and the persistence of native species in the plan area, within U.S. Forest Service authority and consistent with the inherent capability of the plan area (36 CFR 219.9). This complementary approach includes ecosystem and species-specific plan components.

In our 2018 SSA, we identified Forest Plans as important ''federal mechanisms'' that, in combination with State wildlife action plans, ''will alleviate effects associated with potential impacts related to stressors discussed in this report.'' However, in our 2018 SSA, we reviewed only four Forest Plans and did not identify in those plans any specific standards (mandatory constraints on project and activity decision-making) for wolverines.

For the wolverine SSA report addendum, we conducted a more comprehensive review of the latest Forest Plans for 20 National Forests within the current breeding range of the contiguous U.S. DPS of North American wolverine. We found a complex array of plan components aimed at achieving the 2012 planning rule's complementary ecosystem and species-specific approach, while balancing the U.S. Forest Service's multiple-use mandate. Some plans provided wolverine-specific guidelines, objectives, and direction to minimize effects of roads, winter recreation, and other sources of human disturbance, but we did not identify any wolverine-specific standards. The focus of wolverine-specific plan components, when they were included, was most often limited to protection of known den sites and maternal habitat during the denning season.

Course-filter protections of habitat-types and ecosystems contained in the plans will undoubtably provide some conservation benefits to wolverines. For example, generally wolverines will benefit from wilderness area protections (calculated as 18 percent of the extent of wolverine occurrence and 41 percent of core wolverine habitats in the western United States (Service 2018, p. 103)); limitations on development and road construction; limitations on road densities in certain areas for the grizzly bear (*Ursus arctos horribilis*) or other species; and restrictions on over-snow travel. However, quantifying these benefits outside of wilderness areas is challenging given the variability in Forest Plan standards and conservation measures across the U.S. range of the wolverine.

U.S. Forest Service regulations require National Forests to designate roads, trails, and off-road areas that are open and closed to motor vehicle use (36 CFR 212.5). In 2015, the U.S. Forest Service published a final rule indicating that it will also designate roads, trails, and areas open or closed to over-snow motor vehicle use (80 FR 4500; January 28, 2015). These designations are done on a Forest-by-Forest basis, resulting in variability in the amount of wolverine habitat impacted by these designations. For example, a recent draft environmental assessment for the Idaho Panhandle National Forests proposed to increase the area available to motorized over-snow use, resulting in projected increased impacts to primary wolverine habitat (from 39 percent currently to 52 percent under the proposed action) and maternal denning habitat (from 44 percent currently to 52 percent under the proposed action) (U.S. Forest Service 2023, p. 67). Conversely, the Gallatin National Forest reduced the amount of area open to over-snow use from 42 percent of wolverine denning habitat on the Forest to 25 percent (U.S. Forest Service 2006, chapter 3–623). This variability, and the lack of a rangewide assessment that overlays the areas of U.S. Forest Service over-snow vehicle use closures and wolverine habitat, make it difficult to characterize the effects of over-snow travel management planning on wolverines in the contiguous United States.

Several large National Parks contain core habitat for wolverines, including Yellowstone, Grand Teton, Glacier, North Cascades, and Mount Rainer National Parks. These areas are largely protected from development, although they may be impacted by winter recreation to varying degrees.

Although the Bureau of Land Management (BLM) manages relatively little land within wolverine core habitats, they do manage some of the valley bottoms between these core habitats. The wolverine is listed as a special status species by the following BLM offices: Montana/Dakotas (revision 2020), Idaho (revision 2022), and Oregon/Washington (revision 2021). The objectives of the BLM's special-status species policy are: (1) to conserve and/or recover species listed under the Act and the ecosystems on which they depend so that the protections of the Act are no longer needed for these species; and (2) to initiate proactive conservation measures that reduce or eliminate threats to BLM sensitive species to minimize the likelihood of and need for listing of these species under the Act. We did not identify any wolverine-specific standards in BLM resource management plans.

State and Provincial Regulatory Mechanisms

Wolverine trapping remains closed throughout the western United States and wolverines have retained various protected status designations in these States (Service 2023, table 10). Therefore, legal trapping is no longer an active direct stressor on wolverines in the contiguous United States. Nevertheless, the legacy effects of recent overharvest in southern Canada could negatively affect the wolverine's population resilience, distribution, and gene flow in the contiguous United States in the future (see *Overutilization for Commercial, Recreational, Scientific or Educational Purposes,* above).

In response to studies showing that wolverine harvest was unsustainable in southeastern British Columbia (Mowat et al. 2020, entire), the provincial government closed Resource Management Region 4 (Kootenay) in the southeastern portion of British Columbia to wolverine trapping and imposed a more intensive mortality recording system in that region in the fall of 2020 (British Columbia 2022, p. 76). Regions 2 (Lower Mainland) and 8 (Okanagan) remain closed to wolverine trapping under a temporary moratorium; therefore, the entire area of British Columbia along the U.S.-Canada border is now closed to wolverine trapping (British Columbia 2022, p. 76). Wolverine trapping remains open seasonally in British Columbia Resource Management Units 3, 5, 7A, 7B, and portions of Unit 6 (British Columbia 2022, p. 76), as well as in the Rocky Mountain region of southwestern Alberta (Alberta Environment and Parks 2022, pp. 14–15).

Resource management units in southern British Columbia remain open to trapping for several other furbearers, and incidental trapping of two wolverines has been documented following the closure in the Kootenay Resource Management Unit to wolverine trapping (Vander Vennen 2020, in litt.). Given the likelihood that there is some noncompliance with reporting incidental captures, the

precise number of wolverines incidentally trapped in Canada is not known (Vander Vennen 2022, in litt.). We note here that we have no indication that noncompliance with reporting incidental captures is a concern in the contiguous United States. There are many State regulations and guidelines in place to limit incidental wolverine trapping, and we have gathered the most up-to-date information on incidental captures from States within the range for inclusion in this rule (see *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes,* above).

Aside from regulated taking of wolverines, regulatory mechanisms available to States for conserving wolverines are largely related to maintaining habitat conditions that support wolverine connectivity. This is because the majority of the primary habitat cores for wolverines in the contiguous United States are on lands managed by the U.S. Forest Service. We are not aware of any other State regulatory mechanisms specific to wolverines that limit development, winter recreation, or other human disturbances in areas important to wolverine connectivity in the contiguous United States. Several States and other organizations, however, are implementing a number of voluntary monitoring or conservation measures for wolverines (see below).

Voluntary Conservation Measures

Western States continue to invest in monitoring wolverine occupancy. A notable effort includes that of the Western Association of Fish and Wildlife Agencies (WAFWA) Western States Wolverine Working Group, now referred to as the Forest Carnivore Sub-Committee. The purpose of this subcommittee is to develop a ''statistically defensible'' multi-State monitoring plan for States where wolverine populations exist (Wyoming, Montana, Idaho, and Washington), to seek funding to implement the monitoring plan, to coordinate development of individual State wolverine conservation plans for States with suitable wolverine habitat, and to coordinate and prioritize research efforts (WAFWA 2022, p. 1).

In 2020, the Wyoming Game and Fish Department (WGFD) developed a wolverine management plan for the State of Wyoming that includes management and conservation strategies in Wyoming. Its goals are to: (1) promote long-term wolverine viability, (2) support expansion of wolverines into suitable habitat, (3) support multi-State monitoring efforts, and (4) support management of the wolverine as a protected animal (WGFD 2020, p. 2).

Since 2018, Montana Fish, Wildlife and Parks has completed 10 habitat conservation projects in wolverine habitat that conserve 59,725 acres through fee title acquisition or perpetual conservation easement. A spatial toolset is now available for western Montana to help prioritize these types of acquisitions and easements (Carroll et al. 2021b, entire). Other tools such as the Crucial Areas Planning System (CAPS), a web-based landscape-scale planning tool, have also been put in place to help guide future developments that can impact wolverine habitat (MFWP 2022, in litt., p. 6).

In January 2023, the Idaho Fish and Game Commission (IFGC) adopted a revised management plan for the conservation of fisher (*Pekania pennanti*), wolverine, and Canada lynx. This plan provides updated guidance and identifies management priorities for the conservation of this suite of species over the next 6 years in Idaho. These priorities include four objectives and step-down actions related to connectivity, climate, incidental trapping, and increasing our knowledge of the relationship of wolverine denning and snow. Under the objective of addressing connectivity, IFGC proposes to continue contributing to the transboundary landscape genetics study, to develop products to support project planning and review, to develop voluntary partnerships to facilitate protections of important areas for movement and dispersal, to provide technical assistance to licensing and permitting authorities, and to maintain and to conserve wolverine populations and habitats through cooperative agreements. For the climate change objective, IFGC intends to improve modeling and monitoring. For the incidental trapping objective, IFGC intends to continue providing guidance and mandatory training to minimize nontarget capture of wolverines in traps. Lastly, to fill knowledge gaps, IFGC proposes to identify denning sites and will, if feasible, develop a model to predict denning areas to inform land management planning efforts.

The Utah Wildlife Migration Initiative, founded in 2017, identifies and protects connective corridors that allow fish and wildlife to migrate to necessary habitat areas around the State. The mission is to document, preserve, and enhance wildlife movement for species throughout Utah using state-of-the-art tracking and data management technologies, strong collaborative partnerships, and compelling outreach. The Migration Initiative and its partners are mapping the movements of wildlife, including wolverines, so crossing structures can be placed in areas that coincide with movement corridors. Similar work is being conducted in other States and is coordinated between States.

Colorado Parks and Wildlife had previously considered reintroducing wolverines to Colorado as a nonessential experimental population to further their conservation (see 78 FR 7890; February 4, 2013). However, that proposal was withdrawn in 2014, when we withdrew our proposed listing rule (see 79 FR 47522; August 13, 2014). There is currently no formal proposal to reintroduce wolverines to Colorado.

Since 2019, Woodland Park Zoo has been coordinating the Washington Wolverine Research and Monitoring Group, a coalition of researchers and conservationists who lead wolverine projects in Washington (Woodland Park Zoo 2022, in litt.). The goal of this group is to help advance North American wolverine research and monitoring in Washington by strengthening communication and collaboration among wolverine projects Statewide. This group meets several times a year to discuss research efforts, share results and insights, and strategize around wolverine research and conservation in Washington.

Summary of Conservation Efforts and Regulatory Mechanisms

The various Federal, State, and provincial regulatory mechanisms and voluntary conservation efforts described above are expected to provide some benefit to North American wolverine conservation in the contiguous United States. However, these mechanisms and efforts are inadequate to protect the subspecies from the impacts of climate change in the future when the cold and snowy conditions this subspecies is adapted to are expected to decrease.

Summary of Current Condition

Currently, in the contiguous United States, North American wolverines are distributed in five primary core areas (identified as management regions in Inman et al. 2013), including the Northern Cascades in Washington; the Salmon-Selway in central Idaho, including the Wallowa Mountains of northeastern Oregon; the northern Continental Divide in northwest Montana; the Central Linkage region of Idaho and Montana; and the Greater Yellowstone Ecosystem (Service 2023, figure 14). Although long-distance dispersers (primarily males) occasionally reach potentially suitable habitat in other regions, known breeding

populations are currently limited to these core regions.

The precise size of the wolverine populations in the contiguous United States are currently unknown but may be small due in part to their large territories and the limited amount of available habitat in the contiguous United States. Estimates based on extrapolations of densities and suitable habitat suggest there could have been approximately 318 wolverines (95 percent CI = 249–926) in the contiguous United States more than a decade ago (Inman et al. 2013, p. 282). The best available estimates of effective population size of wolverines in the contiguous U.S. portions of the Northern Rocky Mountains and North Cascades are likely fewer than 50 combined (Schwartz et al. 2009, p. 3226).

We evaluated previously modeled wolverine primary habitat in the contiguous United States (Inman et al. 2013, entire) and estimated that 96 percent of this area is owned or managed by Federal agencies and 41 percent of this area is located in designated wilderness areas (Service 2018, p. 72). Within Idaho, Montana, Washington, and Wyoming, non-spatial occupancy model estimates were slightly lower in 2021–2022 (mean occupancy = 0.33; 95 percent CI 0.21–0.34) compared to 2016–2017 (mean occupancy = 0.27, 95 percent CI 0.27–0.39), but with overlapping confidence intervals (Mosby et al. 2023, p. 4; Service 2023, table 2). Despite overlapping confidence intervals, Bayesian analysis revealed an 85 percent chance that the occupancy estimate from 2021–2022 was outside the 95 percent CI of the 2016–2017 occupancy estimate (Mosby et al. 2023, p. 4). The percentage of surveyed cells that were occupied decreased between the sampling periods in Montana (43.7 to 17.0 percent) and Washington (34.6 to 12.5 percent), increased in Wyoming (11.5 to 25.5 percent), and remained relatively unchanged in Idaho (33.8 to 34.5 percent) (Service 2023, table 2). Spatial occupancy models by geographic area showed substantial differences between the sampling periods, with both lower and higher occupancy probabilities depending on the geographic area (Service 2023, table 3; Mosby et al. 2023, pp. 4–7). Although no wolverines were detected during the 2021–2022 survey in the sampled cells of Oregon, Utah, or Colorado (Service 2023, table 2), recent wolverine detections from other research efforts or incidental observations have been reported in Oregon, Utah, and California (Service 2023, p. 6). Despite differences between the sampling periods, Mosby et al. (2023, p. 7) indicate that interpretations of the relationship between the two estimates be considered cautiously, and that repeated surveys into the future will be helpful in ultimately interpreting any trends in occupancy estimates. The reasons for the observed changes in occupancy by geographic region are not yet clear, and could be sampling anomalies, a real shift in distribution, or some combination of factors (Mosby et al. 2023, p. 7). This aligns with our analysis of wolverine observations from State wildlife agencies, the U.S. Forest Service, the National Park Service, Tribes, researchers, and others in the western United States from 2009–2022, which shows wolverines continue to occupy much of the core habitat within their breeding range in the contiguous United States (Service 2023, figure 2).

Contiguous U.S. contemporary wolverine populations are most likely descendants of immigrants from Canada (Service 2018, p. 49). Wolverine genetic diversity in the contiguous United States is relatively low, and there are no known unique mitochondrial DNA haplotypes present in contiguous U.S. wolverine populations (Sawaya et al. 2023, pp. 10–11). Due to the limited amount of potential wolverine habitat in the United States, connectivity and gene flow with Canada is necessary for the long-term genetic health and viability of wolverines in the western United States. In the North Cascades, new GPS tracking information shows that wolverines in western Washington and southern British Columbia form a small transboundary population (Aubry et al. 2023, p. 4), although they are isolated from other wolverine populations in the United States and Canada (Sawaya et al. 2023, pp. 9–13, 16). In the Northern Rocky Mountains, the best available data indicate genetic differences between populations despite some (mostly male-mediated) gene flow (Cegelski et al. 2006, pp. 204–205, 208; Sawaya et al. 2023, pp. 12, 17). Measurable differences have been reported in mitochondrial DNA haplotype diversity and nuclear microsatellite DNA allele frequencies between the U.S. Rocky Mountain populations and Canada populations (Cegelski et al. 2006, p. 203, Sawaya et al. 2023, pp. 12, 17). There is currently no evidence of inbreeding depression in wolverine populations in the contiguous United States; however, there is potential for inbreeding given the relatively small population sizes of wolverines here, especially in the Cascades (Sawaya 2023, pers. comm.).

Wolverine populations in much of North America are still recovering from large losses of individuals from intensive hunting and unregulated predator control in the late 1880s into the mid-20th century (Service 2018, p. 104). Trapping and poisoning from the late 1800s/early 1900s contributed to extirpation in the contiguous United States during that time, but individuals have come back (from Canada) over the years since. Trapping or hunting of wolverines remains prohibited in the United States, and mortality from incidental trapping is currently rare. Over the past century, there has been enough connectivity with Canada for wolverines to repopulate the contiguous United States. New genetic research provides further evidence of this recolonization via dispersers from Canada (Service 2023, pp. 27–28). However, connectivity in recent years is less certain.

In our October 13, 2020, withdrawal document (85 FR 64618), we determined that wolverines in the contiguous United States were connected to and an extension of the Canadian population. We now know that there are potential barriers to recent movement of wolverines to and from the contiguous United States, as evidenced by the genetic profile of wolverines in the contiguous United States (Sawaya et al. 2023, entire). Trapping in Canada near the international border was thought to be occurring at sustainable levels at the time we published our October 13, 2020, withdrawal document (85 FR 64618). In a portion of southwestern Canada encompassing a Rocky Mountain National Park complex and surrounding unprotected lands, the wolverine population declined approximately 40 percent (approximately 15–20 wolverines) from 2011–2020, likely due largely to overharvest through trapping (Barrueto et al. 2022, p. 4). This area may be an important source of dispersing individuals, and overharvest could reduce pressure for surplus wolverines, particularly females, to disperse south towards the contiguous United States. In addition, genetic analysis shows that recent dispersing individuals from Canada have been exclusively male wolverines and major highways in Southern Canada appear to limit female dispersal (Sawaya et al. 2023, pp. 12–14, 17). Also, various studies that have come available since the 2018 SSA report reinforce the understanding that wolverines avoid areas of significant human development and that development may inhibit dispersal of wolverines between home ranges and

habitat patches (Service 2023, pp. 34–36). Even though there is low genetic diversity in the contiguous U.S. population, the population is relatively small, and habitat is somewhat fragmented, there is no current evidence of inbreeding depression in contiguous U.S. wolverines and the population appears stable from an occupancy perspective.

We evaluated several threats that may be affecting wolverine populations or their habitats, including effects from roads, disturbance due to winter recreational activities, human disturbance and development, effects from wildland fire, disease and predation, overutilization, genetic diversity, small population effects, and climate change. Although these threats may affect individual wolverines, none of these threats is currently impacting wolverine resiliency (the subspecies' ability to rebound from environmental stochasticity) in the contiguous United States at a population level. In the future, the synergistic effect of some of these threats coupled with the impact of climate change (increased temperatures and decreased spring snowpack) could reduce resiliency of the contiguous U.S. population (see *Summary of Future Condition,* below), although climate change is not currently impacting the DPS. Currently, the contiguous U.S. population appears resilient because despite the potential threats analyzed, the population continues to show stability and wolverines occupy a large portion of the available habitat in the western United States, providing redundancy to withstand potential catastrophes. Wolverine breeding populations in the western United States are currently distributed across four unique ecoregions (Service 2023, figure 16). This ecoregion variation can correlate with species-wide evolutionary potential, providing representation (the ability to adapt to changes in the biological and physical environment). The North American wolverine's wide distribution across multiple ecoregions and differential exposure to various stressors also affords the DPS redundancy against catastrophic events. Overall, the current resiliency, redundancy, and representation of the contiguous U.S. population of wolverines supports current DPS viability.

Summary of Future Condition

In the wolverine SSA report addendum, we provide a comprehensive analysis of the future condition of wolverines in the contiguous United States, which we summarize here (Service 2023, pp. 61–69). Wolverine habitat in the contiguous United States is projected to decrease and become more fragmented by the end of the century as a result of climate changes that result in increasing temperatures, earlier spring snowmelt, and loss of deep, persistent spring snowpack, primarily at lower elevations (see *Climate Change,* above). Winter recreation, which has been shown to negatively influence wolverine behavior during an important time of year when females are denning and raising young, in these diminished habitats may increase as human populations increase (U.S. Forest Service 2016, pp. 12–14). In addition, snow-dependent recreation that was formerly distributed over a wider elevation gradient will be constrained to that part of the gradient that contains quality snow into the future. Concurrently, human development may continue to expand in areas between core habitats that are important for maintaining wolverine population connectivity. While wolverines are capable of crossing areas with some human disturbance during dispersal, they also have shown some sensitivity to human development and other human impacts in rugged areas located between typical core wolverine habitats (Balkenhol et al. 2020, p. 799; Barrueto et al. 2022, p. 4). Increased human development, infrastructure, and associated anthropogenic disturbance are expected to have direct and indirect effects to wolverine populations in the contiguous United States, including reducing the number of wolverines that can be supported by available habitat, reducing the ability of wolverines to travel between patches of suitable habitat, and reducing potential dispersers from Canada. A reduction in population size and connectivity within the contiguous United States and with Canada may affect metapopulation dynamics, making it more difficult for subpopulations to recolonize currently extirpated areas and augment the genetics or demographics of adjacent subpopulations. We expect wolverine resiliency and redundancy in the contiguous United States to decline in the future.

We have identified significant uncertainties that hamper our ability to predict the scope, scale, and timing of future demographic outcomes for wolverines in the contiguous United States. These include uncertainties in mechanistic habitat relationships; census and effective population sizes; and the cumulative impact of multiple stressors on population connectivity, survival, and reproduction. Nevertheless, habitat loss through climate change, combined with other stressors, is likely to negatively impact wolverines in the contiguous United States over the next century by reducing resiliency, redundancy, and representation. Moreover, there are few actions that are reasonably certain to occur in the future that would compensate for these negative impacts.

We evaluated the contiguous U.S. DPS of North American wolverine's ability to respond to environmental change in two ways. First, we examined core attributes of the contiguous U.S. DPS of North American wolverine's adaptive capacity in relation to standardized attributes to characterize the likelihood that wolverines in the western United States will be able to adapt to changed conditions (representation) (Thurman et al. 2020, entire; Service 2023, figure 15). Second, we evaluated the current and potential distribution of wolverines across ecological regions of the western United States given that ecological changes may vary across space and that wolverines in different ecological contexts may have dissimilar responses to these changes.

The contiguous U.S. DPS of North American wolverine's ability to adapt to climate change and other environmental changes, its adaptive capacity (representation), is key to reducing its vulnerability to these changes. Our qualitative adaptive capacity analysis for the contiguous U.S. DPS of North American wolverine was based on life-history characteristics and shows that several intrinsic factors make North American wolverines susceptible to negative outcomes from future environmental change (Service 2023, pp. 66–69). Their specialized habitat associations, low genetic diversity and population size, narrow ecological niche, low tolerance for human disturbance, and slow reproductive rate all contribute to the contiguous U.S. DPS of North American wolverine's relative difficulty in adapting in-place to future environmental change (Service 2023, table 14). Factors that may partially mitigate the contiguous U.S. DPS of North American wolverine's low adaptive capacity are their ability to disperse long distances, their relatively wide distribution in the Northern Rocky Mountains and in the North Cascades (albeit in a narrow climactic niche), and their flexible diet (Service 2023, table 14). Stressors that lessen the ability of North American wolverines to disperse, or that decrease their distribution, are likely to also degrade their adaptive capacity (redundancy), leaving them more vulnerable to environmental change.

Maintaining a species, or in this case a subspecies, across its full breadth of ecological variation can reduce extinction risk (Forester et al. 2022, p. 512). To further assess the contiguous U.S. DPS of North American wolverine's future evolutionary potential, we examined the DPS's current distribution across different ecoregion provinces. Ecoregion provinces incorporate temperature, precipitation, and vegetation data, and therefore represent landscapes with similar environmental traits (Bailey 2016, entire). Wolverine breeding populations in the western United States currently exist in 4 of 10 ecoregions where there is potential wolverine core habitat (Service 2023, figure 16). Outside of the area with known wolverine breeding, several ecoregions in the western United States contain only a relatively small area of potential wolverine core habitat. Except for the Sierran Steppe-Forest-Alpine ecoregion, wolverine breeding populations currently inhabit all the ecoregions of the western United States with large contiguous blocks of potential wolverine core habitat (Service 2023, figure 16).

Despite their relatively wide distribution among ecoregions, wolverines in the contiguous United States have low genetic diversity compared to Canadian populations and are unlikely to have evolved specialized adaptations to southern climates given their recent recolonization following extirpation (McKelvey et al. 2014, p. 332). The historical population of wolverines in the Sierra Nevada may have possessed unique evolutionary potential given the distinct genetic and taxonomic characteristics of historical museum samples; however, the wolverines in the Sierras were extirpated in the early 1900s, and their matrilines were eliminated from North America (McKelvey et al. 2014, p. 332). Nevertheless, the DPS's distribution across multiple ecoregions means that parts of their range may have less exposure to future stressors. Expansion into unoccupied ecoregions where there is suitable habitat could further decrease their risk of exposure to future stressors.

Wolverine populations in the contiguous United States are currently small, fragmented, and relatively isolated from larger populations in Canada (Cegelski et al. 2006, pp. 206–207, 210; Sawaya 2023, pers. comm.). Although male-mediated dispersal shows some level of wolverine population connectivity between the United States and Canada along the Rocky Mountains, female wolverines appear to have virtually no recent population connectivity based on recent genetic analyses (Sawaya 2023, pers. comm.). Small, isolated populations are more vulnerable to extinction through interactions between environmental, genetic, and demographic factors (Caughley 1994, pp. 221–227). Stochasticity in demographic rates at small population sizes causes outsized impacts to vital rates, even in a constant environment, which can greatly increase extinction risk. Small, isolated populations also lose genetic diversity over time, primarily through inbreeding and genetic drift, which can exacerbate extinction risk if demographic rates are further degraded through inbreeding depression (Benson et al. 2016, p. 8). Low genetic diversity can also reduce future adaptive capacity and evolutionary potential, reducing representation.

Although historical wolverine populations were likely naturally small and distributed among patches of high-elevation alpine habitats in the contiguous United States, core wolverine habitats in the contiguous United States are projected to become smaller and more fragmented in the future as a result of climate change and human disturbance. These changes may degrade the DPS's resiliency and redundancy over time, although there are uncertainties in the precise amount of degradation, how much this degradation will affect wolverine viability in the contiguous United States, or the time period over which the degradation would happen. Despite their current distribution across several ecological regions of the West, the core attributes related to adaptive capacity exhibited by wolverines may limit the ability of this DPS to adapt and persist in the face of projected environmental change. Long-distance dispersal and recolonization of some of the larger areas outside of the current breeding range of the contiguous U.S. DPS of North American wolverine (*e.g.,* Sierra Nevada and central Rocky Mountains) could partially mitigate their susceptibility to environmental change. Dispersal between currently occupied core habitats may become more difficult in the future with anticipated increases in human development between the alpine core areas and increased backcountry winter recreation in core habitats. However, wolverine dispersal could be maintained or improved by human intervention (*e.g.,* conserving wildlife corridors between alpine habitats, constructing highway crossing structures for wildlife).

Overall, the wolverine population in the contiguous United States is expected to decrease in resiliency, redundancy, and representation in the future. We acknowledge that new information suggests populations in the contiguous United States may be less secure in the future than we described in our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618). We also acknowledge that uncertainty remains around gene flow between the United States and Canada, core habitats and key dispersal corridors among core areas of the contiguous United States, and the effective population size in the contiguous United States. Nevertheless, the best available information suggests that habitat loss as a result of climate change, and the resulting exacerbating effect on other stressors, is likely to decrease the viability of wolverines in the contiguous United States over the next century.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the wolverine SSA report and SSA report addendum, we have analyzed the cumulative effects of identified threats and conservation actions on the DPS. To assess the current and future condition of the DPS, we evaluate the effects of all the relevant factors that may be influencing the DPS, 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 DPS, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Determination of North American Wolverine'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 endangered species or 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

In our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618), we noted that during the late 1800s and early 1900s, the wolverine population declined or was extirpated in much of the contiguous United States. This decline and range contraction has been attributed to unregulated trapping and habitat degradation (Hash 1987, p. 583). However, given the high-elevation core habitats of wolverines in the contiguous United States, direct mortality through predator poisoning campaigns and unregulated trapping were likely the primary culprits.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to North American wolverines in the contiguous United States including climate change (Factors A and E); effects from roads (Factors A and E); disturbance due to winter recreational activity (Factors A and E); other human disturbance (Factors A and E); effects from wildland fire (Factor A); disease (Factor C); predation (Factor C); overutilization (trapping) (Factor B); genetic diversity (Factor E); and small population effects (Factor E). We also assessed the adequacy of existing regulatory mechanisms (Factor D).

After evaluating threats that may be currently affecting wolverines in the contiguous United States, we have determined that although these threats may affect individual wolverines, there are no threats currently impacting wolverines in the contiguous United States at a population level. In the future, the synergistic effect of some threats coupled with the impacts of climate change (increased temperatures and decreased spring snowpack) are expected to reduce resiliency of the contiguous U.S. population, although climate change is not currently impacting wolverines occurring in the United States. Currently, the contiguous U.S. population appears resilient, as wolverines continue to consistently occupy a large portion of the available habitat in the western United States. Furthermore, wolverine breeding populations in the western United States are currently distributed across four ecoregions, which affords the DPS redundancy against catastrophic events. This ecoregion variation influences representation by potentially providing evolutionary potential to adapt to changes in the biological and physical environment. Thus, wolverines in the contiguous United States are not currently in danger of extinction throughout their range.

We expect wolverine populations in the contiguous United States to decrease in resiliency, redundancy, and representation within the foreseeable future. We consider 2100 to be the foreseeable future in this case. The main threat to wolverines is the effect of climate change on spring snow. We were able to reliably model changes in spring snow out to 2100 in our climate change analysis, and we are able to reasonably determine the wolverine's response to this threat is likely in the foreseeable future. Wolverine populations in the contiguous United States are small, fragmented, and relatively isolated from larger populations in Canada (Cegelski et al. 2006, pp. 206–207, 210; Sawaya et al. 2023, entire). Although male-mediated dispersal shows some level of wolverine population connectivity between the United States and Canada along the Rocky Mountains, female wolverines appear to have virtually no recent population connectivity based on recent genetic analyses (Sawaya et al. 2023, pp. 12–14, 17). Small, isolated populations are more vulnerable to extinction through interactions between environmental, genetic, and demographic factors (Caughley 1994, pp. 221–227). Stochasticity in demographic rates at small population sizes causes outsized impacts to vital rates, even in a constant environment, which can greatly increase extinction risk. Small, isolated populations also lose genetic diversity over time, primarily through inbreeding and genetic drift, which can exacerbate extinction risk if demographic rates are further degraded through inbreeding depression (Benson et al. 2016, p. 8). Low genetic diversity can also reduce adaptive capacity and evolutionary potential.

Although historical North American wolverine populations were likely naturally small and distributed among patches of high-elevation alpine habitats in the contiguous United States, core wolverine habitats in the United States are projected to become smaller and more fragmented in the future as the result of climate change and human disturbance. These changes are expected to degrade wolverine resiliency and redundancy over time, although there are uncertainties in the precise amount of degradation, how much this degradation will affect wolverine viability in the contiguous United States, and the precise time period over which the degradation would happen. Despite these uncertainties, the best available information indicates the impacts are such that the DPS's viability will decrease within the foreseeable future. Although wolverines are currently distributed across several ecological regions of the U.S. West, the core attributes related to their adaptive capacity may limit the ability of this DPS to adapt and persist in the face of projected environmental change. Long-distance dispersal and recolonization of some of the larger areas outside of the current breeding range of North American wolverines (*e.g.,* Sierra Nevada and central Rocky Mountains) could partially mitigate their susceptibility to environmental change. However, natural dispersal between currently occupied core habitats is expected to become more difficult in the future with anticipated increases in human development between the alpine core areas and increased backcountry winter recreation in core habitats.

After evaluating threats to the DPS and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we find that wolverine populations in the contiguous United States are less secure in the future than we described in our 2018 SSA and October 13, 2020, withdrawal document (85 FR 64618). The best available information suggests that habitat loss as a result of climate change and impacts from other stressors are likely to negatively impact the viability of wolverines in the contiguous United States over the next century. Thus, after assessing the best available information, we conclude that the contiguous U.S. DPS of North American wolverine in is not currently 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'' (Final Policy; 79 FR 37578; July 1, 2014) that provided if the Service determines that a species is threatened throughout all of its range, the Service 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 there are any significant portions of the North American wolverine's range in the contiguous United States where the DPS is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for the DPS, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the DPS and the threats that the DPS faces to identify portions of the range where the DPS may be endangered.

We evaluated the range of the contiguous U.S. DPS of North American wolverine to determine if the DPS is in danger of extinction now in any portion of its range. The range can theoretically be divided into portions in an infinite number of ways. We focused our analysis on portions of the range that may meet the Act's definition of an endangered species. For this DPS, we considered whether the threats or their effects on the DPS are greater in any biologically meaningful portion of the range than in other portions such that the DPS is in danger of extinction now in that portion.

We examined the following threats: climate change (Factors A and E); effects from roads (Factors A and E); disturbance due to winter recreational activity (Factors A and E); other human disturbance (Factors A and E); effects from wildland fire (Factor A); disease (Factor C); predation (Factor C); overutilization (trapping) (Factor B); genetic diversity (Factor E); and small population effects (Factor E), including cumulative effects.

The North Cascades portion of the DPS's range is the only biologically meaningful portion that we identified that could potentially have a different status than the remainder of the range. It is largely isolated by an expanse of unsuitable habitat from the larger Rocky Mountains portion of the range. All of the threats affecting wolverines are ubiquitous throughout the contiguous U.S. range; however, the low genetic diversity of the Cascades population could potentially affect this portion more so than the rest of the range due to the apparent lack of recent genetic connectivity with Canada in that portion (Sawaya 2023, pers. comm.). The North Cascades wolverines are isolated from other wolverine populations in the United States and Canada and likely went through a genetic bottleneck with few founders (Sawaya 2023, pers. comm.). The effective population size of the North Cascades population is estimated at $N_e = 4$, and the population may be vulnerable to inbreeding and loss of genetic diversity when considered in isolation. Recent genetic research shows the population has low heterozygosity (less than 0.5) and may be experiencing some level of inbreeding (Sawaya 2023, pers. comm.). However, there is currently no indication that individuals or population dynamics are being negatively affected by inbreeding depression (Sawaya 2023, pers. comm.) or that wolverines in this portion are currently being more severely or differently affected by any other threats. Gene flow with wolverines in Canada in the future is important to the long-term genetic health of the North Cascades population, but this portion is not currently in danger of extinction, as the population is currently showing stability in occupancy and not expressing any deleterious effects of inbreeding.

We found no biologically meaningful portion of the DPS's range where threats are impacting individuals differently from how they are affecting the DPS elsewhere in the range, or where the biological condition of the DPS differs from its condition elsewhere in the range such that the status of the DPS in that portion differs from any other portion of the DPS's range.

Therefore, no portion of the DPS's range provides a basis for determining that the DPS is in danger of extinction in a significant portion of its range, and we determine that the DPS 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

Our review of the best scientific and commercial data available indicates that the contiguous U.S. DPS of the North American wolverine meets the Act's definition of a threatened species. Therefore, we are listing that DPS 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, 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 Ecological Services Program, Pacific Region (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.

Once this DPS 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 States of California, Colorado, Idaho, Montana, Oregon, Utah, Washington, and Wyoming will be eligible for Federal funds to implement management actions that promote the protection or recovery of the North American wolverine. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/service/financial-assistance.*

Please let us know if you are interested in participating in recovery efforts for the contiguous U.S. DPS of the North American wolverine. Additionally, we invite you to submit any new information on this DPS 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 (see 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.

Examples of discretionary actions for the contiguous U.S. DPS of the North American wolverine that may be subject to consultation procedures under section 7 are land management or other landscape-altering activities on Federal lands administered by the U.S. Forest Service, National Park Service, and Bureau of Land Management, as well as actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or 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 local Service Field Office (see **FOR FURTHER INFORMATION CONTACT**) with any specific questions on section 7 consultation and conference requirements.

It is the policy of the Service, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the extent known at the time a species is listed, specific activities that will not be considered likely to result in violation of section 9 of the Act. To the extent possible, activities that will be considered likely to result in violation will also be identified in as specific a manner as possible. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within the range of the species. Although most of the prohibitions in section 9 of the Act apply to endangered species, sections 9(a)(1)(G) and 9(a)(2)(E) of the Act prohibit the violation of any regulation, including any regulation issued under section 4(d) of the Act, pertaining to any threatened species of fish or wildlife, or threatened species of plant, respectively. Section 4(d) of the Act directs the Secretary to promulgate protective regulations that are necessary and advisable for the conservation of threatened species. As a result, we interpret our policy to mean that, when we list a species as a threatened species, to the extent possible, we identify activities that will or will not be considered likely to result in violation of the protective regulations under section 4(d) for that species.

The following activities could potentially result in a violation of section 9 of the Act; this list is not comprehensive: Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the listed subspecies, including import or export across State lines and international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act.

Questions regarding whether specific activities will constitute violation of section 9 of the Act should be directed to the Service's Pacific Regional Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Interim Rule Issued Under Section 4(d) of the Act

Background

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. The U.S. Supreme Court has noted that statutory language similar to the language in section 4(d) of the Act authorizing the Secretary to take action that she ''deems necessary and advisable'' affords a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592, 600 (1988)). 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. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting one or more of the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard 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 [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, or [s]he 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).

The provisions of this 4(d) rule will promote conservation of the contiguous U.S. DPS of the North American wolverine by encouraging management of the landscape in ways that meet the conservation needs of the wolverine. The provisions of this rule are one of many tools that we will use to promote the conservation of the DPS.

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.

These requirements are the same for a threatened species with 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 that has a species-specific 4(d) rule, the agency will still need to informally consult with the Service and obtain 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 and the formulation of a biological opinion (50 CFR 402.14(a)). The Service will take into account the exceptions of any 4(d) rule when issuing a biological opinion and any associated incidental take statement, but a 4(d) rule does not eliminate the Federal agency's obligation to consult under section 7(a)(2) of the Act.

We proposed a 4(d) rule along with our proposed listing rule for the contiguous U.S. DPS of the wolverine in 2013 (78 FR 7864; February 4, 2013). In the proposed 4(d) rule, we stated that we would prohibit take of any wolverine in the contiguous United States when associated with or related to trapping, hunting, shooting, collection, capturing, pursuing, wounding, killing, and trade. We further stated that, in this context, any activity where wolverines are attempted to be, or are intended to be, trapped, hunted, shot, captured, or collected, in the contiguous United States, would be prohibited. Additionally, we said that it would also be prohibited to incidentally trap, hunt, shoot, capture, pursue, or collect wolverines in the course of otherwise legal activities. We also clarified that all otherwise legal activities involving wolverines and their habitat that are conducted in accordance with applicable State, Federal, Tribal, and local laws and regulations would not be considered to be take under the proposed 4(d) rule. We identified several risk factors for the U.S. DPS of the wolverine that, in concert with climate change, may result in reduced habitat value for the DPS. These risk factors included human activities like dispersed recreation, land management activities by Federal agencies and private landowners, and infrastructure development. However, in 2013, we considered these risk factors to be small in scope and scale, and ultimately not a concern for the conservation of the DPS. As a result, we did not propose to prohibit take associated with these activities.

New information on the threats to this DPS and how these threats may affect the future condition of wolverines in the contiguous United States (see Summary of Biological Status and Threats, above) has changed our understanding of what provisions are appropriate for the contiguous U.S. DPS of the North American wolverine. We are now tailoring the provisions of this interim 4(d) rule informed by new information. This is an interim rule, meaning that it will go into effect on the effective date specified above under **DATES**, but we are also accepting public comments on the 4(d) rule (see **DATES** and **ADDRESSES**, above). We will assess any comments we receive on the 4(d) rule and publish either an affirmation of this interim rule or a revised final rule for the 4(d) rule.

Provisions of the Interim 4(d) Rule

Exercising the Secretary's authority under section 4(d) of the Act, we have developed a rule that is designed to address the contiguous U.S. DPS of the North American wolverine's conservation needs. As discussed previously in Summary of Biological Status and Threats, we have concluded that the DPS is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss as a result of climate change and the cumulative impacts of other, lower-level stressors, including winter recreation, development, and major roads. 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 find that the protections, prohibitions, and exceptions in this 4(d) 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 DPS.

The protective regulations for the contiguous U.S. DPS of the North American wolverine incorporate prohibitions from section 9(a)(1) to address the threats to the DPS. Section 9(a)(1) prohibits the following activities for endangered wildlife: 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. This interim 4(d) rule includes all of these prohibitions, with limited exceptions, for the DPS. With these general protective prohibitions in

place, the 4(d) rule reinforces the preservation of the DPS's populations by prohibiting activities that would incentivize the killing of wolverines for commercial gain.

As noted, this 4(d) rule generally prohibits the ''take'' of wolverines in the DPS. 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 regulation at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating take will help preserve the DPS's remaining populations and decrease the effects to wolverines from the synergistic, negative effects from other ongoing or future threats. Therefore, we are prohibiting take of wolverines in the DPS, except for take resulting from those actions and activities specifically excepted by the 4(d) rule.

Exceptions to the prohibition on take include all of the general exceptions to the prohibition on take of endangered wildlife, as set forth in 50 CFR 17.21(c) and (d), and additional exceptions, as described below.

The interim 4(d) rule also provides for the conservation of the DPS by establishing exceptions to the general prohibition against ''take'' of wolverines in the DPS in support of conservation actions and otherwise lawful activities that could incidentally take a wolverine but at minimal levels not likely to have a negative impact on the DPS's conservation. We considered a variety of exceptions and determined that not all were necessary (*e.g.,* we do not include an exception for take of depredating wolverines because wolverines rarely take livestock) or would provide conservation benefits (*e.g.,* we do not include exceptions for backcountry winter recreation because recreating in these areas can be detrimental to wolverines). The exceptions to these prohibitions, described in further detail below, include certain standard exceptions, as well as purposeful take due to scientific research on wolverines, take incidental to forest management activities for the purposes of reducing the risk or severity of wildfire, and take incidental to legal trapping of species other than the wolverine that is conducted consistent with State trapping laws and regulations and that contains steps to minimize the potential for capture of wolverines.

Nothing in this interim 4(d) rule will change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the wolverine. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service.

Standard Exceptions

We may, under certain circumstances, issue permits to carry out one or more of the otherwise prohibited activities. These include permits issued for the following purposes: for scientific research and conservation purposes (for an activity that would not fall within the research exception for incidental take in the 4(d) rule, as described below); to enhance propagation or survival; for economic hardship; for zoological exhibition; for educational purposes; for incidental taking (for an activity not already excepted in the 4(d) rule); or for special purposes consistent with the purposes of the Act (see 50 CFR 17.32). The Act also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship 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 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, will be able to conduct activities designed to conserve the contiguous U.S. DPS of the North American wolverine that may result in otherwise prohibited take without additional authorization.

Scientific Research

Future scientific research on North American wolverines in the contiguous United States will aid conservation and recovery by leading to a better understanding of the biology and ecology of this elusive and hard-to-study species. WAFWA, in coordination with Tribal partners, formed a multi-State, multi-agency working group (Western States Wolverine Working Group) to design and implement the Western States Wolverine Conservation Project (WSWCP)–Coordinated Occupancy Survey (Service 2018, p. 52). The primary objectives of the WSWCP include: (1) implement a monitoring program to define a baseline wolverine distribution and genetic characteristics of the metapopulation across Montana, Idaho, Wyoming, and Washington; (2) model and maintain the connectivity of the wolverine metapopulation in the western United States; and (3) develop policies to address socio-political needs to assist wolverine population expansion as a conservation tool, including translocation of wolverines (Service 2018, p. 52). Activities associated with scientific research may include capture, anesthesia, collaring, tracking, genetic sampling, the use and baiting of camera and DNA traps, den monitoring, and aerial surveying. State agencies with approved cooperative agreements (see cooperative agreements discussion above for additional information) and the Service will not be required to obtain separate ESA permits for take associated with these actions, as we are including the exceptions at 50 CFR 17.31(b) in the 4(d) rule. To facilitate Federal agencies or federally recognized Tribes to participate in and assist with these activities, we are also including an exception that allows biologists, acting in an official capacity, from other Federal agencies or federally recognized Tribes to take wolverine for scientific or research purposes that are associated with wolverine conservation efforts, as identified by the Service, provided such taking does not result in death or permanent injury to the wolverine(s) involved. Taking that results in death or permanent injury must be reported to the appropriate U.S. Fish and Wildlife Service law enforcement office and to appropriate State and Tribal authorities.

Forest Management Activities for the Purposes of Reducing the Risk or Severity of Wildfire

As discussed in the February 4, 2013, proposed listing rule (78 FR 7864) and October 13, 2020, withdrawal document (85 FR 64618), management activities (*e.g.,* timber harvest, wildland firefighting, prescribed fire, and silviculture) can modify wolverine habitat, but this generalist species appears to be affected little by changes to the vegetative characteristics of its habitat. In addition, most wolverine breeding habitat in the contiguous United States occurs at high elevations in rugged terrain that is not conducive

to intensive forms of silviculture and timber harvest. Forest management activities for the purposes of reducing the risk or severity of wildfire are generally not a threat to wolverines in the contiguous United States.

Under this interim 4(d) rule, incidental take caused by forest vegetation management for the purpose of wildfire mitigation that promotes the long-term stability and diversity of forests will not be prohibited. Broadly, the forest vegetation and fire management activities referred to above may include, but are not limited to, silviculture practices and forest-management activities that address fuels management; insect and disease impacts; vegetation management in existing utility rights-of-way; and wildlife-habitat management, including planting seedlings or sowing seeds, mechanical cuttings as a restoration tool in stands experiencing advancing succession, full or partial suppression of fires, allowing fires to burn, and survey and monitoring of forest health. Because no forest vegetation management activities for the purposes of reducing the risk or severity of wildfire pose any threat to the North American wolverine at the DPS level, we purposefully do not specify in detail what types of these activities are included in this exception, or how, when, or where they must be conducted, as long as they are conducted in accordance with applicable law; these activities may also vary in how they are conducted across the DPS' wide range. Therefore, this interim 4(d) rule will facilitate the continuation of forest vegetation management activities because these activities pose no or minimal threats to the North American wolverine at the DPS level and result in only de minimis forms of take. Forest management can also contribute to the DPS's conservation into the future by maintaining overall forest health in and adjacent to wolverine habitat. This exception, and any relevant future section 7 consultations with Federal agencies, also allow for flexibility to accommodate specific physical conditions, resource needs, and constraints across the DPS's range.

Incidental Trapping

Wolverines are occasionally incidentally trapped and killed in the contiguous United States in the course of legal trapping for other species, typically wolf trapping. This occurs at low levels in a portion of the wolverine's breeding range (mainly Idaho and Montana) and does not currently represent a stressor to the wolverine in the contiguous United States at the population or subspecies level. Since 2012, there have been 10 nontarget wolverine captures (average = fewer than 1/year) resulting in 3 mortalities in Montana (MFWP 2023, in litt., p. 1). In Idaho, 14 nontarget captures (0.7/year) of wolverines have occurred during licensed trapping activities, with no demonstrable trend in capture rates over the past 20 years (IDFG 2022, in litt., p. 3). Between November 2017 and August 2022, IDFG reported that nine wolverines were incidentally trapped, with two resulting in mortalities (IDFG 2022, in litt., pp. 5, 16–22). We have no recent reports of wolverines incidentally trapped in other States within the range during the course of legal trapping activities.

In 2021, in both Idaho and Montana, laws and regulations were enacted that may increase the amount of wolf trapping and the risk of incidental trapping of wolverines because of the use of snares, extended trapping seasons, and financial incentives (Service 2023, p. 39). However, because wolverines differ from wolves in size, distribution, and behavior, and State laws and guidelines influence trappers to use trap tension, site selection, and snare height to reduce the likelihood of incidental capture, we expect minimal effects. In addition, year-round wolf trapping seasons in Idaho are limited to private lands, where there is very little core wolverine habitat, further reducing the potential for incidental taking through trapping.

As discussed above under *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes,* States within the North American wolverine's range in the contiguous United States have enacted multiple regulations and recommendations to limit incidental trapping mortality of wolverines. Additionally, the legal trapping that occurs for other species, like bobcat and marten, does not lend itself to wolverine incidental trapping due to the types of traps used, placement of those traps, and habitat in which they would be deployed. We expect incidental trapping of wolverines to continue to be very limited throughout the DPS's range.

Incidental trapping mortality of wolverines in the contiguous United States is minimal and does not impact wolverines at a population or species level. Mowat et al. (2020, p. 221) concluded the maximum sustainable harvest rate for wolverines is about 8 percent. Based on a recent analysis of an area in Canada that was experiencing population declines related to overharvest, Mowat et al. (2020, p. 224) recommended reducing direct trapping mortality to no more than 4 percent per year across their study area to promote wolverine population recovery. In the contiguous United States, where there is no direct trapping, incidental trapping rates have been well below this recommended rate. If we assume there are approximately 300 wolverines in the contiguous United States and assume 2 wolverine mortalities per year from incidental trapping (a conservative estimate from the incidental trapping mortalities we know of since 2012), that would be only 0.67 percent of the population per year. This minimal level of loss will not significantly impact the contiguous U.S. population of North American wolverines and will not inhibit conservation of the DPS. We conclude that the overall impact of incidental trapping that is conducted in accordance with State or Tribal trapping laws and regulations and in a manner that uses best practices to minimize capture and mortality of wolverines, is not expected to negatively affect conservation and recovery efforts for the contiguous U.S. DPS of the North American wolverine. Therefore, take due to this type of trapping will not be prohibited. Take due to trapping that is not in compliance with applicable State or Tribal laws or regulations and that results in the incidental trapping of a wolverine is prohibited and subject to penalties under section 9 of the Act. Any take of wolverine from incidental trapping should be reported to the nearest U.S. Fish and Wildlife Service law enforcement office and to the appropriate State wildlife agency or Tribal wildlife authorities within 5 days of occurrence. Unharmed individuals are to be released immediately.

We anticipate that the additional take excepted by this interim 4(d) rule will only have a minimal impact on wolverine habitat and individuals in the contiguous United States. The activities associated with scientific research, forest management for the purposes of reducing the risk or severity of wildfire, and legal trapping of other species in a manner that reduces risk to wolverines are expected to result in low levels of take of individuals given the limited scope and scale of these activities.

We conclude that take of wolverines excepted by this interim 4(d) rule will be small and will not pose a significant impact on the conservation of the DPS as a whole. However, we recognize that there is some uncertainty regarding the level of take that may result and that there are other approaches and additional conservation measures that could improve the overall conservation outcome of this interim 4(d) rule. We

are seeking public comments on this interim 4(d) rule (see Public Comments Solicited on the Interim 4(d) Rule, below), and we will publish either an affirmation of this interim rule or a final revised rule after we fully consider all comments we receive.

Need for Interim Rule

We initially proposed a 4(d) rule for the wolverine in 2013, in association with our proposal to classify the wolverine as a threatened species (78 FR 7864; February 4, 2013). We accepted comments on that 2013 proposed 4(d) rule and have considered the comments we received regarding the proposed 4(d) rule in developing this interim 4(d) rule. Thus, we engaged in notice-and-comment rulemaking, and we could have issued the 4(d) rule as a final rule rather than as an interim rule with an additional comment period. However, we have elected to issue the 4(d) rule as an interim rule and to accept public comments to ensure a robust opportunity for the public to consider the prohibitions and exceptions prescribed, while providing protections for the threatened DPS and complying with our court-ordered deadline to finalize the listing determination.

The Service considered segregating the 4(d) rule from the listing determination and issuing a revised proposed rule for notice and comment before finalizing the 4(d) rule. However, under 5 U.S.C. 553(b)(3)(B) of the Administrative Procedure Act (APA), we find good cause to proceed without reproposing the 4(d) rule and undertaking notice and comment before finalizing the 4(d) rule. If the Secretary were to repropose a 4(d) rule and finalize it through the standard rulemaking process, we would be unable to finalize the protective regulations set forth in this interim 4(d) rule concurrently with the final listing rule for the DPS. This would result in no protections for the DPS until we complete a process to repropose and finalize a 4(d) rule. That outcome would be contrary to the public interest in this case because immediate implementation of the interim 4(d) rule when the species' listing is effective (see **DATES**, above) has the advantage of providing a conservation benefit to the North America wolverine in the contiguous United States. Under this interim 4(d) rule, the DPS will be protected by the general section 9(a)(1) prohibitions, with the aforementioned exceptions. Alternatively, another option left to the agency's discretion would be to have no prohibitions for a species determined to be threatened under the Act. However, as stated, we think that it is appropriate to provide some protection for this DPS now so that wolverines in the United States have the best chance of surviving in the face of climate change impacts and other threats. We find that this interim 4(d) rule provides appropriate protections to promote the conservation of the DPS across its range while providing the flexibility for certain otherwise lawful activities to occur without significantly impacting the DPS or its habitat. The final rule listing the contiguous U.S. DPS of the North American wolverine as a threatened species under the Act is published as a part of this document and is effective on the date specified in **DATES**, above. To avoid any confusion arising from varying effective dates, and because we cannot establish a 4(d) rule for a species that is not yet listed, this interim 4(d) rule will also be effective on the date specified in **DATES**, above, to coincide with the effective date of the listing.

Public Comments Solicited on the Interim 4(d) Rule

We request comments or information from other concerned Federal and State agencies, Tribes, the scientific community, or any other interested party concerning the interim 4(d) rule. With regard to the interim 4(d) rule, we particularly seek comments regarding:

(1) Whether the 4(d) rule as a whole is necessary and advisable to provide for the conservation of the contiguous U.S. DPS of the North American wolverine.

(2) Information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule.

(3) Whether we should consider any additional exceptions from the prohibitions, such as take as a result of other categories of activities beyond those described, and, if so, under what conditions and with what conservation measures, if any.

(4) Additional provisions the Service may wish to consider for a revision to the interim 4(d) rule in order to conserve, recover, and manage the DPS.

Our determination to affirm or revise the interim 4(d) rule will take into consideration all written comments and any additional information we receive. Please note that comments merely stating support for or opposition to the interim 4(d) rule without providing supporting information, although noted, will not be considered. Our final 4(d) rule may differ from this interim 4(d) rule, based on our review of all information we receive during this rulemaking proceeding. 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 regulations, including those additional prohibitions, are necessary and advisable to provide for the conservation of the species. 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 species.

Our intent is to issue an affirmation of this interim 4(d) rule or issue a revised 4(d) rule for the contiguous U.S. DPS of the North American wolverine by December 2024.

As we state above under **DATES**, we are opening a 60-day public comment period on the interim 4(d) rule. You may submit your comments and materials concerning the interim 4(d) 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.* Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this rule, will be available for public inspection on *https://www.regulations.gov,* or by appointment, during normal business hours, at the Pacific Region Ecological Services Program (see **FOR FURTHER INFORMATION CONTACT**).

III. Critical Habitat

Background

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.

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.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the contiguous U.S. DPS of the North American wolverine and habitat characteristics where the DPS is located. A careful assessment of the economic impacts that may occur due to a critical habitat designation has yet to occur, and we will be working to acquire the complex information needed to perform that assessment. Therefore, due to the current lack of data sufficient to perform required analyses, we conclude that the designation of critical habitat for the DPS is not determinable at this time in accordance with 50 CFR 424.12(a)(2)(i). 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), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes 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. During the development of the wolverine SSA report addendum, we asked for information and concerns from all the federally recognized Tribes in the contiguous U.S. range of the North American wolverine in California, Colorado, Idaho, Montana, Oregon, Utah, Washington, and Wyoming. While we did not receive any information regarding the wolverine from any Tribe specific to the SSA report addendum, we remain committed to engaging with interested Tribes regarding the interim 4(d) rule, future proposed critical habitat designation, and future recovery planning for the contiguous U.S. DPS of the North American wolverine.

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 Pacific Region Ecological Services Program (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Pacific Region Ecological Services Program.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we 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. Amend § 17.11, in paragraph (h), by adding an entry for ''Wolverine, North American [Contiguous U.S. DPS]'' to the List of Endangered and Threatened Wildlife in alphabetical order under MAMMALS to read follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
MAMMALS				
*	*	*	*	*
Wolverine, North American [Contiguous U.S. DPS].	*Gulo gulo luscus*	Where found within the contiguous U.S.A.	T	88 FR [**INSERT FEDERAL REGISTER PAGE WHERE THE DOCUMENT BEGINS**], 11/30/2023; 50 CFR 17.40(u).[4d]
*	*	*	*	*

■ 3. Amend § 17.40 by adding paragraph (u) to read as follows:

§ 17.40 Special rules—mammals.

* * * * *

(u) North American wolverine (*Gulo gulo luscus*), contiguous U.S. DPS.

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the contiguous U.S. distinct population segment (DPS) of the North American wolverine. Except as provided under paragraph (u)(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 DPS:

(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 DPS, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(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 caused by scientific or research activities for wolverine undertaken by a biologist from a Federal agency other than the U.S. Fish and Wildlife Service, or a federally recognized Tribe, when acting in the course of their official duties, provided that such taking does not result in the death or permanent injury to the wolverine(s) involved and that the taking is reported to the nearest U.S. Fish and Wildlife Service law enforcement office and to the appropriate State wildlife agency or Tribal wildlife authorities. Activities associated with scientific research may include capture, anesthesia, collaring, tracking, genetic sampling, the use and baiting of camera and DNA traps, den monitoring, and aerial surveying.

(vi) Take incidental to an otherwise lawful activity caused by:

(A) Forest vegetation management activities for the purpose of reducing the risk or severity of wildfire.

(B) Trapping of species other than wolverine, provided that the trapping is conducted in accordance with State or Tribal trapping laws and regulations, the trapping is conducted in a manner that uses best practices to minimize the potential for capture and mortality of wolverines, and any take of wolverine is reported to the nearest U.S. Fish and Wildlife Service law enforcement office and to the appropriate State wildlife agency or Tribal wildlife authorities within 5 days of occurrence. Unharmed individuals are to be released immediately.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2023–26206 Filed 11–29–23; 8:45 am]

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FEDERAL REGISTER

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 878

Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes and Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2023–N–3392]

RIN 0910–A126

Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) are proposing to classify certain types of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals (unclassified, preamendments devices) as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. FDA currently regulates these unclassified devices as devices requiring premarket notification (510(k) requirements), with the product codes FRO, GER, MGP, MGQ, and EFQ, but FDA intends to create new product codes for these proposed classifications upon finalization of this classification action. FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a high level of antimicrobial resistance (AMR) concern (*i.e.,* medically important antimicrobials) into class III. In addition, FDA is proposing to classify certain wound dressings and liquid wound washes containing antimicrobials with a medium or low level of AMR concern and/or other chemicals, into class II (subject to special controls and 510(k) requirements).

DATES: Either electronic or written comments on the proposed rule must be submit by February 28, 2024.

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 February 28, 2024. 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–2023–N–3392 for ''Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes.'' 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: Brandon Kitchel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4626, Silver Spring, MD 20993–0002, 301–796–6055, *brandon.kitchel@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to classify certain unclassified, preamendments wound dressings and liquid wound washes containing antimicrobials and/or other chemicals into three separate classification regulations: (1) solid wound dressings; (2) wound dressings formulated as a gel, cream, or ointment; and (3) liquid wound washes. A list of examples of antimicrobials and a list of categories and examples of other chemicals contemplated by this proposed rule are found in table 2 and table 3, respectively. For solid wound dressings, the intended use is to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. For wound dressings formulated as a gel, cream, or ointment, the intended use is to maintain appropriate moisture balance within the wound. For liquid wound washes, the intended use is to mechanically irrigate and physically remove debris from external wounds. It is also to moisten solid wound dressings to maintain appropriate moisture balance within the dressing.

FDA currently regulates these unclassified devices [1] as devices requiring premarket notification (510(k) requirements), with the product codes FRO, GER, MGP, MGQ, and EFQ.[2] FDA intends to create new product codes for these proposed classifications upon finalization of this classification action.[3] This proposed classification is based, in part, on the recommendations of multiple General and Plastic Surgery Devices Panel meetings (held on November 27, 1998 (Ref. 1), August 25 and 26, 2005 (Ref. 2), and September 20 and 21, 2016 (Ref. 3)) regarding the classification of wound dressings, public comments received on such recommendations, FDA's experience with these wound dressings and liquid wound washes, and other available information.

As discussed further in this preamble, FDA believes that with clarification of intended use claims, wound dressings and liquid wound washes subject to this proposed rule, including those with antimicrobials, should be regulated only as ''devices'' and not as combination products.[4] These products, though perhaps previously identified as combination products, are within the scope of this classification. Additionally, wound dressings and liquid wound washes that do not contain a component that achieves a primary intended purpose of the product through chemical action within or on the body are considered devices, even if these products contain components that are regulated as drugs in other contexts.[5] Further discussion of these products is included in the intended use(s) section under section V.B.

The proposed classification for solid wound dressings is intended to be a split classification. FDA is proposing to classify solid wound dressings containing medically important antimicrobials acting as protectants (Ref. 4) [6] into class III due to their high level of antimicrobial resistance (AMR) [7] concern (as discussed in Section III.B Terminology). Table 1 of the World Health Organization's (WHO) 2018 publication ''Critically Important Antimicrobials for Human Medicine: 6th Edition'' (Ref. 4) has a list of all classes of medically important antimicrobials. For the purposes of this proposed rule, an antimicrobial is considered medically important if, and only if, it falls within any of these classes regardless of the level of importance specified by the WHO (*i.e.,* critically important, highly important, or important). FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such wound dressings, and these dressings present a potential unreasonable risk of illness or injury. FDA is proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of premarket approval applications (PMAs) for such devices.

FDA is proposing to classify solid wound dressings containing antimicrobials that are acting as protectants with medium or low level of AMR concern and/or other chemicals into class II (special controls). Please see Section III.B Terminology for more information on antimicrobials that are acting as protectants and on other chemicals. Antimicrobials acting as protectants are used to reduce microbial growth within the dressing while in use or to provide an antimicrobial barrier to microbial penetration through the dressing. FDA is proposing this classification action based on the determination that general controls

[1] We refer to these products as devices because of their device mode of action, although, as noted later in the document, many of the products with wound management claims, based on a broad interpretation of such claims, have previously been generally identified as combination products. As explained later in the document, one of the purposes of this rulemaking is to clarify the intended uses of these products for classification purposes, based on the recommendations of the General and Plastic Surgery Devices Panel, by proposing not to include broad ''wound management'' claims in product labeling and be clarified to reflect the specific functions discussed in this document (*e.g.,* ''to protect and cover a wound''). Products that continue to have broad wound management claims, which may be unclear or misleading or indicate an objective intent outside of the clarified intended uses, will not be covered by and benefit from this proposed rulemaking and classification. After this proposed rule is finalized and the classification becomes effective, such products could be subject to a different type of marketing authorization, depending on the product claims. For example, products containing antimicrobials that make certain wound managements claims may be considered combination products or drugs and regulated as such.

[2] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to help categorize and assure consistent regulation of medical devices. A product code consists of three characters that are assigned at the time a product code is generated and is unique to a product type. The three characters carry no other significance and are not an abbreviation.

[3] See ''Medical Device Classification Product Codes—Guidance for Industry and FDA Staff,'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.*

[4] See definition of combination product at 21 CFR 3.2(e).

[5] For information on the classification of products as drugs, devices, or biological products, please see the guidance ''Classification of Products as Drugs and Devices and Additional Product Classification Issues,'' available at *https://www.fda.gov/media/80384/download.*

[6] For the purposes of this proposed rule and classification action, medically important antimicrobials are antimicrobial drugs that are important for therapeutic use in humans and associated with a high level of AMR concern. WHO has worked to categorize medically important antimicrobials based on the level of importance these drugs play in human medicine (*https://www.who.int/publications/i/item/9789241515528*). While the Agency has made similar efforts to categorize medically important antimicrobials, such as the work to address the use of medically important antimicrobial drugs in food-producing animals (*https://www.fda.gov/media/172347/download?attachment*), the current classification efforts do not attempt to further stratify the degree of importance of these antimicrobial drugs.

[7] For the purposes of this proposed rule and classification action, antimicrobial resistance is the ability of a microorganism (*e.g.,* bacteria or fungi) to resist the effects of an antimicrobial.

alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these solid wound dressings, and there is sufficient information to establish special controls, in combination with general controls, to provide such assurance.

Similarly, FDA is proposing a split classification for wound dressings formulated as a gel, cream, or ointment. FDA is proposing to classify wound dressings formulated as a gel, cream, or ointment containing medically important antimicrobials acting as preservatives into class III due to their high level of AMR concern. FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such wound dressings and that these dressings present a potential unreasonable risk of illness or injury. FDA is proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of PMAs for such devices.

FDA proposes to classify wound dressings formulated as a gel, cream, or ointment containing antimicrobials acting as preservatives (as discussed in Section III.B Terminology) with medium or low AMR risk and/or other chemicals into class II. Antimicrobials acting as preservatives are used to maintain shelf life for a nonsterile, single-use wound dressing or a multiple-use wound dressing for single patient use only with compromised sterility after opening and using for a defined period. FDA is proposing this action based on the determination that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these wound dressings, and there is sufficient information to establish special controls, in combination with general controls, to provide such assurance.

FDA is also proposing a split classification for liquid wound washes. FDA is proposing to classify liquid wound washes containing medically important antimicrobials acting as preservatives into class III due to their high level of AMR concern. FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such liquid wound washes and these washes present a potential unreasonable risk of illness or injury. FDA is proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of PMAs for such devices.

FDA is proposing to classify liquid wound washes containing antimicrobials acting as preservatives with medium or low level AMR concern and/or other chemicals into class II. FDA is proposing this classification action based on the determination that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these wound washes and that there is sufficient information to establish special controls, in combination with general controls, to provide such assurance. Additionally, if this proposed rule is finalized, FDA plans to publish a notice in the **Federal Register** announcing its intent to exempt liquid wound washes containing water or 0.9 percent saline only, which do not contain antimicrobials, other chemicals, or animal-derived materials, from the requirements of submitting a 510(k), subject to certain limitations, under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

B. Summary of the Major Provisions of the Proposed Rule

This rule proposes to classify certain of the following unclassified, preamendments wound dressings and liquid wound washes containing antimicrobials and/or other chemicals: (1) solid wound dressings; (2) wound dressings formulated as a gel, cream, or ointment; and (3) liquid wound washes. The proposed rule, if finalized, would establish the identifications and classifications for certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes.

The proposed classification action proposes to classify into class III and require the filing of a PMA for wound dressings and liquid wound washes (*i.e.,* solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes) containing medically important antimicrobials used for preservative or protectant purposes. This proposed classification action proposes also to classify solid wound dressings containing antimicrobials acting as protectants with a medium or low level of AMR concern and/or other chemicals into class II. Wound dressings formulated as a gel, cream, or ointment and liquid wound washes containing antimicrobials acting as preservatives with a medium or low level of AMR concern and/or other chemicals are being proposed for classification into class II. These certain class II wound dressings and liquid wound washes would be classified with special controls that require specific information relating to performance testing and technical specifications, specific labeling requirements, and other requirements to mitigate the risks to health and demonstrate a reasonable assurance of safety and effectiveness, in combination with general controls.

If this proposed rule is finalized, FDA plans to exempt from 510(k) certain liquid wound washes containing water or 0.9 percent saline only, which do not contain antimicrobials, other chemicals, or animal-derived materials, subject to certain limitations. An exemption from the requirement of 510(k) does not mean that the device type is exempt from any other statutory or regulatory requirements unless such exemption is explicitly provided by order or regulation.

C. Legal Authority

The Agency is proposing this classification under the authority of section 301 of the FD&C Act (21 U.S.C. 301). Specifically, the relevant authority related to the proposed classification includes sections 513(a) through (d) of the FD&C Act regarding device classes, classification, and panels; section 515 of the FD&C Act regarding PMAs; and section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

D. Costs and Benefits

If the proposed rule is finalized, society may experience welfare gains from reductions in AMR due to the rule. These welfare gains would be in the form of decreased mortality, morbidity, and medical costs. Unfortunately, the magnitude of these potential benefits is difficult to forecast, and we do not quantify these impacts in the analysis.

The quantifiable benefits of the proposed rule, if finalized, accrue to manufacturers of wound dressings and liquid wound washes and FDA. These benefits are the result of clarifications in the 510(k) submission process, specifically defined regulatory classification, and published special controls. This additional clarity in requirements should result in fewer additional information submissions to FDA.

We estimate annualized cost savings ranging from approximately $1.12 million to $6.31 million at a 3 percent discount rate, and approximately $1.14 million to $6.42 million at a 7 percent discount rate. Our primary annualized estimates are approximately $2.66 million at a 3 percent discount rate and $2.71 million at a 7 percent discount rate. The primary estimates of the present value of total cost savings in the 10 years following any final rule that may be issued based on this proposed

rule are $24.55 million at a 3 percent rate of discount and $19.02 million at a 7 percent rate of discount.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, preparing and submitting PMAs, and other costs related to the PMA process and maintaining the class III designation. FDA also incurs costs from reviewing PMAs, annual and supplemental reports, and inspection activities. When annualized over a period of 10 years, we estimate these costs range from approximately $0.72 million to $1.25 million at a 3 percent discount rate, and approximately $0.65 million to $1.17 million at a 7 percent discount rate. Our primary annualized estimates are approximately $0.92 million at a 3 percent discount rate and $0.85 million at a 7 percent discount rate. The primary estimates of the present value of total costs in the 10 years following any final rule that may be issued based on the proposed rule are approximately $7.23 million at a 3 percent discount rate and $6.48 million at a 7 percent discount rate.

II. Table of Abbreviations/Acronyms Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
510(k)	Premarket Notification.
AMR	Antimicrobial Resistance.
CDC	Centers for Disease Control and Prevention.
CDRH	Center for Devices and Radiological Health.
CFR	Code of Federal Regulations.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FRO	The current product code for unclassified, preamendments wound dressings containing antimicrobials and/or other chemicals.[8]
GER	The product code for unclassified, preamendments devices known as external gauze with drug/biologic/animal source material.[9]
MGP	The product code for unclassified, preamendments devices known as occlusive wound and burn dressing.[10]
MGQ	The product code for unclassified, preamendments devices known as wound and burn hydrogel dressing with drug and/or biologic.[11]
EFQ	The product code for unclassified, preamendments devices known as internal gauze and sponge.[12]
HHS	Department of Health and Human Services.
PHMB	Polyhexamethylene Biguanide.
PMA	Premarket Approval Application.
OIRA	Office of Information and Regulatory Affairs.
U.S	United States.
WHO	World Health Organization.

III. Background

A. Need for the Regulation

Currently, certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes that contain antimicrobials and/or other chemicals are unclassified devices subject to premarket notification (510(k)) under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Until an unclassified device type has been formally classified by regulation, and such formal classification may or may not require a different type of premarket submission depending on the classification, marketing of new devices within this device type requires FDA clearance of a 510(k). As described below, these devices have generally been subject to premarket review through the 510(k) pathway and have been cleared for marketing if their intended use and technological characteristics are ''substantially equivalent'' to devices that were in commercial distribution prior to the passage of the Medical Device Amendments on May 28, 1976.

Wound dressings and liquid wound washes subject to this proposed rule and classification action can be subcategorized into three broad categories based on their physical form, including: (1) solid wound dressings; (2) gels, creams, or ointments; and (3) liquid wound washes. Irrespective of physical form, these wound dressings and liquid wound washes have typically been indicated for use on a variety of acute (*e.g.,* traumatic wounds, surgical wounds, etc.) and chronic (*e.g.,* venous stasis ulcers, diabetic foot ulcers, arterial ulcers, etc.) wounds. Solid wound dressings have also been cleared with uses such as to provide or support a moist wound environment, absorb wound exudate, and protect against external contamination. Wound gels, ointments, and creams have been cleared to provide or support a moist wound environment. Liquid wound washes have been cleared to rinse or irrigate a wound and to remove foreign material, such as debris and wound exudate. Refer to table 1 for a tabular overview of the wound dressings and liquid wound washes within the scope of this proposed classification action.

[8] Some products cleared under this product code are within scope for this proposed rule and proposed classification action. Other products under this product code are not within scope of this proposed rule and will be addressed via a separate classification action.

[9] Ibid.

[10] Ibid.

[11] Ibid.

[12] Ibid.

TABLE 1—PROPOSED CLASSIFICATION OF THE WOUND DRESSINGS AND LIQUID WOUND WASHES CONTAINING ANTIMICROBIALS AND/OR OTHER CHEMICALS

Proposed classification	Solid wound dressings containing antimicrobials and/or other chemicals (Proposed new 21 CFR 878.4016)	Wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals (Proposed new 21 CFR 878.4017)	Liquid wound washes (Proposed new 21 CFR 878.4019)
Class III (Proposing to require the filing of a PMA).	Products containing medically important antimicrobials acting as protectants (Proposed § 878.4016(b)(1)).	Products containing medically important antimicrobials acting as preservatives (Proposed § 878.4017(b)(1)).	Products containing medically important antimicrobials acting as preservatives (Proposed § 878.4019(b)(1)).
Class II (Special Controls + General Controls) Subject to 510(k) Requirements.	Products containing antimicrobials acting as protectants with a medium or low level of AMR concern, and/or other chemicals (Proposed § 878.4016(b)(2)).	Products containing antimicrobials acting as preservatives with a medium or low level of AMR concern, and/or other chemicals (Proposed § 878.4017(b)(2)).	Products containing antimicrobials acting as preservatives with a medium or low level of AMR concern, and/or other chemicals (Proposed § 878.4019(b)(2)).

Outside of the scope for this rulemaking, FDA has previously classified certain wound dressings (which have similar intended uses as the products in scope for this proposed rule, but do not contain antimicrobials or other chemicals) as class I and exempt from 510(k) requirements (see 21 CFR 878.4014, 878.4018, 878.4020, and 878.4022). FDA has also previously determined wound dressings intended to accelerate the normal rate of wound healing that serve as a replacement for full-thickness skin grafting (*e.g.,* artificial skin substitute) or treat full-thickness (*i.e.,* third degree) burns to be class III medical devices. An example of a class III wound dressing is the Integra Omnigraft Dermal Regeneration Matrix that was approved through PMA P900033.[13] In addition to wound care products regulated by Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research regulates certain drugs used in wound care, such as silver sulfadiazine cream indicated for the prevention and treatment of wound sepsis,[14] and the Center for Biologics Evaluation and Research regulates certain wound care products, such as the OrCel Bilayered Cellular Matrix composed of human allogeneic skin cells (PMA P010016).[15]

Wound dressings and liquid wound washes containing antimicrobials and/or other chemicals play a critical role in wound care for patients in the United States. Human skin wounds pose substantial risks to patients and increasing challenges to the U.S. public health (Ref. 5). The prevalence rate for chronic, nonhealing wounds is ~2 percent of the general population (Ref. 6). This prevalence rate is similar to that of heart failure, but unlike heart failure, little is known regarding the outcome of these patients or the comparative effectiveness of the treatment they receive (Ref. 7). An aging population and its requisite medical interventions, the continuing rise in diabetes and obesity, and the increase in traumatic wounds all translate to large increases in skin wounds needing treatment (Refs. 6 and 8). Patients with the hardest to heal wounds include those with diabetes, obesity, sickle cell ulcers, vasculitis, and scleroderma (Refs. 6 and 8).

The cost of wound care in the United States alone exceeds $50 billion annually (Refs. 9–12). It is estimated that chronic, nonhealing wounds affect approximately 6.5 million people annually in the United States (Ref. 13). Often, these wounds become infected, interrupting and delaying wound healing and leading to increased treatment times, suffering, risk of severe complications, and expenses (Ref. 14). The annual wound care products market is expected to reach $22 billion by 2024, which demonstrates the magnitude of their impact on public health (Ref. 15).

B. Terminology

1. Medically Important Antimicrobial

For the purposes of this proposed rule and this classification action, the term ''medically important'' antimicrobial refers to an antimicrobial drug that is important for therapeutic use in humans (Ref. 16). Table 1 of the WHO's 2018 publication entitled ''Critically Important Antimicrobials for Human Medicine: 6th Edition'' (Ref. 4) has a list of all classes of medically important antimicrobials. For the purposes of this proposed rule and classification action, an antimicrobial is considered medically important if, and only if, it falls within any of these classes regardless of the level of importance specified by the WHO (*i.e.,* critically important, highly important, or important).

2. High, Medium, and Low AMR Concern

For the purposes of this proposed rule and this classification action, the level of AMR concern has been defined based on the following antimicrobial characteristics:

- High-level of AMR concern results from wound dressings and liquid wound washes that contain a medically important antimicrobial as these products may directly contribute to the development and spread of organisms in the patient that are resistant to medically important antimicrobials, potentially further limiting a clinician's therapeutic options.
- Medium-level AMR concern results from wound dressings and liquid wound washes that contain a nonmedically important antimicrobial which may indirectly select for organisms with medically important antimicrobial resistance mechanisms via coselection mechanisms such as coresistance and cross-resistance.[16]
- Low-level AMR concern results from wound dressings and liquid wound washes that contain a nonmedically important antimicrobial which lacks the ability to coselect for organisms with medically important antimicrobial resistance mechanisms. As microbial resistance mechanisms are constantly evolving, the categorization of low level of AMR concern for a particular antimicrobial may be upgraded to a medium level of AMR concern based on future emerging resistance information, such as evidence of coresistance or cross-resistance to medically important antimicrobials.

[13] FDA Premarket Approval, Integra Omnigraft Dermal Regeneration Matrix, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P900033S042.*

[14] Drugs at FDA, Silver Sulfadiazine Cream, *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/017381s053lbl.pdf.*

[15] FDA Premarket Approval, OrCel™ (Bilayered Cellular Matrix), *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010016.*

[16] Coresistance occurs when there are different resistance determinants present on the same genetic element. Cross-resistance occurs when the same genetic determinant is responsible for resistance to multiple types of antimicrobials, such as antibiotics and metals. *See* Baker-Austin C., M. Wright, R. Stepanauskas, et al., ''Co-Selection of Antibiotic and Metal Resistance,'' *Trends in Microbiology,* 14(4), 2006. Available at *https://www.cell.com/trends/microbiology/fulltext/S0966-842X(06)00051-5.*

3. Antimicrobials as Preservatives or Protectants

To be within the scope of this proposed rule and classification action, antimicrobials could only be included within these wound dressings and liquid wound washes for two functions or roles to support the use of the dressing or wash: (1) a preservative or (2) a protectant of the product.

For the purposes of this proposed rule and proposed classification action, an antimicrobial is considered a preservative when added to wound dressings formulated as a gel, cream, or ointment and liquid wound washes solely to prevent or reduce contamination or deterioration thereof while in its packaging during shelf storage.[17] This preservative role helps maintain product integrity and safety throughout a defined shelf life and/or use life. A preservative may be included in wound dressings formulated as a gel, cream, or ointment or liquid wound washes when there is a scientific need for the inclusion of the preservative. For example, preservatives may be needed when the product is provided to the user nonsterile, or when the product is provided as a sterile single-patient, multiple-use product which contains a preservative to reduce microbial growth in the product over a specified period after the sterile seal has been broken. In these situations, the preservative may be used to maintain sufficiently low bioburden and to prevent or retard deterioration of the product prior to application of the wound dressings formulated as a gel, cream, or ointment or liquid wound washes.

Antimicrobials that are not used solely to support the use of the wound dressings formulated as a gel, cream, or ointment or liquid wound washes by preventing or reducing contamination or deterioration thereof while in its packaging, or those in which the use is not scientifically needed, are not considered preservatives for the purposes of this proposed rule. As discussed later, other uses, such as delivery of antimicrobials to the wound, suggest an intent for the treatment of infection, which is generally achieved through chemical action within or on the wound and may not fall under CDRH's jurisdiction. Additionally, as solid wound dressings are generally provided as sterile, single-use products, the inclusion of antimicrobial preservatives in solid wound dressings would not be necessary.

For the purposes of this proposed rule and proposed classification action, an antimicrobial is considered a protectant when added to a solid wound dressing to prevent or reduce contamination or deterioration of the dressing while in contact with the wound. This protectant role supports the use of solid wound dressings (*i.e.,* to cover and protect a wound, absorb exudate, and maintain appropriate moisture balance within the wound) throughout a defined use life. A protectant may be included in solid wound dressings when there is a scientific need for the inclusion of the protectant (*e.g.,* solid wound dressings which may be applied to a wound for a period of multiple days and the dressing may be susceptible to microbial colonization and biofouling). FDA is unaware of a clinical need for including a protectant in wound dressings formulated as a gel, cream, or ointment or liquid wound washes, as an application of these products is not designed to remain on the body for sufficient time to justify clinical concern with microbial colonization of the product. Refer to table 2 for a tabular overview of examples of antimicrobials that are within the scope of this proposed classification action.

TABLE 2—LIST OF EXAMPLES OF ANTIMICROBIALS * THAT ARE WITHIN THE SCOPE OF THE PROPOSED RULE AND THE PROPOSED CLASSIFICATION ACTION FOR CERTAIN WOUND DRESSINGS AND LIQUID WOUND WASHES

Antimicrobials with high-level AMR concern *	Antimicrobials with medium-level AMR concern	Antimicrobials with low-level AMR concern
Polymyxin B	Silver	Parabens.
Silver sulfadiazine	Zinc	Hypochlorous acid.
Bacitracin	Copper	Peroxide.
	Chlorhexidine	Polyhexamethylene biguanide (PHMB).
	Benzalkonium chloride	Iodine.

* As identified in the WHO's "Critically Important Antimicrobials for Human Medicine," Polymyxin B falls within the Polymyxcin class of medically important antimicrobials, Silver sulfadiazine falls within the Sulfonamide class of medically important antimicrobials, and Bacitracin falls within the Cyclic polypeptide class of medically important antimicrobials.

4. Other Chemicals

Wound dressings and liquid wound washes may contain other chemicals. Categories of other chemicals are wound protectants, honey, synthetic peptides, or botanical extracts. For the purposes of this proposed rule and proposed classification action, these ingredients are grouped as "other chemicals" and are only used to contribute to the uses of wound dressings and liquid wound washes by physical means (see table 3). Ingredients that achieve their primary intended purposes through chemical action would not fall under "other chemicals" for purposes of this proposed rule and proposed classification action and are therefore outside its scope.

- *Wound protectants.*[18] Wound dressings may contain wound protectants that provide a physical barrier to the external environment and help maintain moisture balance within the wound.

[17] Based on FDA's experience, in rare occasions, an antimicrobial may be added to a sterile, single-use amorphous wound dressing as a manufacturing aid to reduce bioburden prior to the manufacturing of the final, finished device.

[18] Ingredients in the "wound protectant" category of "other chemicals" overlap in some cases with active ingredients included in the over-the-counter (OTC) drug product monograph for "skin protectant drug products," which was codified in 21 CFR part 347. These provisions now appear in the final order for skin protectant drug products under section 505G of the FD&C Act (21 U.S.C. 355g), which was added by the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (2020). Orders for OTC monograph drugs can be found at *https://dps.fda.gov/omuf.* Under section 3621 of the Food and Drug Omnibus Reform Act of 2022, Public Law 117–328, 136 Stat 4459, which added section 503(h) to the FD&C Act (21 U.S.C. 353(h), products meeting the definition of "OTC monograph drug" under section 744L of the FD&C Act (21 U.S.C. 379j–71), including certain skin protectants, are deemed to be drugs. When intended for marketing in accordance with this proposed rule, however, products containing these ingredients, which may be included as "wound protectants," would not be considered OTC monograph drugs or otherwise considered drug constituent parts. Please note that to be considered a "wound protectant" in accordance with this proposed rule and classification action, an ingredient cannot achieve its primary intended purpose through chemical action. Products containing such ingredients are outside the scope of this proposed rule and classification action.

• *Honey.* Wound dressings may contain honey, which helps maintain moisture balance within the dressing.

• *Synthetic Peptides.* Wound dressings may include synthetic peptides, which are used to create a fibrous scaffold and provide physical structure to the wound dressing.

• *Botanical extracts.* Wound dressings may contain botanical extracts, which have such uses as to help maintain moisture balance within the dressing (*e.g.,* as moisturizers, humectants, or emollients) and contribute to the physical structure of the dressing (*e.g.,* as thickeners, emulsifiers, or stabilizers). A botanical extract is often a complex mixture of vegetable matter obtained from plants, algae, macroscopic fungi, and/or combinations of these species. For the purposes of this proposed rule, plant-derived materials that are highly purified (*e.g.,* cellulose) or well-characterized (*e.g.,* cotton) are not considered as other chemicals.

TABLE 3—CATEGORIES AND EXAMPLES OF OTHER CHEMICALS THAT ARE WITHIN THE SCOPE OF THE PROPOSED RULE AND THE PROPOSED CLASSIFICATION ACTION FOR CERTAIN WOUND DRESSINGS

Categories of other chemicals	Examples of other chemicals
Wound Protectants	Petrolatum, mineral oil, cod liver oil, white petrolatum, lanolin, glycerin, dimethicone, lanolin, allantoin, zinc oxide, aluminum hydroxide, calamine, sodium bicarbonate, zinc acetate, zinc carbonate.
Honey	Manuka honey, buckwheat honey.
Synthetic Peptides	RADA16 (RADARADARADARADA) peptide, self-assembling peptides.
Botanical Extracts	Olive oil, grape seed extract, aloe, lavender, tea tree oil, vegetable oil, shea butter, sesame oil.

5. Animal-Derived Materials

Solid wound dressings, wound dressings formulated as a gel, cream, or ointment, and liquid wound washes may also contain animal-derived materials. Generally, these animal-derived dressing materials are degradable, but may also contain nondegradable materials. This proposed rule excludes wound dressings and liquid wound washes containing animal-derived materials without the presence of antimicrobials or other chemicals, as these products are currently regulated as a distinct category under the product code KGN. More information regarding the categories of wound dressings and liquid wound washes that are outside the scope of this rulemaking is included in Section V.A Scope/Applicability of this proposed rule.

6. Antimicrobial Resistance

In the past century, the discovery and implementation of medically important antimicrobials (*e.g.,* antibiotics) have revolutionized modern medicine, making once lethal infections readily treatable and extending the average human lifespan by 23 years (Ref. 17). Unfortunately, we now live in an era when people are dying from untreatable infections because of the emergence and spread of AMR—the ability of microorganisms (*e.g.,* bacteria and fungi) to resist the effects of an antimicrobial. The development and spread of AMR are widely recognized as a serious public health threat. According to the U.S. Centers for Disease Control and Prevention (CDC), drug-resistant bacteria cause more than 35,000 deaths and 2.8 million illnesses each year in the United States (Ref. 18). In addition to the impact on patient morbidity and mortality, AMR infections require prolonged and costlier treatments, with estimates suggesting the U.S. economic impact to be around $55 billion per year (Ref. 19).

With a lack of novel antibiotics being developed, it is critical to preserve the effectiveness of our current antimicrobial therapeutic options. Based on the 2016 National Quality Partners' ''Antibiotic Stewardship in Acute Care: A Practical Playbook'' (Ref. 20), 20 percent to 50 percent of antibiotics prescribed in U.S. acute care hospitals are unnecessary or inappropriate, and this overuse and misuse of medically important antimicrobials have contributed to the cultivation of an abundance of drug-resistant organisms that are becoming increasingly difficult to treat. Changes to clinical practice patterns to promote appropriate use of antimicrobial drugs are essential, and in 2014, the CDC called on all U.S. hospitals to implement antimicrobial stewardship programs (Ref. 21) that measure and improve how antimicrobials are prescribed and used by patients. Additionally, public health agencies in the Department of Health and Human Services, including FDA, are engaged in efforts to promote antimicrobial stewardship practices to maintain a more judicious use of antimicrobials and curb the spread of AMR (Ref. 22).

While an antimicrobial is effective when applied at an appropriate concentration, this effectiveness is only exhibited on a limited segment of the microbial world. Some species of bacteria are naturally resistant to a given antimicrobial, while others may eventually acquire resistance (*e.g.,* via random mutation or acquisition of a resistance gene) (Ref. 23). After decades of antimicrobial exposure, microorganisms have developed a vast array of antimicrobial resistance mechanisms, including the expression of hydrolytic enzymes, activation of efflux pump systems, and the alteration of cell wall permeability (Ref. 23). Many antimicrobial resistance genes are found on plasmids, which not only play an integral role in the horizontal transfer of resistance between organisms, but can also stack multiple resistance genes together on a single mobile element (Ref. 24). As a result, many of today's hospital-acquired infections involve bacteria that are resistant to multiple classes of antimicrobials, which may include both medically important antimicrobials along with other broad-spectrum antimicrobials (*e.g.,* metals, biguanides, quaternary ammonium compounds) (Refs. 25 and 26).

Although all antimicrobial resistance is important, additional consideration is needed based on the level of importance a particular antimicrobial plays in human medicine and the availability of other therapeutic options to treat or mitigate specific infections (Refs. 6, 27–29). While medically important antimicrobials (*e.g.,* antibiotics) are the focal point of antimicrobial stewardship practices and resistance classification efforts, there are other antimicrobials that are routinely utilized in healthcare, such as antiseptics (which inhibit or kill microorganisms in or on living tissue, such as hand washes) and disinfectants (which inhibit or kill microorganisms on inanimate objects or surfaces) (Ref. 30).

Historically, wound dressings and liquid wound washes have utilized a wide range of antimicrobials as preservatives or protectants, each with a varying degree of AMR information

detailed in the literature. When evaluating the level of AMR concern associated with antimicrobials used as preservatives or protectants in wound dressings and liquid wound washes, the probable benefit of the wound dressing and liquid wound wash should outweigh the probable risk of contributing to the development and spread of resistance, and, particularly, resistance to medically important antimicrobials. As such, FDA is proposing a risk-based approach for assessing the level of AMR concern (high, medium, or low) associated with wound dressings and liquid wound washes containing antimicrobials, as described in Section III.B Terminology.

Based on feedback from the 2016 Panel, a high level of AMR concern is associated with the use of medically important antimicrobials (*e.g.,* antibiotics), as this may present an unreasonable risk of illness or injury by directly contributing to the selection of organisms in the patient that are resistant to medically important antimicrobials, potentially further limiting a clinician's therapeutic options. Likewise, it is important to understand and evaluate the potential for an antimicrobial to indirectly select for organisms with medically important antimicrobial resistance mechanisms via coselection mechanisms, such as coresistance and cross-resistance.

As antimicrobial resistance is an evolving topic with emerging resistance mechanisms being routinely developed and discovered, this risk-based approach provides the flexibility needed to address changes in future antimicrobial utility and the expanding AMR landscape. Classifying these wound dressings and liquid wound washes will provide clarity and transparency regarding the regulatory requirements (*e.g.,* general controls, special controls, or premarket approval) necessary to provide a reasonable assurance of safety and effectiveness. As antimicrobial resistance remains a priority for FDA, such an effort will further enhance our ongoing activities related to slowing the development of AMR to help ensure safe and effective use of antimicrobials in wound dressings and liquid wound washes intended for human use.

C. FDA's Current Regulatory Framework

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (general controls and special controls), and class III (premarket approval and general controls).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 of the FD&C Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness, or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 of the FD&C Act or any combination of such sections) and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d) of the FD&C Act, FDA refers to devices that were in commercial distribution before the 1976 amendments as ''preamendments devices.'' FDA classifies these devices after the Agency: (1) receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device (section 513(d)(1) of the FD&C Act). FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III through premarket notification procedures without submission of a PMA until FDA issues a final regulation order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of PMAs for such devices.

After the enactment of the 1976 amendments, FDA undertook to identify and classify all preamendments devices in accordance with section 513(d) of the FD&C Act. As part of this effort, FDA has completed the classification process to classify four types of wound dressings, as class I medical devices: (1) nonresorbable gauze/sponge for external use at § 878.4014; (2) hydrophilic wound dressing at § 878.4018; (3) occlusive wound dressing at § 878.4020; and (4) hydrogel wound dressing and burn dressing at § 878.4022. However, wound dressings that contain antimicrobials and/or other chemicals were not included in these prior actions and have not been separately classified to date.

D. History of This Rulemaking

As described previously, certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing antimicrobials and/or other chemicals are unclassified, preamendments devices. These devices have been subject to premarket review through a 510(k) submission and have been cleared for marketing if FDA considers the device to be substantially equivalent to a legally marketed predicate in accordance with section 513(i) of the FD&C Act. Currently, there are more than 500 legally marketed unclassified, preamendments wound dressings and liquid wound washes containing antimicrobials and/or other chemicals

which have been cleared through the 510(k) pathway that would be subject to this proposed classification regulation.

Consistent with the FD&C Act, FDA convened the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee and held multiple meetings regarding the classification of wound dressings on: (1) November 27, 1998 (Ref. 1); (2) August 25 and 26, 2005 (Ref. 2); and (3) September 20 and 21, 2016 (Ref. 3). From these meetings, and FDA's research and findings, the Agency understands that wound dressings and liquid wound washes containing medically important antimicrobials pose more AMR risk than other wound dressings and liquid wound washes. Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify unclassified, preamendments wound dressings and liquid wound washes containing medically important antimicrobials into class III. FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of the safety and effectiveness of these devices and these devices present a potential unreasonable risk of illness or injury. The proposed rule would also establish the identification, classification, and regulatory controls for certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes that contain antimicrobials and/or other chemicals.

1. 1998 General and Plastic Surgery Devices Panel

On November 27, 1998, FDA convened the General and Plastic Surgery Devices Panel (the 1998 Panel) to discuss the classification of five wound dressing categories and the reclassification of topical oxygen chambers for extremities (Ref. 1). At the meeting, FDA presented the following five types of unclassified, preamendments wound dressings for the 1998 Panel's classification recommendations: (1) nonresorbable gauze/sponges for external use; (2) hydrophilic wound dressings; (3) occlusive wound dressings, (4) hydrogel wound dressings; and (5) porcine wound dressings. FDA requested the 1998 Panel consider the proposed classifications for each of these wound dressings, including the product description and intended uses that should be included in the classification regulation for each dressing. FDA also requested the 1998 Panel discuss the risks to health for each dressing. FDA asked the 1998 Panel, as part of their deliberations, to consider the potential risk of viral transmission posed by porcine wound dressings.

The 1998 Panel unanimously concurred with a recommendation that all five identified wound dressings be classified in class I. The 1998 Panel also recommended that four of the five dressings: (1) nonresorbable gauze/sponges for external use; (2) hydrophilic wound dressings; (3) occlusive wound dressings; and (4) hydrogel wound dressings, be classified as exempt from premarket notification requirements. Subsequently, FDA classified these four dressing types under §§ 878.4014, 878.4018, 878.4020, and 878.4022, respectively (Ref. 4). Therefore, since these four dressings were previously classified, they are outside the scope of this proposed rule and will not be discussed further in this proposed rule. The fifth dressing type, porcine wound dressings, remained unclassified following the 1998 Panel meeting.

Although the 1998 Panel recommended that porcine wound dressings should be class I, the 1998 Panel believed that porcine wound dressings should not be exempt from premarket notification requirements due to concerns of potential viral contaminants and infectious diseases. Since FDA believes the risks of porcine wound dressings identified at the 1998 Panel meeting are also relevant to the wound dressings composed of animal-derived materials described in this proposed rule, a brief summary of the 1998 Panel discussion on porcine wound dressings is provided here. After considering the information provided by FDA, the open discussions during the 1998 Panel meeting, and the 1998 Panel members' experiences with these wound dressings at that time, the 1998 Panel provided reasons in support of its recommendation for classifying porcine wound dressings used to provide or support a moist wound environment, to cover a wound, to absorb exudate, and/or to minimize fluid loss into class I, not exempt from premarket notification requirements.

2. 2005 General and Plastic Surgery Devices Panel

On August 25 and 26, 2005, the General and Plastic Surgery Devices Panel (the 2005 Panel) met to provide advice and recommendations on the classification of five unclassified preamendments medical devices: (1) bone wax; (2) medical maggots; (3) medicinal leeches; (4) tissues expanders; and (5) wound dressings containing antimicrobials and/or other chemicals; however, for the purposes of this proposed rule, only the 2005 Panel's recommendations regarding wound dressings containing antimicrobials and/or other chemicals will be discussed (Ref. 2). At the 2005 Panel meeting, FDA proposed to describe the intended uses for these wound dressings containing antimicrobials and/or other chemicals, whether sterile or nonsterile, as being used to cover a wound, to absorb exudate, to provide or support a moist environment within the dressing, and to control bleeding or fluid loss. These wound dressings consist of nonabsorbable materials and contain added antimicrobials and/or other chemicals.

The 2005 Panel unanimously concurred to recommend that FDA classify wound dressings containing antimicrobials and/or other chemicals as class II medical devices requiring a 510(k) submission, subject to special controls. Some of the major risks identified by the 2005 Panel included the possibility that the antimicrobials and/or other chemicals could contribute to antimicrobial resistance, could sensitize the skin, interfere with wound healing, or result in selective colonization. But the 2005 Panel agreed with FDA that there is sufficient information to establish special controls that, together with general controls, would mitigate the risks to health and provide a reasonable assurance of safety and effectiveness for these products.

3. 2016 General and Plastic Surgery Devices Panel

The most recent Panel, held on September 20 and 21, 2016 (the 2016 Panel), met for the purposes of obtaining recommendations about the classification of products, including: (1) solid wound dressings; (2) wound dressings formulated as a gel, cream, or ointment; and (3) liquid wound washes. FDA held the 2016 Panel to obtain input on the benefits and risks of wound dressings and liquid wound washes that contain antimicrobials and/or other chemicals, as well as on the clinical relevance of certain indications. The 2016 Panel was asked to recommend to FDA whether such wound dressings and liquid wound washes that contain antimicrobials and/or other chemicals should be classified into class III (subject to PMA and general controls), class II (subject to general and special controls), or class I (subject only to general controls). The 2016 Panel was also asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications, as well as the appropriate controls necessary to mitigate the risks to health and assure the safety and

effectiveness of these types of wound dressings and liquid wound washes.

For each type of wound dressing and liquid wound wash, FDA presented the proposed risks to health and proposed mitigation measures. FDA identified risks to health applicable to wound dressings and liquid wound washes, including adverse tissue reaction, delayed wound healing, incompatibilities with other therapies, increased risk of AMR, infection, microbial growth, and product degradation. Further, FDA identified that additional risks to health applicable to solid wound dressings included loss of barrier function and retention of dressing material in the wound. FDA also identified that an additional risk applicable to liquid wound washes was the inability to remove wound debris. Following the 2016 Panel meeting, an additional risk to health was identified based on emerging reports in the literature (Refs. 31–37) regarding the understood role that our skin microbiota plays in the wound healing cascade. As such, antimicrobials that leach from wound dressings may inadvertently negatively impact the patient's skin microbiota in the periwound area resulting in impaired wound healing.

FDA presented information on the proposed mitigation measures for the risks to health of these wound dressings and liquid wound washes, which included biocompatibility, in vivo evaluation, clinical evaluation of dressings for specific intended uses and indications for use, labeling, evaluation and identification of any probable risk and mechanisms for AMR, sterilization and shelf-life validation, preservative effectiveness testing, and antimicrobial effectiveness testing. In addition to these identified mitigation measures, FDA proposed that the risk of loss of barrier function associated with solid wound dressings could be mitigated through microbial barrier effectiveness testing and water loss/moisture barrier effectiveness testing. Similarly, FDA proposed that the risk of inability to remove wound debris and foreign materials associated with liquid wound washes could be mitigated through appropriate bench performance testing. Regarding the understood risk that antimicrobials may inadvertently negatively impact the skin microbiota in the periwound area and impair wound healing, FDA proposes that this risk may be mitigated through antimicrobial characterization, performance testing, and labeling.

Regarding the benefit and risk assessments, the 2016 Panel noted that it is important to consider the heterogeneity in wound types when evaluating whether labeling claims represent clinically meaningful benefit to patients. For example, a labeling claim specifying use for a specific amount of time may be highly beneficial for dressings intended to be placed over a central venous catheter, but may not be as beneficial for burn wounds. The 2016 Panel also noted that when assessing the benefit-risk profile of a product, higher risk may be tolerated when known benefit is high, whereas lower risk should be tolerated when known benefit is low or not established.

Regarding factors to consider when more than one antimicrobial is included in a single product, the 2016 Panel stated that it would be important to evaluate whether use of multiple antimicrobials in a single product would produce antagonistic, synergistic, or additive effects with respect to reducing bioburden and/or promoting AMR. The 2016 Panel noted that it is currently not well understood how the inclusion of more than one antimicrobial would impact the likelihood of developing AMR. When certain antimicrobials are used together, there is surveillance data that shows that the risk of selecting for resistance is higher. However, the 2016 Panel noted that sufficient surveillance data does not exist for many other groupings of antimicrobials.

For solid wound dressings, a majority of the 2016 Panel members recommended that these products be classified into class II, subject to special controls, with the exception of certain solid wound dressings containing antimicrobials, such as antibiotics (with similar consideration to antimicrobial agents that may select for resistance in indirect ways). For these exceptions, several members of the 2016 Panel recommended that these wound dressings be classified into class III, with one Panel member noting that ''antibiotics should be held to an extremely high set of standards to prove value because of the risk of [antimicrobial] resistance]''. Further, the 2016 Panel meeting included discussion to note that special controls, such as testing in an animal model, could not be used to evaluate and/or mitigate the risk of AMR, supporting the assertion of several Panel members that solid wound dressings containing antibiotics should be classified as class III devices. As such, some of the 2016 Panel members recommended that the AMR risk posed by certain antimicrobials, such as antibiotics, could be mitigated through the increased controls of the PMA regulatory pathway that would be applied to these wound dressings as class III devices.

Several of the 2016 Panel members stated that additional risks associated with solid wound dressings containing antimicrobials may include leaching and systemic absorption of the antimicrobials, delayed wound healing, retention of dressing material in the wound, and loss of barrier function. Regarding mitigation of risks, some 2016 Panel members stated that bench testing could be a potential mitigation measure for the risk of retention of dressing material in the wound. One Panel member added that labeling would be an additional mitigation measure for loss of barrier function since barrier function would be dependent on proper application of the wound dressing. The risk of leaching and systemic adsorption of antimicrobials and/or other chemicals is also covered in adverse tissue reaction and toxicity.

For wound dressings formulated as a gel, cream, or ointment, a majority of the 2016 Panel members recommended that these products be classified into class II, subject to special controls, with the exception of certain wound dressings formulated as a gel, cream, or ointment containing antimicrobials, such as antibiotics (with similar consideration to antimicrobial agents that may select for resistance in indirect ways), for which some members of the 2016 Panel recommended class III. Several of the 2016 Panel members referenced the prior discussion on solid wound dressings, wherein they recommended that classification should be stratified by the risk of the ingredients within the dressing. The reasons certain wound dressings formulated as a gel, cream, or ointment should be classified as class III devices, based on the inclusion of certain antimicrobials, such as antibiotics, aligned with the rationale discussed during the deliberations on solid wound dressings. Also, some 2016 Panel members stated that cumulative residual material in the wound could present an additional potential risk that could be mitigated by specific labeling requirements. The risks of systemic absorption and topical toxicity were also concerning to the 2016 Panel. Some 2016 Panel members questioned whether antimicrobials should be included in a gel, cream, or ointment at all when there may be physical or non-antimicrobial means to reduce bioburden in the product.

For liquid wound washes, a majority of the 2016 Panel recommended that these products be classified into class I or class II, subject to special controls, depending on the toxicity of the product, with the exception of certain liquid wound washes containing antimicrobials, such as antibiotics (with

similar consideration to antimicrobial agents that may select for resistance in indirect ways), for which some members of the 2016 Panel recommended class III. To support this opinion on classifying liquid wound washes containing antimicrobials, such as antibiotics, as class III devices, several of the 2016 Panel members referenced the prior discussion regarding solid wound dressings, where it was noted that special controls could not mitigate the risks posed by these products and that classification of these products should be stratified based on risk of AMR. Some of the 2016 Panel members felt that the identified risk of ''inability to remove wound debris and foreign materials'' would be better refined as ''inadequate or possible incomplete removal of wound debris and foreign materials.'' The 2016 Panel discussed the clinical value of debridement and irrigation and questioned the value of added agents. There was agreement that agents in the liquid wound wash would affect the wound directly, and there was skepticism regarding whether these products should contain antimicrobials at all.

IV. Legal Authority

The Agency is proposing this classification under the authority of section 301 of the FD&C Act (21 U.S.C. 301). Specifically, the relevant authority related to the proposed classification includes sections 513(a) through (d) of the FD&C Act regarding device classes, classification, and panels; section 515 of the FD&C Act regarding PMAs; and section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

V. Description of the Proposed Rule

A. Scope/Applicability

We are proposing to amend subpart E of 21 CFR part 878 by adding § 878.4016 to classify solid wound dressings containing antimicrobials and/or other chemicals used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound; § 878.4017 to classify wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals used to maintain appropriate moisture balance within the wound; and § 878.4019 to classify liquid wound washes used to mechanically irrigate and physically remove debris from external wounds and to moisten solid wound dressings in accordance with section 513(d) of the FD&C Act. Please note that wound dressings and liquid wound washes generally achieve the maintenance of a moist wound environment through nonchemical action (*e.g.,* by acting as a barrier).

Wound dressings and liquid wound washes that achieve the maintenance of a moist wound environment through chemical action would be outside the scope of this proposed rule and may be drugs or combination products. For information on the classification of products as drugs, devices or biological products, see the guidance ''Classification of Products as Drugs and Devices and Additional Product Classification Issues'' (Ref. 38). Examples of antimicrobials and categories and examples of other chemicals are identified in tables 2 and 3, respectively. This proposed classification rule applies to certain wound dressings and liquid wound washes currently regulated under the product codes FRO, GER, MGP, MGQ, and EFQ. The proposed rule only applies to wound dressings and liquid wound washes that are for use on external cutaneous (skin) wounds.

The following categories of wound dressings are outside the scope of this proposed rule and classification action because they are currently regulated either as a distinct category within the product code FRO or under a different product code,[19] as identified:

- Wound dressings composed of animal-derived materials without the presence of antimicrobials and/or other chemicals, as they are currently regulated under product code KGN.
- Wound dressings with or without an added antimicrobial or biologic (*e.g.,* thrombin) that is used to provide hemostasis through accelerated blood clotting when combined with manual compression, as they were discussed in October 2022 at a Classification Panel.[20] [21]
- Absorbable synthetic wound dressings without antimicrobials that are intended to degrade and be resorbed into the wound.[22]
- Catheter securement dressings containing antimicrobials that are intended for reduction or prevention of infection (*e.g.,* central line-associated bloodstream infection).[23] [24]
- Dressings with topical analgesics, such as lidocaine or benzocaine.[25]
- Dressings with hydrocortisone.[26]
- Wound dressings used on mucosa, such as for oral uses or use in the gastrointestinal tract. The following categories of wound dressings are outside the scope of this proposed rule and classification action because FDA has previously classified them:
- Nonresorbable gauze/sponge for external use at § 878.4014 (Product Codes: MAC, OVR, LZM, NAB, OHO, PKD, PXY, PYJ, PYK, PYL);
- Hydrophilic wound dressing at § 878.4018 (Product Codes: KOZ, MGO, NAC);
- Occlusive wound dressing at § 878.4020 (Product Code: NAD);
- Hydrogel wound dressing and burn dressing at § 878.4022 (Product Codes: NAE, OJJ, PXQ);
- Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive at § 878.4015 (Product Code: NYS).

(Refs. 39–40)

B. Device Description

1. Solid Wound Dressings Containing Antimicrobials and/or Other Chemicals

Solid wound dressings containing antimicrobials and/or other chemicals are used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound (see intended uses in section V.B). The antimicrobials (see table 2) contained in solid wound dressings are used as a protectant to prevent or reduce contamination or deterioration of the dressing while in contact with the wound. A solid wound dressing may contain one or more of the antimicrobials (see table 2) and/or other chemicals (see table 3). Such a wound dressing may also contain animal-derived materials (*e.g.,* collagen, gelatin, decellularized extracellular matrix).

The dressing materials are resorbable or nonresorbable, synthetic or naturally derived materials (including animal-derived materials), which are provided

[19] More detail about the medical device names and associated information for the product codes listed here is available in the Product Code Classification Database, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.*

[20] 87 FR 60691, October 6, 2022. Available at *https://www.govinfo.gov/content/pkg/FR-2022-10-06/pdf/2022-21746.pdf.* FDA will add a link to the meeting materials once they are publicly available.

[21] These dressings are currently regulated under product code FRO, but FDA's intent will be to assign a new product code for these wound dressings as they are out of the scope of this proposed rule and proposed classification action.

[22] Id.

[23] The majority of the catheter securement dressings with antimicrobials are in scope for this proposed rule and proposed classification action. Catheter securement dressings containing antimicrobials that are intended for reduction or prevention of infection are outside the scope of this proposed rule.

[24] These dressings are currently regulated under product code FRO, but FDA's intent will be to assign a new product code for these wound dressings, as they are out of scope of this proposed rule and proposed classification action.

[25] Id.

[26] Id.

sterile in a form able to hold structural integrity permanently or temporarily. Solid wound dressings containing antimicrobials and/or other chemicals may be in the form of a woven or nonwoven fabric pad, foam, or as a cross-linked hydrogel that has sufficient structural integrity to hold a physical form, such as a scaffold or matrix. Some wound dressings are multilayered, with each layer made of a different solid form, such as a four-layered dressing with a woven layer, foam layer, hydrocolloid layer, and occlusive adhesive backing layer. The types of materials used in these wound dressings generally include polyester, cellulose, polyurethane, nylon, poly(vinyl alcohol), alginate, cross-linked collagen, poly(ethylene glycol), and poly(lactic-co-glycolic acid).

2. Wound Dressings Formulated as a Gel, Cream, or Ointment Containing Antimicrobials and/or Other Chemicals

A wound dressing formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals is used to maintain appropriate moisture balance within the wound (see intended uses in section V.B). The antimicrobials contained in such wound dressings are used for preservative purposes to maintain shelf life for a nonsterile wound dressing or a multiple-use wound dressing for single patient use only (see table 2). A wound dressing formulated as a gel, cream, or ointment may contain one or more of the antimicrobials (see table 2) and/or other chemicals (see table 3). Such a wound dressing may also contain animal-derived materials.

The wound dressing materials are synthetic or naturally derived materials (including animal-derived materials), which are provided in an amorphous form. Wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals are amorphous and can have high water content with thickening agents or consist of an oil-water emulsion. These products are generally packaged in tubes or containers that can be for single use only or labeled for multiple use for single patient use only after the package has been opened. While some wound dressings are terminally sterilized and labeled for single use, many other wound dressings cannot be terminally sterilized given the sensitivity of the materials to sterilization methods, or they may require a preservative for multiple-use wound dressings for single patient use only.

3. Liquid Wound Washes

A liquid wound wash is a water-based solution used to mechanically irrigate and physically remove debris from external wounds. It is also used to moisten solid wound dressings to maintain appropriate moisture balance within the dressing (see intended use(s) in section V.B). The antimicrobials contained in such liquid wound washes are used for preservative purposes to maintain shelf life for a nonsterile liquid wound wash or a multiple-use liquid wound wash for single patient use only (see table 2). Some liquid wound washes are terminally sterilized and labeled for single use, or they may require a preservative for multiple-use liquid wound washes for single patient use only. Liquid wound washes may contain one or more of the antimicrobials (see table 2) and/or other chemicals (see table 3).

Liquid wound washes are generally water- or saline-based liquid solutions. They are typically packaged in bottles with plain caps or pump sprays and may or may not be terminally sterilized. Such liquid wound washes may also contain animal-derived materials.

4. Proposed Intended Use(s)

Based on the collective recommendations from the 2005 and 2016 Panels, FDA's experience with these wound dressings and liquid wound washes, and other available information, FDA proposes the following intended uses for the three wound dressing and liquid wound wash types discussed in this proposed rule. Additionally, since the utilization of these wound dressings and liquid wound washes is not to treat an infection, FDA is proposing that the intended uses for these wound dressings and liquid wound washes remain the same whether the product is used for an infected or noninfected wound because the role of the antimicrobial is limited to acting within the dressing and not on the wound itself. The proposed uses are the following:

- *Solid Wound Dressings Containing Antimicrobials and/or Other Chemicals:* A solid wound dressing containing antimicrobials and/or other chemicals is used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound.
- *Wound Dressings formulated as a Gel, Cream, or Ointment Containing Antimicrobials and/or Other Chemicals:* A wound dressing formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals is used to maintain appropriate moisture balance within the wound.
- *Liquid Wound Washes:* A liquid wound wash is a water-based solution used to mechanically irrigate and physically remove debris from external wounds. It is also used to moisten solid wound dressings to maintain appropriate moisture balance within the dressing.

Within those intended uses, antimicrobials may support the intended use through the following means:

- *Antimicrobial preservative:* An antimicrobial preservative is used in wound dressings formulated as a gel, cream, or ointment or liquid wound washes to maintain low bioburden while in its packaging during storage to improve its shelf life. An antimicrobial preservative use is not appropriate for a sterile, single-use product. Further, preservative effectiveness claims are within the scope of this proposed rule for the proposed classifications only when used for a specified period of use for multiple-use wound dressings and liquid wound washes for single patient only use.
- *Antimicrobial protectant:* An antimicrobial protectant, when added to a sterile, single-use solid wound dressing, is intended to support the use of the wound dressing by reducing degradation or biofouling of the dressing while in use. Antimicrobial protectant claims are within the scope of this proposed rule for the proposed classifications only when used for reducing microbial growth within the solid wound dressing for a specified maximum period of clinical use.

Prior to this proposed rulemaking, wound dressings and liquid wound washes containing antimicrobials intended for wound management were generally identified as combination products.[27] This was because the term ''wound management'' could be interpreted broadly, encompassing uses not only including to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance, but also uses such as treatment of wounds/wound infection. As discussed in more detail below, for a product to be within the scope of this proposed rulemaking and benefit from the proposed classification action, FDA is proposing that the term ''wound management'' not be included in the product labeling and the product labeling be clarified to reflect the

[27] See definition of combination product in 21 CFR 3.2(e).

explicit uses described above (*e.g.,* ''to protect and cover a wound'').

FDA has considered the intended use of these products in this category limited to the uses expressly discussed above (including to cover and protect a wound, to absorb exudate, to maintain appropriate moisture balance, to mechanically irrigate). However, with the inclusion of ''wound management'' and based on feedback during the 2016 Panel (Ref. 3), these limited intended uses were not clear to all users and, thus, created a broader objective intent. Within the scope of this proposed rule, FDA is making manufacturers aware that, for their products to be within the scope of this proposed rulemaking and benefit from the proposed classification action, manufacturers must clarify their labeling to not include ''management'' but instead explicitly include the relevant uses described above. Otherwise, the product could be subject to a different type of marketing authorization, depending on the product claims. In many cases, refinement of the indications will require revisions to the labeling.

FDA believes that, with such clarification of statements in the labeling and the indications, wound dressings and liquid wound washes in this category, including those with appropriate amounts of antimicrobial, should be regulated only as ''devices'' and not as combination products. This is because the antimicrobial, when included in a product that only covers and protects a wound, absorbs exudate, irrigates a wound, and/or maintains appropriate moisture balance would not achieve its primary intended purpose through chemical action within or on the body of man.[28]

Manufacturers who do not intend to update their products' labeling to clarify such claims (*i.e.,* update to remove wound management and other misleading claims discussed below) would not be in compliance with the special controls when the rule is finalized. Hence, these manufacturers' products could be subject to submission of their wound dressing or liquid wound wash to FDA for review via a different type of marketing authorization, depending on the product claims. For example, wound dressings containing antimicrobials that make certain wound management claims may be considered combination products or drugs and regulated as such.

FDA proposes that the following labeling claims are not appropriate for the wound dressings and liquid wound washes proposed for classification in this proposed rule as these claims may be unclear or misleading or indicate an objective intent outside of the intended uses discussed above. While some of these uses may have been previously reviewed in submissions for wound dressings and liquid wound washes within the scope of this rule, FDA is proposing to clarify, consistent with the recommendations of the 2005 and 2016 Panels and FDA's experience with these dressings and washes, that such uses are inappropriate for the wound dressings and liquid wound washes being proposed for classification through this rulemaking. These uses include the following:

- *Wound Management:* While the term has been widely used, it is not consistently used and is unclear from a clinical perspective. Based on the 2016 Panel discussion, the Panel members agreed that specific functions of wound dressings and liquid wound washes had clear benefits, including covering and protecting a wound, keeping the dressing moist, and washing or irrigating a wound. Although the term ''wound management'' was presented as a typical part of the indications and intended use of wound dressings and liquid wound washes, the 2016 Panel members acknowledged that there was not a consistent or frequent use of the term ''wound management'' in describing how the products are used. The 2016 Panel members questioned whether the wound dressings and liquid wound washes are intended to treat the wound or to achieve wound healing. Therefore, consistent with the 2016 Panel's feedback, this proposed rulemaking is clarifying that the term ''wound management'' be replaced with the specific functions of the wound dressing and liquid wound washes (*e.g.,* cover and protect the wound in the case of solid wound dressings).
- *Use of the word ''may'' (e.g., ''may reduce the risk of infection'')*: The word ''may'' is ambiguous and could mislead the end users when describing a specific use (*e.g.,* ''may reduce the risk of infection''); instead, intended uses, indications, and claims should be clearly stated and supported by appropriate data. This is supported by the fact that the 2016 Panel discussed whether the term ''may reduce the risk of infection'' represented a clinically meaningful benefit to the patient, and noted that such a claim does not appear to be meaningful and is likely confusing to patients.
- *Treatment of or cure for wounds:* This use is for wound healing through active interaction with the wound. Such a use falls within the scope of product codes MGR or MDD, which are regulated as a postamendments class III device, subject to PMA.
- *Deliver antimicrobials to the wound:* Such use suggests an intent for the treatment or prevention of infection that generally would be achieved through chemical action within or on the wound and may not fall under CDRH's jurisdiction. For the purposes of this classification action, the role of the antimicrobial(s) is limited to acting within the wound dressing or liquid wound wash as either a preservative or a protectant of the product.
- *Antimicrobial preservative claims for a sterile, single-use product:* Use of a preservative in this context is limited only to nonsterile, single-use or multiple-use wound dressings for single patient use only.[29]

FDA encourages sponsors to consider the following in support of their proposed intended use(s) when demonstrating they fall within the scope of this proposed rule and classification action.

- Preservative effectiveness claims for wound dressings formulated as a gel, cream, or ointment, and liquid wound washes should be defined for a specified period of shelf storage, and supported by appropriate in vitro testing as outlined in USP <51> ''Antimicrobial Effectiveness Testing,'' including following specific recommendations concerning test organisms and acceptance criteria.
- Antimicrobial effectiveness claims for solid wound dressings should describe the general level of effectiveness (*i.e.,* reduced microbial growth within the solid dressing or barrier to microbial penetration through a solid dressing over a specified period of use) and should be supported by in vitro test results from a broad selection of representative clinically relevant microbial species, as described in the proposed performance testing special controls identified in section V.B. However, due to the genetic diversity within the different microbial species, effectiveness claims on product labeling should only describe the general level of effectiveness, without listing specific

[28] See section 201(h) of the FD&C Act (21 U.S.C. 321(h))—for the definition of device. For guidance on how products are classified as devices, please see the guidance ''Classification of Products as Drugs and Devices and Additional Product Classification Issues'' (*https://www.fda.gov/media/80384/download*).

[29] In rare cases, antimicrobials can be included as a process control to reduce bioburden during manufacturing, and this should be supported with proper justification and discussed with the review team. No performance claims should be made regarding the use of antimicrobials as manufacturing process controls.

test organisms, species, or strains (including drug resistant strains such as Methicillin-resistant *Staphylococcus aureus*).

• Antimicrobial effectiveness claims for solid wound dressings should clearly distinguish the types of data used to support the claim; for example, whether the claim is based on results from in vitro testing, in vivo testing, or supporting clinical data. For claims that are solely supported by in vitro testing, the submission and product labeling should clearly state that the claims are solely based on in vitro testing and that clinical studies were not conducted or that the clinical benefit has not been evaluated.

• Antimicrobial and preservative effectiveness claims for all wound dressings containing antimicrobials should not state or imply that these products have an antimicrobial impact on organisms in the wound environment since claims regarding effectiveness against wound microorganisms and biofilms would be outside the scope of this proposed rule.

C. Risks to Health and Public Health Benefits

In evaluating the risks to health associated with the use of wound dressings and liquid wound washes, FDA considered information from the 1998 Panel, the 2005 Panel, and the 2016 Panel regarding the classification of wound dressings and liquid wound washes; the adverse event reports for these wound dressings and liquid wound washes in FDA's Manufacturer and User Facility Device Experience database examined through July 2022; and the published scientific literature, which is discussed in FDA's executive summary for the 2016 Panel meeting (Ref. 3).

FDA also considered scientific literature published since the 2016 Panel meeting. A contemporary literature search was conducted in September 2022 and identified eight articles (Refs. 41–48) published since June 2016 that are relevant to the safety and effectiveness of wound dressings and liquid wound washes containing antimicrobials. In the review of these references, the information from the contemporary literature analysis is consistent with the findings of the prior literature analysis presented at the 2016 Panel meeting.

FDA also reviewed recalls reported under product code FRO from 2003 to July 2022.[30] There were no recalls for solid wound dressings; wound dressings formulated as a gel, cream, or ointment; or liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives during this same timeframe. Out of the 29 recalls identified for wound dressings and liquid wound washes containing medium or low level of AMR concern and/or other chemicals, there was 1 class I recall, 23 class II recalls, and 5 class III recalls. The reason for the one class I recall was potential microbial contamination of the product. Reasons for class II and class III recalls include erroneous device labeling, devices not meeting stability specifications, and potential sterility breach of the product. Based on this information, FDA believes the risks to health associated with the use of these wound dressings and liquid wound washes are those discussed below.

Based on this information, FDA has identified the following risks to health to the different categories of wound dressings and liquid wound washes which are within the scope of this proposed rule and classification action:

• *Solid Wound Dressings:* adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, loss of barrier function, retention of dressing material in wound, and negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.

• *Wound Dressings Formulated as a Gel, Cream, or Ointment:* adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, and negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.

• *Liquid Wound Washes:* adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, inability to remove wound debris and foreign materials, and negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.

Below is a brief description of each of the identified risks to health:

• *Adverse tissue reaction:* Erythema, irritation, inflammation of the wound or host tissue, immune response, and hemolysis can occur as a result of an unwanted tissue response associated with the materials or leachables/extractables in wound dressings and liquid wound washes.

• *Immunological reaction:* This can result from a device derived from a new animal source or protein denaturation/modification due to the manufacturing conditions.

• *Transmission of pathogens and parasites* (*e.g.,* bacteria, mycoplasma, fungi, viruses, and other transmissible spongiform encephalopathy agents): This can result from contaminated animal sources, feed, inadequate processing, and viral inactivation of the animal-derived materials.

• *Toxicity:* Local and/or systemic toxicity, tissue necrosis, reduced tissue viability, and genotoxicity can occur due to toxic antimicrobials or other chemicals in the wound dressings or liquid wound washes, which can result in adverse tissue effects, leading to toxicity. This also includes allergic reaction and sensitization, as individuals with known sensitivity to the materials in the wound dressings and liquid wound washes may experience allergic reactions, which may be severe depending on the degree of sensitivity.

• *Delayed wound healing:* Cytotoxicity resulting in dead or necrotic tissue can delay healing.

• *Incompatibilities with other therapies:* An undesirable (*e.g.,* antagonistic) reaction could occur between the materials contained in/on the wound dressings or liquid wound washes and other therapies applied to the wound.

• *Contribution to the spread of AMR:* Use of antimicrobials in wound dressings and liquid wound washes can inadvertently select for and cultivate antimicrobial resistant organisms in patients and further limit a clinician's therapeutic options to treat infections.

• *Infection:* Unsafe methods of manufacturing processes, such as inadequate aseptic processing, inadequate packaging and/or product storage can result in contaminated product that may be a source of infection. This risk includes bacterial and fungal infections and superinfections which may result from the use of an antimicrobial-containing

[30] Only the product code FRO was queried for the recall analysis, as the majority of the products in scope for this proposed rule fall within FRO. The types of recalls reported within FRO are expected to be representative of all products in scope for this proposed rule.

wound dressing or liquid wound wash that introduces contaminating microorganisms to the wound or disrupts the natural balance of skin flora around the wound.

• *Microbial growth within the product:* This can occur from inadequate sterilization, preservative effectiveness failure, unsafe methods of manufacturing processes, inadequate packaging and/or product storage. This can lead to a change in product composition or characteristics (*e.g.,* loss of tensile strength, change in pH) and may also result in infection or adverse tissue reaction.

• *Product degradation during stated shelf storage:* Inadequate packaging and/or inappropriate storage of wound dressings or liquid wound washes can result in product degradation during storage. Product degradation can also change the composition or characteristics of the product over time and lead to patient harm.

• *Retention of dressing material in wound:* This risk is generally applicable to solid wound dressings, which can occur due to a loss in solid dressing integrity or unintended degradation of solid wound dressings. It may also occur due to a healthcare provider inadvertently leaving material in the wound. This can lead to adverse tissue reaction, delay in wound healing, or infection.

• *Inability to remove wound debris and foreign materials:* Ineffective washing of the wound can occur. Debris and foreign material remaining in the wound can delay healing or lead to infection. This risk is applicable to the liquid wound washes containing antimicrobials and/or other chemicals.

• *Loss of barrier function:* This risk is applicable to solid wound dressings indicated as barriers to microbial penetration through the wound dressing (either via mechanical or antimicrobial properties). Loss of this barrier function can introduce microbial contamination from the environment into the wound and can lead to delay in wound healing or infection.

• *Impact to skin microbiota in the periwound area:* This risk is applicable to each category of antimicrobial-containing wound dressings. Inadvertent leaching of antimicrobials away from the dressing may negatively impact the skin microbiota in the periwound area by reducing the presence of beneficial commensal microorganisms that play a role in the wound healing cascade, resulting in impaired wound healing.

The purported benefits associated with the use of wound dressings and liquid wound washes that are proposed to be classified into either class III or II are discussed below.

In evaluating the benefits associated with the use of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals, FDA considered information from the 1998 Panel, the 2005 Panel, and the 2016 Panel regarding the classification of wound dressings and liquid wound washes and the published scientific literature, including clinical guidelines for wound care, which is discussed in FDA's executive summary for the 2016 Panel meeting (Ref. 3). Based on this information, there appears to be a lack of clinical data to demonstrate a clear clinical benefit (*e.g.,* improved clinical outcomes from the use of antimicrobial dressings over non-antimicrobial dressings for the prevention or treatment of local wound infections or to improve wound healing) regarding the use of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals. It is generally understood from the literature review and discussion with the 2016 Panel members that the collection of such clinical data has been challenging, as a result of many factors (*e.g.,* difficulties grouping patients with different wound types, lack of controls, unclear endpoints, other treatments including use of systemic antibacterial drugs, exclusion criteria, and identifying a sufficient number of patients to power these studies). Despite the lack of clear clinical data, several benefits to wound dressings and liquid wound washes containing antimicrobials and/or other chemicals have been identified, including the following:

• *Maintaining a moist wound healing environment:* Clinical guidelines note that a moist wound environment is ideal for wound healing. Wound dressings can provide this benefit based on their ability to absorb and manage wound exudate levels. Wound dressings may include ingredients that aid in moisture management, for example, through acting as a humectant to manage moisture levels within the dressing or forming a barrier to moisture loss.

• *Providing effective barrier to environmental contaminants:* This benefit applies to solid wound dressings that utilize either a mechanical barrier (*e.g.,* polyurethane film layer) or an antimicrobial barrier to eliminate the penetration of external microorganisms through the dressing and into the wound.

• *Reducing microbial growth within the dressing:* This benefit applies to solid wound dressings that utilize an antimicrobial to reduce microbial growth and colonization of dressings, which can reduce soiling and degradation of a dressing and extend the length of time a dressing may be applied before needing to be changed.

• *Extending the shelf life of nonsterile and/or multiuse wound dressings:* This benefit applies to wound dressings formulated as a gel, cream, or ointment and liquid wound washes that utilize an antimicrobial as a preservative to reduce microbial growth within the product during shelf storage. This helps keep dressings from prematurely degrading or becoming a source of cross-contamination.

Finally, it is noted that selection of certain wound dressings and liquid wound washes is based on wound bed characteristics, and due to their heterogenous nature, no single wound dressing or liquid wound wash is suitable for all types of wounds. As such, the robust number and diversity of wound dressings and liquid wound washes currently on the market provides an overall benefit of choice for healthcare professionals and other end users to select wound dressings and liquid wound washes that are tailored to the wound characteristics of a particular patient.

D. Proposed Classification and FDA's Findings

1. Level of AMR Concern and Medically Important Antimicrobials

FDA is proposing the following risk-based paradigm for evaluating the level of AMR concern (high, medium, or low) associated with wound dressings and liquid wound washes containing antimicrobials discussed in this proposed classification rule. The proposed paradigm is based on a detailed characterization of the antimicrobials contained in wound dressings and liquid wound washes cleared by FDA under product codes FRO, GER, MGP, MGQ, and EFQ, and by relying on FDA's experience in this area, literature review, the 2005 and 2016 Panels' recommendations, and other available information.

To evaluate the level of AMR concern and the proposed risk-based paradigm, a literature review was conducted to identify the following attributes: (1) current applications of the antimicrobial, (2) known resistance mechanisms, (3) if any of the resistance genes are plasmid-mediated, (4) evidence of potential for coselection of medically important antimicrobial resistance via mechanisms such as coresistance or cross-resistance, and (5) known resistant microbial species. FDA is proposing to categorize certain wound

dressings and liquid wound washes as either having a high, medium, or low level of AMR concern, which then corresponds with the proposed classification of the wound dressings and liquid wound washes containing antimicrobials (as either being in class III or class II, based on the criteria in section 513(a)(1) of the FD&C Act).

2. Proposed Classification of Solid Wound Dressings Containing Antimicrobials and/or Other Chemicals (Proposed § 878.4016)

Based on FDA's experience with certain wound dressings, the collective 2005 and 2016 Panels' recommendations, and other available information, FDA is proposing to classify solid wound dressings containing medically important antimicrobials used as protectants (see table 2) into class III when intended to be used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound (proposed § 878.4016(b)(1)). These wound dressings may additionally contain other chemicals (see table 3). FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such wound dressings and these wound dressings present a potential unreasonable risk of illness or injury. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of a PMA if these wound dressings are classified into class III, which will only be finalized if FDA classifies such wound dressings as class III.

In proposed § 878.4016(b)(2), FDA is proposing to classify solid wound dressings containing antimicrobial(s) used as protectants with a medium or low level of AMR concern (see table 2) and/or other chemicals (see table 3) into class II (special controls). FDA is proposing this action based on the determination that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these wound dressings, and there is sufficient information to establish special controls to provide such assurance.

The special controls proposed in § 878.4016(b)(2)(i) through (vii) for these proposed class II wound dressings include performance testing and descriptive information, antimicrobial characterization and performance testing, AMR risk assessment, biocompatibility evaluation, risk management assessment for animal-derived materials and/or botanical extracts, labeling, shelf life validation, and sterilization validation.

3. Proposed Classification for Wound Dressings Formulated as a Gel, Cream, or Ointment Containing Antimicrobials and/or Other Chemicals (Proposed § 878.4017)

Based on FDA's experience with certain wound dressings, the collective 2005 and 2016 Panels' recommendations, and other available information, FDA is proposing to classify wound dressings formulated as a gel, cream, or ointment containing medically important antimicrobials used as preservatives (see table 2), into class III when intended to maintain appropriate moisture balance within the wound (proposed § 878.4017(b)(1)). These wound dressings may additionally contain other chemicals (see table 3). FDA is proposing this classification as FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of the safety and effectiveness for such wound dressings and these wound dressings present a potential unreasonable risk of illness or injury. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of a PMA if these wound dressings are classified into class III, which will only be finalized if FDA classifies such wound dressings as class III.

In proposed § 878.4017(b)(2), FDA is proposing to classify wound dressings formulated as a gel, cream, or ointment containing antimicrobials used as preservatives with a medium or low level of AMR concern (see table 2) and/or other chemicals (see table 3) into class II (special controls). FDA is proposing this action based on the determination that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these wound dressings, and there is sufficient information to establish special controls to provide such assurance.

The special controls proposed in § 878.4017(b)(2)(i) through (vii) include performance testing and descriptive information, antimicrobial characterization and preservative effectiveness testing, AMR risk assessment, biocompatibility evaluation, risk management assessment for animal-derived materials and/or botanical extracts, labeling, shelf-life validation, and sterilization validation.

4. Proposed Classification for Liquid Wound Washes (Proposed § 878.4019)

Based on FDA's experience with certain wound dressings and liquid wound washes, the collective 2005 and 2016 Panels' recommendations, and other available information, FDA is proposing to classify liquid wound washes containing medically important antimicrobials used as preservatives (see table 2) into class III when intended to irrigate the wound and to moisten solid wound dressings to maintain appropriate moisture balance within the dressing (proposed § 878.4019(b)(1)). These liquid wound washes may additionally contain other chemicals (see table 3). FDA is proposing this classification as it believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such liquid wound washes and these washes present a potential unreasonable risk of illness or injury. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of a PMA if these liquid wound washes are classified into class III, which will only be finalized if FDA classifies such liquid wound washes as class III.

In proposed § 878.4018(b)(2), FDA is proposing to classify liquid wound washes containing antimicrobials used as preservatives with a medium or low level of AMR concern (see table 2) or other chemicals (see table 3) into class II (special controls). FDA is proposing this action based on the determination that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these liquid wound washes and there is sufficient information to establish special controls to provide such assurance.

The special controls proposed in § 878.4018(b)(2)(i) through (vii) include performance testing and descriptive information, antimicrobial characterization and preservative effectiveness testing, AMR risk assessment, biocompatibility evaluation, risk management assessment for animal-derived materials and/or botanical extracts, labeling, shelf-life validation, and sterilization validation.

In addition, if this proposed rule and classification is finalized, FDA plans to publish a notice in the **Federal Register** announcing its intent to exempt from the premarket notification requirements liquid wound washes containing water or 0.9 percent saline only, which do not contain antimicrobials, other chemicals,

or animal-derived materials, subject to certain limitations. FDA believes that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of this wound wash type, in accordance with section 510(m) of the FD&C Act.

5. Proposed Special Controls

Based on the collective 2005 and 2016 Panels' recommendations, FDA's experience with these wound dressings and liquid wound washes, and other available information, FDA is proposing the special controls identified in this section for wound dressings and liquid wound washes that are proposed to be classified into class II. FDA believes that these special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness of the wound dressings and liquid wound washes containing antimicrobials used as either protectants or preservatives with a medium or low level of AMR concern (see table 2) and/or other chemicals (see table 3). Special controls were discussed at the 2016 Panel (Ref. 2, see section III.B of the Executive Summary). The 2016 Panel agreed that the special controls as presented would provide a reasonable assurance of safety and effectiveness for these wound dressings and liquid wound washes, emphasizing in discussions, among other things, the need for adequate labeling, specific use claims, and sufficient data to support labeling claims.

As noted in Section V.C Risks to Health and Public Health Benefits of this proposed rule, three risks (specifically, toxicity, transmission of pathogens and parasites, and immunological reaction) were added as separate risks since the 2016 Panel meeting, which resulted in changes to the corresponding proposed mitigation measures for the identified risks to health. Additionally, 2016 Panel members suggested we consider including leaching and systemic absorption of antimicrobials or other chemicals as risks. These risks are included within adverse tissue reaction and toxicity and mitigations are included to address them. However, FDA does not believe these need to be added as separate categories of risks to health.

For several of the risks to health, additional mitigation measures are proposed compared to those identified during the 2016 Panel. The proposed mitigations are due to the specific attributes of the materials of the wound dressings and liquid wound washes, which require specific mitigation measures to address the risks identified (*e.g.,* animal-derived materials, botanical extracts). The newly proposed mitigation measures include performance testing and descriptive information and a risk management assessment for animal-derived materials and/or botanical extracts. In addition, certain previously proposed mitigation measures (*e.g.,* labeling, performance data) were recognized to have a role in mitigating more risks than initially proposed during the 2016 Panel meeting. Mitigations have been associated with the relevant identified risks as subsequently discussed in this proposed rule. Following the 2016 Panel meeting, an additional probable health risk was identified based on reports in the literature (Refs. 49–55) regarding the understood role that our skin microbiota plays in the wound healing cascade.

As such, antimicrobials that leach from wound dressings may inadvertently impact the skin microbiota in the periwound area resulting in impaired wound healing. Antimicrobial preservative claims for wound dressings formulated as a gel, cream, or ointment and liquid wound washes; and protectant and microbial barrier claims for solid wound dressings may be supported by in vitro testing, limiting the stated period of effectiveness to that supported by simulated-use testing parameters, as described in the special controls in section V.D of this proposed rule.

FDA believes that the special controls proposed for these wound dressings and liquid wound washes, in addition to the general controls, mitigate the risks to health discussed in Section V.C, Risks to Health and Public Health Benefits of this proposed rule and are necessary to provide reasonable assurance of safety and effectiveness. Tables 4–6 depict how each identified risk to health would be mitigated by the proposed special controls.

TABLE 4—IDENTIFIED RISKS TO HEALTH AND PROPOSED MITIGATION MEASURES FOR SOLID WOUND DRESSINGS CONTAINING ANTIMICROBIALS WITH A MEDIUM OR LOW LEVEL OF AMR CONCERN FOR PROTECTANT PURPOSES ONLY AND/OR OTHER CHEMICALS

Identified risks to health	Proposed mitigation measure(s)
Adverse tissue reaction	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Immunological reaction	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Transmission of pathogens and parasites (*e.g.,* bacteria, mycoplasma, fungi, viruses, and other transmissible spongiform encephalopathy agents).	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material. • Labeling.
Toxicity	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Delayed wound healing	• Performance testing and descriptive information. • Biocompatibility evaluation. • Labeling.
Incompatibilities with other therapies	• Labeling.

TABLE 4—IDENTIFIED RISKS TO HEALTH AND PROPOSED MITIGATION MEASURES FOR SOLID WOUND DRESSINGS CONTAINING ANTIMICROBIALS WITH A MEDIUM OR LOW LEVEL OF AMR CONCERN FOR PROTECTANT PURPOSES ONLY AND/OR OTHER CHEMICALS—Continued

Identified risks to health	Proposed mitigation measure(s)
Contribution to the spread of antimicrobial resistance (AMR)	• Antimicrobial Characterization and Performance Testing. • AMR risk assessment. • Labeling.
Infection	• Antimicrobial Characterization and Performance Testing. • Shelf life validation. • Sterilization validation. • Risk management assessment for animal-derived materials and/or botanical extracts. • Labeling.
Microbial growth within the product during use	• Antimicrobial Characterization and Performance Testing. • Sterilization validation.
Product degradation during stated shelf storage	• Shelf life validation. • Labeling.
Retention of dressing material in wound	• Performance testing and descriptive information. • Labeling.
Loss of Barrier function	• Antimicrobial Characterization and Performance Testing.
Negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.	• Antimicrobial Characterization and Performance Testing. • Labeling.

TABLE 5—IDENTIFIED RISKS TO HEALTH AND PROPOSED MITIGATION MEASURES FOR WOUND DRESSINGS FORMULATED AS A GEL, CREAM, OR OINTMENT CONTAINING ANTIMICROBIALS WITH A MEDIUM OR LOW LEVEL OF AMR CONCERN FOR PRESERVATIVE PURPOSES ONLY AND/OR OTHER CHEMICALS

Identified risks to health	Proposed mitigation measure(s)
Adverse tissue reaction	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Immunological reaction	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Transmission of pathogens and parasites (*e.g.,* bacteria, mycoplasma, fungi, viruses, and other transmissible spongiform encephalopathy agents).	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material. • Labeling.
Toxicity	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Delayed wound healing	• Performance testing and descriptive information. • Biocompatibility evaluation. • Labeling.
Incompatibilities with other therapies	• Labeling.
Contribution to the spread of antimicrobial resistance (AMR)	• Antimicrobial Characterization and Preservative Effectiveness Testing. • AMR risk assessment. • Labeling.
Infection	• Antimicrobial Characterization and Preservative Effectiveness Testing. • Shelf life validation. • Sterilization validation. • Risk management assessment for animal-derived materials and/or botanical extracts. • Labeling.
Microbial growth within the product during storage	• Antimicrobial Characterization and Preservative Effectiveness Testing. • Sterilization validation.
Product degradation during stated shelf storage	• Shelf life validation. • Labeling.
Negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.	• Antimicrobial Characterization and Performance Testing. • Labeling.

TABLE 6—IDENTIFIED RISKS TO HEALTH AND PROPOSED MITIGATION MEASURES FOR LIQUID WOUND WASHES CONTAINING ANTIMICROBIALS WITH A MEDIUM OR LOW LEVEL OF AMR CONCERN FOR PRESERVATIVE PURPOSES ONLY, AND/OR CONTAINING OTHER CHEMICALS

Identified risks to health	Proposed mitigation measure(s)
Adverse tissue reaction	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Immunological reaction	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Transmission of pathogens and parasites (*e.g.,* bacteria, mycoplasma, fungi, viruses, and other transmissible spongiform encephalopathy agents).	• Performance testing and descriptive information. • Risk management assessment for the inclusion of animal-derived material. • Labeling.
Toxicity	• Performance testing and descriptive information. • Biocompatibility evaluation. • Risk management assessment for the inclusion of animal-derived material and/or botanical extracts. • Labeling.
Delayed wound healing	• Performance testing and descriptive information. • Biocompatibility evaluation. • Labeling.
Incompatibilities with other therapies	• Labeling.
Contribution to the spread of antimicrobial resistance (AMR)	• Antimicrobial Characterization and Preservative Effectiveness Testing. • AMR risk assessment. • Labeling.
Infection	• Antimicrobial Characterization and Preservative Effectiveness Testing. • Shelf life validation. • Sterilization validation. • Risk management assessment for animal-derived materials and/or botanical extracts. • Labeling.
Microbial growth within the product during storage	• Antimicrobial Characterization and Preservative Effectiveness Testing. • Sterilization validation.
Product degradation during stated shelf storage	• Shelf life validation. • Labeling.
Inability to remove wound debris and foreign materials	• Performance testing and descriptive information. • Labeling.
Negatively impacting the skin microbiota in the periwound area resulting in impaired wound healing.	• Antimicrobial Characterization and Performance Testing. • Labeling.

VI. Proposed Effective/Compliance Dates

FDA proposes that any final rule, based on this proposed rule, become effective 30 days after its date of publication in the **Federal Register**.

Below, FDA has laid out a proposed tiered approach that we believe will help ensure the efficient and effective implementation of this classification regulation, when finalized.

A. Devices That Are Proposed To Be Classified Into Class III

For devices proposed to be classified into class III in this proposed rule, FDA is publishing a proposed order to require the filing of a PMA elsewhere in this issue of the **Federal Register**.

If this proposed rule and related proposed order to require the filing of a PMA are finalized, wound dressings and liquid wound washes that are proposed to be classified into class III are considered adulterated if a PMA is not filed with FDA within 30 months after the classification of the device into class III, and commercial distribution of the product must cease (see section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B))).

Moreover, manufacturers must cease distribution of devices upon receiving a not approvable or denial decision rendered on a PMA. In such circumstances, to resume distribution, these manufacturers must receive PMA approval for their devices. However, the product may be distributed for investigational use only if the requirements of the investigational device exemptions regulations in 21 CFR part 812 are met.

For currently marketed wound dressings and liquid wound washes that are proposed to be classified into class III, FDA is proposing in the above-mentioned proposed order that it does not intend to enforce compliance with the 30-month deadline by which PMAs must be submitted when a notice of intent to file a PMA is submitted within 90 days of the effective date of the order, if finalized. In circumstances when a notice of intent to file is submitted, FDA is proposing that it does not intend to enforce compliance with the 30-month deadline by which PMAs must be submitted when a PMA is submitted within 90 days after the 30-month deadline. However, as discussed above, even if a notice of intent and PMA are submitted by these dates, manufacturers must cease distribution of devices upon

receiving a not approvable or denial decision rendered on a PMA.

B. Devices That Are Proposed To Be Classified Into Class II

• Devices proposed to be classified into class II that have not been offered for sale prior to the effective date of this rule, when finalized, or have been offered for sale but are required to submit a new 510(k) under § 807.81(a)(3): FDA proposes that before marketing these devices, manufacturers would have to obtain 510(k) clearance (unless exempted from 510(k)), and demonstrate compliance with the applicable special controls, within 6 months after the effective date of this rule, when finalized. After that date, if a manufacturer markets such a device without receiving 510(k) clearance, then FDA would consider taking action against such a manufacturer under its usual enforcement policies.

• Devices proposed to be classified into class II that have prior 510(k) clearance: FDA proposes that it would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and compliance with the special controls. These devices could serve as predicates for new devices. These clearance letters would be made publicly available in FDA's 510(k) database, and compliance with special controls at the time of clearance would be stated in the publicly available 510(k) Summary posted in this database. FDA believes that our public database is a transparent tool allowing consumers to confirm that their devices have been submitted under a new 510(k) and demonstrate compliance with the applicable special controls.

For the devices proposed to be classified into class II, subject to special controls as described in this proposed rule, FDA proposes that the special controls become effective 6 months after the effective date of the rule, when finalized. FDA proposes that if a manufacturer markets such a device 6 months after the effective date of the rule, when finalized, and that device does not comply with the special controls, then FDA would consider taking action against such a manufacturer under its usual enforcement policies.

VII. Preliminary Economic Analysis of Impact

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 not 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 the costs of the proposed rule primarily accrue to larger firms, we propose to certify that the 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 $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule, if finalized, would classify certain types of currently unclassified wound dressings and liquid wound washes containing antimicrobials and/or other chemicals: solid dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. FDA is proposing to classify wound dressings and liquid wound washes containing medically important antimicrobials into class III due to their high level of AMR concern, for which FDA is separately proposing to require the filing of a PMA. FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for such wound dressings and liquid wound washes. In addition, FDA is proposing to classify wound dressings and liquid wound washes containing antimicrobials with a medium or low level of AMR concern into class II subject to general and special controls. FDA is publishing this proposed rule based, in part, on the recommendations of the General and Plastic Surgery Devices Panel regarding the classification of certain types of wound dressings and liquid wound washes.

To estimate costs and benefits associated with the proposed rule, if finalized, we assume that the appropriate baseline is the current state of the United States with unclassified wound dressings and liquid wound washes containing antimicrobials and/or other chemicals. We then compare the likely impacts of the proposed rule against this baseline. The quantifiable benefits of the proposed rule, if finalized, accrue to manufacturers of wound dressings and liquid wound washes and FDA. These benefits are the result of clarifications in the 510(k) submission process, specifically defined regulatory classification, and published special controls. This additional clarity in requirements should result in fewer additional information submissions to FDA.

We estimate annualized cost savings ranging from approximately $1.12 million to $6.31 million at a 3 percent discount rate, and approximately $1.14 million to $6.42 million at a 7 percent discount rate. Our primary annualized estimates are approximately $2.66 million at a 3 percent discount rate and $2.71 million at a 7 percent discount rate. The primary estimates of the present value of total cost savings in the 10 years following any final rule that may be issued based on this proposed rule are $24.55 million at a 3 percent rate of discount and $19.02 million at a 7 percent rate of discount. If the proposed rule is finalized, society may experience welfare gains from reductions in AMR due to the rule. These welfare gains would be in the form of decreased mortality, morbidity, and medical costs. Unfortunately, the magnitude of these potential benefits is difficult to forecast, and we do not quantify these impacts in the analysis. We summarize quantified benefits in table 7.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, preparing and submitting PMAs, and other costs related to the PMA process and maintaining the class III designation. FDA also incurs costs from reviewing PMAs, annual and supplemental reports, and inspection activities. When annualized over a period of 10 years, we estimate these costs range from approximately $0.72 million to $1.25 million at a 3 percent discount rate, and approximately $0.65 million to $1.17 million at a 7 percent discount rate. Our primary annualized estimates are approximately $0.92 million at a 3 percent discount rate and $0.85 million at a 7 percent discount rate. The primary estimates of the present value of total costs in the 10 years following any final rule that may be issued based on the proposed rule are approximately $7.23 million at a 3 percent discount rate and $6.48 million at a 7 percent discount rate. These values are summarized in table 7.

TABLE 7—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$2.71	$1.14	$6.42	2022	7	10	
	2.66	1.12	6.31	2022	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.92	0.72	1.25	2022	7	10	
	0.85	0.65	1.17	2022	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
From/To	From:			To:			
Other Annualized Monetized $millions/year	0.30	0.19	0.58	2022	7	10	
	0.28	0.18	0.56	2022	3	10	
From/To	From: Industry			To: FDA			
Effects:							
State, Local, or Tribal Government: None.							
Small Business: None.							
Wages:							
Growth:							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 56) 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 25.34(b) 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

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does 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, we conclude 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.

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, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

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

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*56. FDA's full preliminary analysis of economic impacts is available in the Docket No. FDA–2023–N–3392 for this proposed rule and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4016 to subpart E to read as follows:

§ 878.4016 Solid wound dressings containing antimicrobials and/or other chemicals.

(a) *Identification.* A solid wound dressing containing antimicrobials and/or other chemicals that are in a category listed in paragraph (a)(2) of this section is used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound and is intended for use only on external cutaneous (skin) wounds. The solid wound dressing materials are resorbable or nonresorbable, synthetic or naturally derived materials (including animal-derived materials such as collagen or chitosan), which are provided sterile in a form able to hold structural integrity temporarily or permanently. This regulation does not include a solid wound dressing that contains only animal-derived materials without the presence of antimicrobials and/or other chemicals.

(1) Antimicrobials are used for protectant purposes only to reduce microbial growth within the solid wound dressing while in use, or to provide an antimicrobial barrier to microbial penetration through the solid wound dressing;

(2) Categories of other chemicals are wound protectants, honey, synthetic peptides, or botanical extracts.

(b) *Classification.* (1) Class III (premarket approval) for solid wound dressings that are identified in paragraph (a) of this section and that contain one or more medically important antimicrobials acting as protectants.

(i) *Date premarket approval application is required.* A PMA is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], for any solid wound dressing, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials acting as protectants and was in commercial distribution before May 28, 1976, or has, on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], been found to be substantially equivalent to any solid wound dressing, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials and that was in commercial distribution before May 28, 1976. Any other solid wound dressing, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials shall have an approved PMA in effect before being placed in commercial distribution.

(ii) [Reserved]

(2) Class II (special controls) for solid wound dressings that are identified in paragraph (a) of this section and that contain one or more antimicrobials acting as protectants with a medium or low level of antimicrobial resistance (AMR) concern and/or other chemicals. The special controls are:

(i) *Performance testing and descriptive information.* Performance testing and descriptive information must demonstrate the functionality of the solid wound dressing to achieve the specified use, including:

(A) The physical and chemical characteristics of the solid wound dressing must be established. The following must be provided:

(1) Identity, quantification, and purpose of each component in the finished product;

(2) Specifications and characterization of each component in the finished product;

(3) Demonstration that each component has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use, including evaluation of expected worst-case conditions; and

(4) Final release specifications for the manufactured solid wound dressing.

(B) The solid wound dressing must be demonstrated to be sterile and the sterilization process must be validated.

(C) The solid wound dressing must be demonstrated to be biocompatible.

(D) Bench performance testing data must demonstrate that the solid wound dressing performs as intended under anticipated conditions of use, including evaluation of expected worst-case conditions.

(E) Performance data must support the shelf life of the solid wound dressing by demonstrating package integrity and product functionality over the identified shelf life.

(ii) *Antimicrobial characterization and performance testing.* For solid wound dressings containing antimicrobials with a medium or low level of AMR concern, antimicrobial characterization and performance testing must address the following:

(A) Performance data must demonstrate that the antimicrobial has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use and storage conditions, including evaluation of worst-case conditions. If the antimicrobial is present as a microbial barrier to cover and protect a wound, microbial barrier testing must be conducted to demonstrate elimination of passage of microorganisms through the solid wound dressing. If the antimicrobial is present to inhibit microbial growth within the solid wound dressing being used to cover and protect a wound, antimicrobial effectiveness testing must be conducted to demonstrate inhibition of microbial growth within the solid wound dressing during use. This testing must include:

(1) Establishment of the Minimum Effective Concentration (MEC) of the antimicrobial in the context of the final solid wound dressing under worst-case conditions.

(2) Identification of the period of effectiveness (*i.e.,* maximum product use life) based on concentration of antimicrobial, leachability data, and performance under worst-case simulated use conditions.

(3) For the tests conducted, evaluation with clinically relevant microbial species, including available strains of challenge organisms containing specific antimicrobial resistance mechanisms as part of worst-case scenario performance testing.

(B) Evaluation and identification of any probable risks for probable contributions to the development and spread of antimicrobial resistance must be provided, and must include:

(1) Identification of the antimicrobial, proposed mechanism(s) of action, and expected spectrum of activity; and

(2) An AMR assessment for each antimicrobial component, including the following characterization elements based on literature review:

(i) Known resistance mechanisms;

(ii) Transmissibility of resistance mechanisms;

(iii) List of resistant microbial species; and

(iv) Potential for coselection (*e.g.,* via coresistance or cross-resistance) for medically important antimicrobial resistance mechanisms.

(iii) If the solid wound dressing contains animal-derived material(s), data must include:

(A) A risk management assessment for the inclusion of animal-derived material(s) which considers any probable risk associated with the presence of the animal tissue in the final finished solid wound dressing (including pathogen and parasite infection and immunological reaction). The risk management assessment must describe how these risks are controlled and mitigated by:

(1) Documentation of the processing methods, including methods of animal husbandry and tissue selection as well as methods for tissue handling, storage, transport, and quarantine, that mitigate the risk of parasites and pathogens.

(2) Performance data which demonstrates the ability of the manufacturing and sterilization procedures to ensure the adequate removal (*i.e.,* clearance or inactivation) of parasites and pathogens (including bacteria, mycoplasma, fungi, virus, and transmissible spongiform encephalopathy agents) from the final finished solid wound dressing.

(B) If the device contains materials derived from a new animal species or from manufacturing processes which cause structural changes (*i.e.,* denaturation, modification) to the animal protein, performance data (*e.g.,* patch and prick testing, human repeat insult patch testing) must demonstrate that the device is not immunogenic.

(iv) If the solid wound dressing contains a botanical extract, additional supporting data must include:

(A) A risk management assessment for including the botanical extract in the solid wound dressing which considers any probable risk associated with the presence of the botanical extract in the final finished solid wound dressing.

(B) The risk management assessment must describe how these risks are

controlled and mitigated by providing the following:

(*1*) The chemical composition of the botanical extract, including the identity and quantification of the chemical constituents and impurities (*e.g.,* elemental impurities, residual solvents and pesticides, microbial contaminants, adventitious toxins, and degradation products) and the lot-to-lot consistency of the botanical extract within the final finished solid wound dressing.

(*2*) Documentation of the botanical extract function and activities after topical application. Such information must describe the purpose of the botanical extract in the solid wound dressing and how it is present in appropriate amounts to perform as intended under anticipated conditions of use, including expected worst-case conditions.

(*3*) Identification of any probable risk to health from use of the botanical extract and how these risks were evaluated and are mitigated via the botanical concentration in the final product, duration of body contact, manufacturing and process controls, performance data, and labeling for the solid wound dressing.

(v) The labeling must include:

(A) A description of the intended user population;

(B) Specific instructions regarding the proper placement, sizing, duration of use for the solid wound dressing, frequency of use, and removal of the solid wound dressing, if applicable;

(C) A list of each ingredient or component within the solid wound dressing, including the functional role of that ingredient within the solid wound dressing;

(D) A warning statement regarding any incompatibilities with other therapies;

(E) A warning statement regarding the potential for the development of infection, including signs of an infection and a description of the steps to take in case of infection;

(F) If the solid wound dressing is nonresorbable, a warning statement for the potential retention of material in the wound or the surrounding area;

(G) A contraindication for any known sensitivity to components within the product;

(H) A shelf life (*i.e.,* maximum period the unopened solid wound dressing is stable while stored on the shelf under a specified range of environmental conditions);

(I) A maximum use life per application of solid wound dressing (*i.e.,* period the solid wound dressing is recommended for use prior to removal);

(J) A statement regarding when to discontinue use of the solid wound dressing after multiple reapplications based on biocompatibility and performance testing; and

(K) For solid wound dressings indicated for over-the-counter use, a statement specifying conditions, uses, or purposes for which the product may be safely administered by a lay user without the supervision of a licensed practitioner.

(vi) If the solid wound dressing contains an antimicrobial, the labeling must also include:

(A) Statement of the role of the antimicrobial in the product.

(B) A warning statement regarding the potential for selection of antibiotic resistant organisms if the wound dressing contains an antimicrobial with a medium level of AMR concern.

(C) Specific instructions regarding how and when to properly dispose of the product.

(D) A statement of general effectiveness, such as ''antimicrobial,'' ''antibacterial,'' or ''microbial barrier,'' without listing specific test organisms or log reduction values.

(E) A statement explaining that the effectiveness of the antimicrobial in affecting wound bioburden has not been evaluated or established.

(F) A warning statement regarding the potential for the antimicrobial to leach from the dressing and negatively impact the skin microbiota in the periwound area which may result in impaired wound healing.

(vii) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of covering and protecting a wound, absorbing exudate, and maintaining appropriate moisture balance within the wound.

■ 3. Add § 878.4017 to subpart E to read as follows:

§ 878.4017 Wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals.

(a) *Identification.* A wound dressing formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals that are in a category listed in paragraph (a)(2) of this section is used to maintain appropriate moisture balance within the wound and is intended for use only on external cutaneous (skin) wounds. The wound dressing materials are synthetic or naturally derived materials (including animal-derived materials such as collagen or chitosan). Wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals are amorphous and can have high water content with thickening agents or consist of an oil-water emulsion. This regulation does not include a wound dressing formulated as a gel, cream, or ointment that contains only animal-derived materials without the presence of antimicrobials and/or other chemicals.

(1) Antimicrobials are used for preservative purposes only to maintain shelf life for a nonsterile wound dressing or a multiple-use wound dressing for single patient use only;

(2) Categories of other chemicals are wound protectants, honey, synthetic peptides, or botanical extracts.

(b) *Classification.* (1) Class III (premarket approval) for wound dressings formulated as a gel, cream, or ointment that are identified in paragraph (a) of this section and that contain one or more medically important antimicrobials acting as preservatives.

(i) *Date premarket approval application is required.* A PMA is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], for any wound dressing formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials acting as preservatives and was in commercial distribution before May 28, 1976, or has, on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], been found to be substantially equivalent to any wound dressing formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials and that was in commercial distribution before May 28, 1976. Any other wound dressing formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials shall have an approved PMA in effect before being placed in commercial distribution.

(ii) [Reserved]

(2) Class II (special controls) for wound dressings formulated as a gel, cream, or ointment that are identified in paragraph (a) of this section and that contain one or more antimicrobials acting as preservatives with a medium or low level of AMR concern and/or other chemicals. The special controls are:

(i) *Performance testing and descriptive information.* Performance testing and descriptive information must demonstrate the functionality of the wound dressing formulated as a gel, cream, or ointment to achieve the specified use, including:

(A) The physical and chemical characteristics of the wound dressing formulated as a gel, cream, or ointment must be established. The following must be provided:

(*1*) Identity, quantification, and purpose of each component in the finished product;

(*2*) Specifications and characterization of each component in the finished product;

(*3*) Demonstration that each component has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use, including evaluation of expected worst-case conditions; and

(*4*) Final release specifications for the manufactured wound dressing formulated as a gel, cream, or ointment.

(B) If labeled as sterile, the wound dressing formulated as a gel, cream, or ointment must be demonstrated to be sterile and the sterilization process must be validated. If labeled as nonsterile, performance data must demonstrate that the product may not be sterilized by established sterilization methods and each manufactured lot of product has an acceptable bioburden level that is maintained throughout the stated shelf life.

(C) The wound dressing formulated as a gel, cream, or ointment must be demonstrated to be biocompatible.

(D) Bench performance testing data must demonstrate that the wound dressing formulated as a gel, cream, or ointment performs as intended under anticipated conditions of use, including evaluation of expected worst-case conditions.

(E) Performance data must support the shelf life of the wound dressing formulated as a gel, cream, or ointment by demonstrating package integrity and product functionality over the identified shelf life. If the product is intended for multiple uses after opening, continued low bioburden, product stability, and functionality over the identified use life must be demonstrated.

(ii) *Antimicrobial characterization and preservative effectiveness testing.* For wound dressings formulated as a gel, cream, or ointment containing antimicrobials with a medium or low level of AMR concern, antimicrobial characterization and preservative effectiveness testing must address the following:

(A) Performance data must demonstrate that the antimicrobial has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use and storage conditions, including evaluation of worst-case conditions. This testing must include:

(*1*) Establishment of the MEC of the antimicrobial in the context of the final wound dressing formulated as a gel, cream, or ointment.

(*2*) Identification of the period of preservative effectiveness for multiple-use products (*i.e.,* after the product has been opened) based on concentration of antimicrobial and preservative effectiveness testing under worst-case simulated use conditions.

(*3*) Preservative effectiveness testing must be conducted on at least three different manufactured lots of the final, finished device that has been real-time aged for the stated shelf life. If the dressing is a multiple-use product, the test articles should also be conditioned based on worst-case simulated use for maximum use life.

(*4*) For nonsterile products, information should be provided regarding the characterization of bioburden within the product.

(B) Evaluation and identification of any probable risks for probable contributions to the development and spread of antimicrobial resistance must be provided, and must include:

(*1*) Identification of the antimicrobial, proposed mechanism(s) of action, and expected spectrum of activity; and

(*2*) An AMR assessment for each antimicrobial component, including the following characterization elements based on literature review:

(*i*) Known resistance mechanisms;

(*ii*) Transmissibility of resistance mechanisms;

(*iii*) List of resistant microbial species; and

(*iv*) Potential for coselection (*e.g.,* via coresistance or cross-resistance) for medically important antimicrobial resistance mechanisms.

(iii) If the wound dressing formulated as a gel, cream, or ointment contains animal-derived material(s), data must include:

(A) A risk management assessment for the inclusion of animal-derived material(s) which considers any probable risk associated with the presence of the animal tissue in the final finished wound dressing formulated as a gel, cream, or ointment (including pathogen and parasite infection and immunological reaction). The risk management assessment must describe how these risks are controlled and mitigated by:

(*1*) Documentation of the processing methods, including animal husbandry and tissue selection as well as methods for tissue storage, transport, and quarantine, that mitigate the risk of parasites and pathogens.

(*2*) Performance data which demonstrates the ability of the manufacturing and sterilization procedures to ensure the adequate removal (*i.e.,* clearance or inactivation) of parasites and pathogens (including bacteria, mycoplasma, fungi, virus, and transmissible spongiform encephalopathy agents) from the final finished wound dressing formulated as a gel, cream, or ointment.

(B) If the device contains materials derived from a new animal species or from manufacturing processes which cause structural changes (*i.e.,* denaturation, modification) to the animal protein, performance data (*e.g.,* patch and prick testing, human repeat insult patch testing) must demonstrate that the device is not immunogenic.

(iv) If the wound dressing formulated as a gel, cream, or ointment contains a botanical extract, additional supporting data must include:

(A) A risk management assessment for including the botanical extract in the wound dressing formulated as a gel, cream, or ointment which considers any probable risk associated with the presence of the botanical extract in the final finished wound dressing formulated as a gel, cream, or ointment.

(B) The risk management assessment must describe how these risks are controlled and mitigated by providing the following:

(*1*) The chemical composition of the botanical extract, including the identity and quantification of the chemical constituents and impurities (*e.g.,* elemental impurities, residual solvents and pesticides, microbial contaminants, adventitious toxins, and degradation products), and the lot-to-lot consistency of the botanical extract within the final finished wound dressing formulated as a gel, cream, or ointment.

(*2*) Documentation of the botanical extract function and activities after topical application. Such information must describe the purpose of the botanical extract in the wound dressing formulated as a gel, cream, or ointment and how it is present in appropriate amounts to perform as intended under anticipated conditions of use, including expected worst-case conditions.

(*3*) Identification of any probable risk to health from use of the botanical extract and how these risks were evaluated and are mitigated via the botanical concentration in the final product, duration of body contact,

manufacturing and process controls, performance data, and labeling for the wound dressing formulated as a gel, cream, or ointment.

(v) The labeling must include:

(A) A description of the intended user population;

(B) Specific instructions regarding the proper application of the product, duration of use for the wound dressing, frequency of use, and instructions regarding the removal of the product residuals prior to reapplication, if applicable;

(C) A list of each ingredient or component within the wound dressing, including the functional role of that ingredient within the wound dressing;

(D) A warning statement regarding any incompatibilities with other therapies;

(E) A warning statement regarding the potential for the development of infection, including signs of an infection and a description of the steps to take in case of infection;

(F) A contraindication for any known sensitivity to components within the product;

(G) A shelf life (*i.e.,* maximum period the unopened wound dressing formulated as a gel, cream, or ointment is stable while stored on the shelf under a specified range of environmental conditions);

(H) The maximum period of use (including reapplications) based on biocompatibility and performance testing; and

(I) For wound dressings formulated as a gel, cream, or ointment indicated for over-the-counter use, a statement specifying conditions, uses, or purposes for which the product may be safely administered by a lay user without the supervision of a licensed practitioner.

(vi) If the wound dressing formulated as a gel, cream, or ointment contains an antimicrobial, the labeling must also include:

(A) Statement of the role of the antimicrobial in the product.

(B) A warning statement regarding the potential for selection of antibiotic resistant organisms if the wound dressing contains an antimicrobial with a medium level of AMR concern.

(C) Specific instructions regarding how and when to properly dispose of the product.

(D) A statement of general effectiveness, such as ''antimicrobial,'' ''antibacterial,'' or ''microbial barrier,'' without listing specific test organisms or log reduction values.

(E) A statement explaining that the effectiveness of the antimicrobial in affecting wound bioburden has not been evaluated or established.

(F) A warning statement regarding the potential for the antimicrobial to leach from the dressing and negatively impact the skin microbiota in the periwound area which may result in impaired wound healing.

(vii) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of maintaining appropriate moisture balance within the wound.

■ 4. Add § 878.4019 to subpart E to read as follows:

§ 878.4019 Liquid wound washes.

(a) *Identification.* A liquid wound wash containing antimicrobials and/or other chemicals that are in a category listed in paragraph (a)(2) of this section is a water-based solution used to mechanically irrigate and physically remove debris from external wounds and intended for use on external cutaneous (skin) wounds. It is also used to moisten solid wound dressings to maintain appropriate moisture balance within the dressing. This regulation does not include liquid wound washes that contain only animal-derived materials without the presence of antimicrobials and/or other chemicals.

(1) Antimicrobials are used for preservative purposes only to maintain shelf life for a nonsterile liquid wound wash or a multiple-use liquid wound wash for single patient use only;

(2) Categories of other chemicals are wound protectants, honey, synthetic peptides, or botanical extracts.

(b) *Classification.* (1) Class III (premarket approval) for liquid wound washes that are identified in paragraph (a) of this section and that contain one or more medically important antimicrobials acting as preservatives.

(i) *Date premarket approval application is required.* A PMA is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], for any liquid wound wash, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials and was in commercial distribution before May 28, 1976, or has, on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], been found to be substantially equivalent to any liquid wound wash, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials and that was in commercial distribution before May 28, 1976. Any other liquid wound wash, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials shall have an approved PMA in effect before being placed in commercial distribution.

(ii) [Reserved]

(2) Class II (special controls) for liquid wound washes that are identified in paragraph (a) of this section and that contain one or more antimicrobials acting as preservatives with a medium or low level of AMR concern and/or other chemicals or when containing water or 0.9 percent saline only. The special controls for this device are:

(i) *Performance testing and descriptive information.* Performance testing and descriptive information must demonstrate the functionality of the liquid wound wash to achieve the specified use, including:

(A) The physical and chemical characteristics of the liquid wound wash must be established. The following must be provided:

(*1*) Identity, quantification, and purpose of each component in the finished product;

(*2*) Specifications and characterization of each component in the finished product;

(*3*) Demonstration that each component has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use, including evaluation of expected worst-case conditions; and

(*4*) Final release specifications for the manufactured liquid wound wash.

(B) If labeled as sterile, the liquid wound wash must be demonstrated to be sterile and the sterilization process must be validated. If labeled as nonsterile, performance data must demonstrate that the product may not be sterilized by established sterilization methods and each manufactured lot of product has an acceptable bioburden level that is maintained throughout the stated shelf life.

(C) The liquid wound wash must be demonstrated to be biocompatible.

(D) Bench performance testing data must demonstrate that the liquid wound wash performs as intended under anticipated conditions of use, including evaluation of expected worst-case conditions.

(F) Performance data must support the shelf life of the liquid wound wash by demonstrating package integrity and product functionality over the identified shelf life. If the product is intended for multiple uses after opening, continued low bioburden, product stability, and functionality over the identified use life must be demonstrated.

(ii) *Antimicrobial characterization and preservative effectiveness testing.* For liquid wound washes containing antimicrobials with a medium or low level of AMR concern, antimicrobial characterization and preservative effectiveness testing must address the following:

(A) Performance data must demonstrate that the antimicrobial has a purpose and is present in appropriate amounts to perform as intended under anticipated conditions of use and storage conditions, including evaluation of worst-case conditions. This testing must include:

(*1*) Establishment of the MEC of the antimicrobial in the context of the final liquid wound wash.

(*2*) Identification of the period of preservative effectiveness for multiple-use products (*i.e.,* after the product has been opened) based on concentration of antimicrobial and preservative effectiveness testing under worst-case simulated use conditions.

(*3*) Preservative effectiveness testing must be conducted on at least three different manufactured lots of the final, finished device that has been real-time aged for the stated shelf life. If the liquid wound wash is a multiple-use product, the test articles should also be conditioned based on worst-case simulated use for maximum use life.

(*4*) For nonsterile products, information should be provided regarding the characterization of bioburden within the product.

(B) Evaluation and identification of any probable risks for probable contributions to the development and spread of antimicrobial resistance must be provided, and must include:

(*1*) Identification of the antimicrobial, proposed mechanism(s) of action, and expected spectrum of activity; and

(*2*) An AMR assessment for each antimicrobial component, including the following characterization elements based on literature review:

(*i*) Known resistance mechanisms;

(*ii*) Transmissibility of resistance mechanisms;

(*iii*) List of resistant microbial species; and

(*iv*) Potential for coselection (*e.g.,* via coresistance or cross-resistance) for medically important antimicrobial resistance mechanisms.

(iii) If the liquid wound wash contains animal-derived material(s), data must include:

(A) A risk management assessment for the inclusion of animal-derived material(s) which considers any probable risk associated with the presence of the animal tissue in the final finished liquid wound wash (including pathogen and parasite infection and immunological reaction). The risk management assessment must describe how these risks are controlled and mitigated by:

(*1*) Documentation of the processing methods, including animal husbandry and tissue selection as well as methods for tissue storage, transport, and quarantine, that mitigate the risk of parasites and pathogens.

(*2*) Performance data which demonstrates the ability of the manufacturing and sterilization procedures to ensure the adequate removal (*i.e.,* clearance or inactivation) of parasites and pathogens (including bacteria, mycoplasma, fungi, virus, and transmissible spongiform encephalopathy agents) from the final finished liquid wound wash.

(B) If the device contains materials derived from a new animal species or from manufacturing processes which cause structural changes (*i.e.,* denaturation, modification) to the animal protein, performance data (*e.g.,* patch and prick testing, human repeat insult patch testing) must demonstrate that the device is not immunogenic.

(iv) If the liquid wound wash contains a botanical extract, additional supporting data must include:

(A) A risk management assessment for including the botanical extract in the liquid wound wash which considers any probable risk associated with the presence of the botanical extract in the final finished liquid wound wash.

(B) The risk management assessment must describe how these risks are controlled and mitigated by providing the following:

(*1*) The chemical composition of the botanical extract, including the identity and quantification of the chemical constituents and impurities (*e.g.,* elemental impurities, residual solvents and pesticides, microbial contaminants, adventitious toxins, and degradation products), and the lot-to-lot consistency of the botanical extract within the final finished liquid wound wash.

(*2*) Documentation of the botanical extract function and activities after topical application. Such information must describe the purpose of the botanical extract in the liquid wound wash and how it is present in appropriate amounts to perform as intended under anticipated conditions of use, including expected worst-case conditions.

(*3*) Identification of any probable risk to health from use of the botanical extract and how these risks were evaluated and are mitigated via the botanical concentration in the final product, duration of body contact, manufacturing and process controls, performance data, and labeling for the liquid wound wash.

(v) The labeling must include:

(A) A description of the intended user population;

(B) Specific instructions regarding the proper application of the product, duration of use for the liquid wound wash, and frequency of use if labeled for a period of multiple use;

(C) A list of each ingredient or component within the liquid wound wash, including the functional role of that ingredient within the liquid wound wash;

(D) A warning statement regarding any incompatibilities with other therapies;

(E) A warning statement regarding the potential for the development of infection, including signs of an infection and a description of the steps to take in case of infection;

(F) A contraindication for any known sensitivity to components within the product;

(G) A shelf life (*i.e.,* maximum period the unopened liquid wound wash is stable while stored on the shelf under a specified range of environmental conditions);

(H) A maximum period of use (including reapplications) based on biocompatibility and performance testing.

(I) For liquid wound washes indicated for over-the-counter use, a statement specifying conditions, uses, or purposes for which the product may be safely administered by a lay user without the supervision of a licensed practitioner.

(vi) If the liquid wound wash contains an antimicrobial, the labeling must also include:

(A) Statement of the role of the antimicrobial in the product as a preservative.

(B) A warning statement regarding the potential for selection of antibiotic resistant organisms if the liquid wound wash contains an antimicrobial with a medium level of AMR concern.

(C) Specific instructions regarding how and when to properly dispose of the product.

(D) A statement of general effectiveness, such as ''antimicrobial,'' ''antibacterial,'' or ''microbial barrier,'' without listing specific test organisms or log reduction values.

(E) A statement explaining that the effectiveness of the antimicrobial in affecting wound bioburden has not been evaluated or established.

(F) A warning statement regarding the potential for the antimicrobial to leach from the dressing and negatively impact the skin microbiota in the periwound

area which may result in impaired wound healing.

(vii) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of mechanically irrigating a wound or maintaining appropriate moisture balance within a solid wound dressing.

Dated: November 21, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–26209 Filed 11–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2023–N–3275]

Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to require the filing of a premarket approval application (PMA) for certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing antimicrobials with a high level of antimicrobial resistance (AMR) concern (*i.e.,* medically important antimicrobials) acting as either protectants or preservatives, which are unclassified, preamendments devices. FDA is summarizing its proposed findings regarding the degree or risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the PMA requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the benefits to the public from the use of the devices.

DATES: Either electronic or written comments on the proposed order must be submitted by February 28, 2024. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to market solid wound dressings, wound dressings formulated as a gel, cream, or ointment, and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives must submit a PMA prior to the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective. See section III for the effective date of any final order that may publish based on this proposed order. See section VI of this document for more information about submitting a PMA.

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 February 28, 2024. 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–2023–N–3275 for ''Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings, Wound Dressings Formulated as a Gel, Cream, or Ointment, and Liquid Wound Washes Containing Medically Important Antimicrobials.'' 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: Brandon Kitchel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4626, Silver Spring, MD 20993–0002, 301–796–6055, *brandon.kitchel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls and general controls), and class III (premarket approval and general controls). Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment on May 28, 1976 of the 1976 amendments (Medical Device Amendments of 1976, Pub. L. 94–295) (generally referred to as ''preamendments devices'') are classified after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a PMA until FDA issues an administrative order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 515(f) of the FD&C Act provides an alternative pathway for meeting the premarket approval requirement. Under section 515(f), manufacturers may meet the premarket approval requirement if they file a notice of completion of a product development protocol (PDP) approved under section 515(f)(4) of the FD&C Act and FDA declares the PDP completed under section 515(f)(6)(B) of the FD&C Act. Accordingly, the manufacturer of a preamendments class III device may comply with a call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, however, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for filing and obtaining approval of a PMA.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: (1) publication of a proposed order in the **Federal Register;** (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments from all affected stakeholders, including patients, payors, and providers.

Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) the proposed order; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA, and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed order and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order,[1] consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order requiring premarket approval for the device, or 30 months after the classification of the device in class III under section 513 of the FD&C Act becomes effective, whichever is later (section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)). Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing antimicrobials with a high level of AMR (*i.e.,* the ability of a microorganism to resist the effects of an antimicrobial) concern to class III. Therefore, if the proposed classification regulation and the order to require PMAs are finalized at the same time, a PMA for these wound dressings must be filed within the 30-month period because that will be the later of the two time periods. If a PMA is not timely filed for such devices, then the device would be deemed adulterated under section 501(f) of the FD&C Act.

Also, a preamendments device subject to the order process under section 515(b) of the FD&C Act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final order requiring the filing of a PMA for the device. At that time, an IDE is required only if a PMA has not been filed. If the manufacturer, importer, or other sponsor of the device submits an IDE application and FDA approves it, the device may be distributed for investigational use. If a PMA is not filed by the later of the two dates, and the device is not distributed for investigational use under an IDE, the device is deemed adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act and subject to enforcement action.

II. Regulatory History of the Devices

After the enactment of the Medical Device Amendments of 1976, FDA undertook an effort to identify and classify all preamendments devices, in accordance with section 513(d) of the FD&C Act. Consistent with the FD&C Act, FDA has held multiple General and Plastic Surgery Devices Panel meetings regarding the classification of wound dressings: on November 27, 1998 (Ref. 1); August 25 and 26, 2005 (Ref. 2); and September 20 and 21, 2016 (the 2016 Panel) (Ref. 3). However, only the 2016 Panel meeting provided the class III recommendations. Certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials (*i.e.,* antimicrobial drugs that are important for therapeutic use in humans and associated with a high level of AMR concern) pose different risks than other

[1] In December 2019, FDA began adding the term ''Proposed amendment'' to the ''ACTION'' caption for these documents to indicate that they ''propose to amend'' the Code of Federal Regulations. This editorial change was made in accordance with the Office of the Federal Register's interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

wound dressings. Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify certain unclassified, preamendments solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials into class III. A PMA, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of these devices.

The proposed rule would also establish the identification, classification, and regulatory controls for certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes that contain antimicrobials acting as either protectants or preservatives with a medium or low level of AMR concern and/or other chemicals. These devices have been subject to premarket review through a 510(k) submission and have been cleared for marketing if FDA considers the device to be substantially equivalent to a legally marketed predicate in accordance with section 513(i) of the FD&C Act. To date, FDA has cleared more than 500 of these devices and has cleared only one of the device types that we believe will be subject to the PMA requirements.

On September 20 and 21, 2016, the 2016 Panel met for the purposes of obtaining recommendations about the classification of products, including (1) solid wound dressings; (2) wound dressings formulated as a gel, cream, or ointment; and (3) liquid wound washes (Ref. 3). FDA held the 2016 Panel to obtain input on the risks to health and benefits of wound dressings and liquid wound washes that contain antimicrobials and/or other chemicals, as well as the clinical relevance of certain indications. The 2016 Panel was asked to recommend to FDA whether such wound dressings and liquid wound washes that contain antimicrobials and/or other chemicals should be classified into class III (subject to premarket approval), class II (subject to general and special controls), or class I (subject only to general controls). The 2016 Panel was also asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications, as well as appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these types of wound dressings and liquid wound washes.

For solid wound dressings containing antimicrobials and/or other chemicals, the 2016 Panel reviewed the list of risks to health and potential mitigation measures provided by FDA and agreed that the list was acceptable. In general, a majority of the 2016 Panel recommended that solid wound dressings should be classified into class II, subject to special controls, with the exception of certain solid wound dressings containing antimicrobials, such as antibiotics (with similar consideration to antimicrobial agents that may select for resistance in indirect ways). Some of the 2016 Panel believed all wound dressings and liquid wound washes containing antimicrobials and/or other chemicals should be classified as class III because of the absence of high-quality evidence of benefit; others recommended class III be considered for any product containing an antibiotic or an antimicrobial that may indirectly contribute to antibiotic resistance.

For wound dressings containing antimicrobials and/or other chemicals formulated as a gel, cream, or ointment, the 2016 Panel reviewed the list of risks to health and potential mitigation measures provided by FDA and agreed that the list was acceptable. In general, a majority of the 2016 Panel recommended that wound dressings formulated as a gel, cream, or ointment should be classified into class II, subject to special controls, with the exception of certain wound dressings formulated as a gel, cream, or ointment containing antimicrobials, such as antibiotics (with similar consideration to agents that may select for resistance in indirect ways), for which some members of the 2016 Panel recommended class III.

For liquid wound washes containing antimicrobials and/or other chemicals, the 2016 Panel reviewed the list of risks to health and potential mitigation measures provided by FDA and agreed that the list was acceptable. In general, a majority of the 2016 Panel recommended that liquid wound washes should be classified into class I or class II, subject to special controls, depending on the toxicity of the product, with the exception of certain liquid wound washes containing antimicrobials, such as antibiotics (with similar consideration to agents that may select for resistance in indirect ways), for which some members of the 2016 Panel recommended class III.

The 2016 Panel recommended that wound dressings and liquid wound washes with medically important antimicrobials [2] (Ref. 4) be classified into class III because there was a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of safety and effectiveness, and these devices present a potential unreasonable risk of illness or injury. FDA agrees with the 2016 Panel's recommendation. It is also FDA's position that there is a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of the devices' safety and effectiveness and that the devices present a potential unreasonable risk of illness or injury. FDA further agrees with the 2016 Panel's recommendation that wound dressings and liquid wound washes with medically important antimicrobials and/or other chemicals be classified into class III subject to PMA.

III. Dates New Requirements Apply

If FDA finalizes the proposed classification of certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives, these devices will be classified into class III. In accordance with sections 501(f)(2)(B) and 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives by the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective.

An applicant whose product was legally in commercial distribution before May 28, 1976, or whose product has been found to be substantially equivalent to such a product, will be permitted to continue marketing such class III product during FDA's review of the PMA, provided that a PMA is timely filed. FDA intends to review any PMA for the device within 180 days. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days, unless the Agency finds that ''. . . the continued availability of the device is necessary for the public health.''

[2] Table 1 of the World Health Organization's (WHO) 2018 publication ''Critically important antimicrobials for human medicine: 6th revision'' (*https://www.who.int/publications/i/item/9789241515528*) has a list of all classes of medically important antimicrobials. For the purposes of this proposed order, an antimicrobial is considered medically important if, and only if, it falls within any of these classes regardless of the level of importance specified by the WHO (*i.e.,* critically important, highly important, or important).

Moreover, manufacturers must cease distribution of devices upon receiving a not approvable or denial decision rendered on a PMA. In such circumstances, to resume distribution, these manufacturers must receive PMA approval for their devices. However, the product may be distributed for investigational use only if the requirements of the investigational device exemptions regulations in part 812 are met. The requirements for investigational use of significant risk devices include submitting an IDE application to FDA for review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under 21 CFR 812.30. FDA, therefore, recommends that IDE applications be submitted to FDA at least 30 days before the date a PMA is required to be filed to avoid interrupting investigations.

For currently marketed wound dressings and liquid wound washes that are proposed to be classified into class III, FDA is proposing that it does not intend to enforce compliance with the 30-month deadline by which PMAs must be submitted, when a notice of intent to file a PMA is submitted within 90 days of the effective date of the order, if finalized. In circumstances when a notice of intent to file is submitted, FDA is proposing that it does not intend to enforce compliance with the 30-month deadline by which PMAs must be submitted when a PMA is submitted within 90 days after the 30-month deadline. However, as discussed above, even if a notice of intent and PMA are submitted by these dates, manufacturers must cease distribution of devices upon receiving a not approvable or denial decision rendered on a PMA.

IV. Devices Subject to This Proposal

A solid wound dressing containing antimicrobials and/or other chemicals is used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. Medically important antimicrobials that are incorporated in the solid wound dressing are used for protectant purposes only to reduce microbial growth within the solid wound dressing while in use or to provide an antimicrobial barrier to microbial penetration through the solid wound dressing.

A wound dressing formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals is used to maintain appropriate moisture balance within the wound. Medically important antimicrobials that are incorporated in a wound dressing formulated as a gel, cream, or ointment are used for preservative purposes only to maintain shelf life for a non-sterile wound dressing or a multiple-use wound dressing for single patient use only.

A liquid wound wash is a water-based solution used to mechanically irrigate and physically remove debris from external wounds. It is also used to moisten solid wound dressings to maintain appropriate moisture balance within the dressing. Medically important antimicrobials that are incorporated in a liquid wound wash are used for preservative purposes only to maintain shelf life for a non-sterile liquid wound wash or a multiple-use wound wash for single patient use only.

FDA currently regulates these unclassified devices as devices requiring a 510(k) submission under product codes FRO, GER, MGP, MGQ, and EFQ.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives in class III and identifies these devices as follows: solid wound dressings containing antimicrobials and/or other chemicals; wound dressings formulated as a gel, cream, or ointments containing antimicrobials and/or other chemicals; and liquid wound washes.

In accordance with section 515(b)(2)(D) of the FD&C Act, interested persons are being offered the opportunity to comment or request a change on the Agency's proposed classification of certain solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives based on new information published elsewhere in this **Federal Register**.

V. Proposed Findings With Respect to Risks and Benefits for Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) the degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA and (2) the benefits to the public from the use of the devices. These findings are based on the reports and recommendations of the 2016 Panel, and any additional information that FDA has obtained. Additional information regarding the risks can be found below, as well as in the proposed rule published elsewhere in this issue of the **Federal Register**, proposing to classify these devices into class III.

Based on this information, FDA has identified the following risks to health to the different categories of wound dressings and liquid wound washes that are within the scope of this proposed rule and classification action:

- *Solid Wound Dressings*:
  - Adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, loss of barrier function, retention of dressing material in wound, and negatively impacting the skin microbiota in the peri-wound area resulting in impaired wound healing.
- *Wound Dressings Formulated as a Gel, Cream, or Ointment:*
  - Adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, and negatively impacting the skin microbiota in the peri-wound area resulting in impaired wound healing.
- *Liquid Wound Washes*:
  - Adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibilities with other therapies, contribution to the spread of AMR, infection, microbial growth within the product, product degradation during stated shelf storage, inability to remove wound debris and foreign materials, and negatively impacting the skin microbiota in the peri-wound area resulting in impaired wound healing.

Below is a brief description of each of the identified risks to health:

- *Adverse tissue reaction:* Erythema, irritation, inflammation of the wound or host tissue, immune response, and hemolysis can occur as a result of an unwanted tissue response associated with the materials or leachables/extractables in wound dressings and liquid wound washes.
- *Immunological reaction:* This can result from a device derived from a new animal source or protein denaturation/

modification due to the manufacturing conditions.

• *Transmission of pathogens and parasites* (*e.g.,* bacteria, mycoplasma, fungi, viruses, and other transmissible spongiform encephalopathy agents): This can result from contaminated animal sources, feed, inadequate processing, and viral inactivation of the animal-derived materials.

• *Toxicity:* Local and/or systemic toxicity, tissue necrosis, reduced tissue viability, and genotoxicity can occur due to toxic antimicrobials or other chemicals in the wound dressings or liquid wound washes, which can result in adverse tissue effects, leading to toxicity. This also includes allergic reaction and sensitization, as individuals with known sensitivity to the materials in the wound dressings and liquid wound washes may experience allergic reactions, which may be severe depending on the degree of sensitivity.

• *Delayed wound healing:* Cytotoxicity resulting in dead or necrotic tissue can delay healing.

• *Incompatibilities with other therapies:* An undesirable (*e.g.,* antagonistic) reaction could occur between the materials contained in/on the wound dressings or liquid wound washes and other therapies applied to the wound.

• *Contribution to the spread of AMR:* Use of antimicrobials in wound dressings and liquid wound washes can inadvertently select for and cultivate antimicrobial resistant organisms in patients and further limit a clinician's therapeutic options to treat infections.

• *Infection:* Unsafe methods of manufacturing processes, such as inadequate aseptic processing, inadequate packaging and/or product storage, can result in contaminated product that may be a source of infection. This risk includes bacterial and fungal infections and superinfections, which may result from the use of an antimicrobial-containing wound dressing or liquid wound wash that introduces contaminating microorganisms to the wound or disrupts the natural balance of skin flora around the wound.

• *Microbial growth within the product:* This can occur from inadequate sterilization, preservative effectiveness failure, unsafe methods of manufacturing processes, inadequate packaging and/or product storage. This can lead to a change in product composition or characteristics (*e.g.,* loss of tensile strength, change in pH) and may also result in infection or adverse tissue reaction.

• *Product degradation during stated shelf storage:* Inadequate packaging and/or inappropriate storage of wound dressings or liquid wound washes can result in product degradation during storage. Product degradation can also change the composition or characteristics of the product over time and lead to patient harm.

• *Retention of dressing material in wound:* This risk is generally applicable to solid wound dressings, which can occur due to a loss in solid dressing integrity or unintended degradation of solid wound dressings. It may also occur due to the healthcare provider inadvertently leaving material in the wound. This can lead to adverse tissue reaction, delay in wound healing, or infection.

• *Inability to remove wound debris and foreign materials:* Ineffective washing of the wound can occur. Debris and foreign material remaining in the wound can delay healing or lead to infection. This risk is applicable to the liquid wound washes containing antimicrobials and/or other chemicals.

• *Loss of barrier function:* This risk is applicable to solid wound dressings indicated as barriers to microbial penetration through the wound dressing (either via mechanical or antimicrobial properties). Loss of this barrier function can introduce microbial contamination from the environment into the wound and can lead to delay in wound healing or infection.

• *Impact to skin microbiota in the peri-wound area:* This risk is applicable to each category of antimicrobial-containing wound dressings. Inadvertent leaching of antimicrobials away from the dressing may negatively impact the skin microbiota in the peri-wound area by reducing the presence of beneficial commensal microorganisms that play a role in the wound healing cascade, resulting in impaired wound healing.

A. Summary of Data

FDA conducted queries of the Manufacturer and User Facility Device Experience database to identify adverse events related to use of solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives. The queries resulted in the identification of 1,973 Medical Device Reports (MDRs) on these devices as of July 21, 2022. The reports were received by FDA from 1994 to July 21, 2022. The number of MDRs received between 1994 and 2004 were consistently low, at fewer than 20 per year. Between 2005 and 2016, the number of MDRs increased to an average of 111 reports per year with a peak in 2015, at 298 MDRs. MDRs received between 2016 and 2022 averaged 148 ± 17 MDRs per year.

Additionally, FDA conducted a comprehensive literature review to identify and gather relevant published information regarding the safety and effectiveness of solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives. Consequently, FDA concludes there is inadequate information characterizing the safety and effectiveness of wound dressings and liquid wound washes containing medically important antimicrobials. The 510(k) clearances of these devices were based solely on nonclinical information and determinations of substantial equivalence to the preamendments device in accordance with section 513(i) of the FD&C Act, which, in light of the available information regarding the risks with no information supporting the benefit of these devices, is inadequate to support a reasonable assurance of safety and effectiveness for these devices.

FDA also reviewed recalls reported under product code FRO from 2003 to July 2022.[3] There are no recalls for solid wound dressings; wound dressings formulated as a gel, cream, or ointment; or liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives.

On September 20 and 21, 2016, FDA convened the General and Plastic Surgery Device Panel described in section II (Ref. 3). The majority of the 2016 Panel members noted that there is a lack of clinical data to demonstrate a clear clinical benefit regarding the use of wound dressings and liquid wound washes containing medically important antimicrobials. Several of the 2016 Panel members noted that wound dressings and liquid wound washes containing medically important antimicrobials, such as antibiotics, present an unreasonable risk of illness or injury to the patient (*e.g.,* directly contributing to the spread of antimicrobial resistance, further limiting clinician's therapeutic options), especially given the lack of probable benefit. Additionally, the 2016 Panel members discussed that special

[3] Only the product code FRO was queried for the recall analysis as the majority of the products in scope for this proposed order fall under FRO. The types of recalls reported under FRO are expected to be representative of all products in scope for this proposed order.

controls, such as testing in an animal model, could not be used to evaluate and/or mitigate the high level of AMR risk. As such, several panelists concluded that these wound dressings and liquid wound washes should be classified as class III and subject to increased regulatory controls to mitigate the high level of AMR risk.

B. Benefits of the Device

The purported benefit of the use of wound dressings and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives include maintaining a moist environment, providing an effective barrier to environmental contaminants, reducing microbial growth within the dressing, and extending the shelf life of non-sterile and/or multiple-use wound dressings and liquid wound washes; however, FDA is not aware of clinical evidence supporting the stated benefit of wound dressings and liquid wound washes containing medically important antimicrobials. FDA is proposing a PMA be filed to require that manufacturers demonstrate that a reasonable assurance of safety and effectiveness exists for solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives.

C. Risks to Health

The unreasonable risk profile of solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives includes adverse tissue reaction, immunological reaction, transmission of pathogens and parasites, toxicity, delayed wound healing, incompatibility with other therapies, contribution to the spread of AMR, infection, microbial growth within the product during use, product degradation during stated shelf storage, retention of dressing material in wound, loss of barrier function, inability to remove wound debris and foreign materials, and negatively impacting the skin microbiota in the peri-wound area resulting in impaired wound healing.

FDA agrees with certain 2016 Panel members that wound dressings and liquid wound washes containing medically important antimicrobials present an unreasonable risk of illness or injury. FDA further agrees that because insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness, wound dressings and liquid wound washes containing medically important antimicrobials should be class III subject to PMA.

VI. PMA Requirements

A PMA for solid wound dressings; wound dressings formulated as gels, creams, and ointments; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks identified in section V, as well as a discussion of the effectiveness of the product for which premarket approval is sought. In addition, a PMA must include all data and information on the following: (1) any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the solid wound dressing; wound dressing formulated as gels, creams, and ointments; or liquid wound wash containing medically important antimicrobials acting as either protectants or preservatives for its intended use (see § 860.7(c)(2) (21 CFR 860.7(c)(2))). FDA defines valid scientific evidence in § 860.7(c)(2).

To present reasonable assurance of safety and effectiveness of solid wound dressings; wound dressings formulated as gels, creams, and ointments; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives, FDA tentatively concludes that manufacturers should submit performance testing to support PMA approval. Existing published clinical literature relevant to the product may also be leveraged as part of the PMA submission. In addition, FDA strongly encourages manufacturers to meet with the Agency early through the Q-Submission Program [4] for any assistance in preparation of their PMA.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) 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.

VIII. Paperwork Reduction Act of 1995

While this proposed order 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 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information in part 812 have been approved under OMB control number 0910–0078.

IX. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

X. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification of the device. A request for a change in the classification of solid wound dressings; wound dressings formulated as gels, creams, and ointments; and liquid wound washes containing medically important antimicrobials acting as either protectants or preservatives, as described in this document, should be provided in response to the proposed rule issued elsewhere in this issue of the **Federal Register** and contain the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for

[4] See FDA guidance, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff.'' June 2, 2023, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.*

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

* 1. General and Plastic Surgery Devices Panel, ''Transcript of the FDA General and Plastic Surgery Devices Panel meeting—November 17, 1998.'' Available at *https://web.archive.org/web/20180125235924/https://www.fda.gov/ohrms/dockets/ac/98/transcpt/3483t1.pdf.*
* 2. General and Plastic Surgery Devices Panel, ''Brief Summary from the General and Plastic Surgery Devices Panel Meeting—August 25–26, 2005.'' Available at *https://wayback.archive-it.org/7993/20170405192855/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Generaland PlasticSurgeryDevicesPanel/ucm124755.htm.*
* 3. General and Plastic Surgery Devices Panel, ''2016 Meeting Materials of the General and Plastic Surgery Advisory Panel—September 20–21, 2016.'' Available at *https://wayback.archive-it.org/7993/20201227032045/https://www.fda.gov/advisory-committees/general-and-plastic-surgery-devices-panel/2016-meeting-materials-general-and-plastic-surgery-advisory-panel.*
4. WHO, Critically Important Antimicrobials for Human Medicine. 2018. Available at *https://www.who.int/publications/i/item/9789241515528.*

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 878.4016, as proposed to be added in FR 2023–26209, published elsewhere in this issue of the **Federal Register**, by adding paragraph (c) to read as follows:

§ 878.4016 Solid wound dressings containing antimicrobials and/or other chemicals.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], for any solid wound dressing, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials acting as protectants and was in commercial distribution before May 28, 1976, or has, on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], been found to be substantially equivalent to any solid wound dressing, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as protectants and that was in commercial distribution before May 28, 1976. Any other solid wound dressing, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as protectants shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

■ 3. Amend § 878.4017, as proposed to be added in FR 2023–26209, published elsewhere in this issue of the **Federal Register**, by adding paragraph (c) to read as follows:

§ 878.4017 Wound dressings formulated as a gel, cream, or ointment containing antimicrobials and/or other chemicals.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], for any wound dressing formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials acting as preservatives and was in commercial distribution before May 28, 1976, or has, on or before [A DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF FINAL RULE], been found to be substantially equivalent to any wound dressings formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as preservatives and that was in commercial distribution before May 28, 1976. Any other wound dressing formulated as a gel, cream, or ointment, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as preservatives shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

■ 4. Amend § 878.4019, as proposed to be added in FR 2023–26209, published elsewhere in this issue of the **Federal Register**, by adding paragraph (c) to read as follows:

§ 878.4019 Liquid wound washes.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF THE FINAL RULE], for any liquid wound wash, as identified in paragraph (a) of this section, that either contains one or more medically important antimicrobials acting as preservatives and was in commercial distribution before May 28, 1976, or has, on or before [DATE OF THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER EFFECTIVE DATE OF THE FINAL RULE], been found to be substantially equivalent to any liquid wound wash, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as preservatives and that was in commercial distribution before May 28, 1976. Any other liquid wound wash, as identified in paragraph (a) of this section, that contains one or more medically important antimicrobials acting as preservatives shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: November 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26208 Filed 11–29–23; 8:45 am]

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